As confidentially submitted to the Securities and Exchange Commission on December 12, 2018 as Amendment No. 1 to the Confidential Submission dated October 19, 2018. This draft registration statement has not been publicly filed with the Securities and Exchange Commission and all information herein remains strictly confidential.

Registration No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

TransMedics Group, Inc.
(Exact name of registrant as specified in its charter)

Massachusetts	**3845**	**83-2181531**
(State or other jurisdiction of incorporation or organization)	**(Primary Standard Industrial Classification Code Number)**	**(I.R.S. Employer Identification Number)**

200 Minuteman Road
Andover, MA 01810
(978) 552-0900

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Waleed H. Hassanein, M.D.
President and Chief Executive Officer
TransMedics Group, Inc.
200 Minuteman Road
Andover, MA 01810
(978) 552-0900
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Tara Fisher	**Richard D. Truesdell, Jr., Esq.**
Paul Kinsella	**Marcel Fausten, Esq.**
Ropes & Gray LLP	**Davis Polk & Wardwell LLP**
Prudential Tower	**450 Lexington Avenue**
800 Boylston Street	**New York, NY 10017**
Boston, MA 02116	**(212) 450-4000**
(617) 951-7000	

Approximate date of commencement of proposed sale to the public: As soon as practicable after this Registration Statement is declared effective.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☐

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer	☐	Accelerated Filer	☐
Non-Accelerated Filer	☒	Smaller Reporting Company	☒
		Emerging Growth Company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided to Section 7(a)(2)(B) of the Securities Act. ☐

CALCULATION OF REGISTRATION FEE

Title of each Class of Securities to be Registered	**Proposed Maximum Aggregate Offering Price(1)(2)**	**Amount of Registration Fee(3)**
Common Stock, no par value per share	$	$

(1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended.
(2) Includes the offering price of shares that the underwriters may purchase pursuant to an option to purchase additional shares.
(3) To be paid in connection with the initial filing of the registration statement.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment that specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until this registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and we are not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

PROSPECTUS
Subject to Completion, dated , 2018

shares

TransMedics Group, Inc.

COMMON STOCK

TransMedics Group, Inc. is offering shares of common stock. This is our initial public offering, and no public market currently exists for our common stock. We anticipate that the initial public offering price will be between $ and $ per share.

We have applied to list our common stock on the Nasdaq Global Market under the symbol "TMDX."

We are an "emerging growth company" as defined under the federal securities laws and, as such, have elected to comply with certain reduced public company reporting requirements for this prospectus and future filings.

Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page 14.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

PRICE $ A SHARE

	Price to Public	***Underwriting Discounts and Commissions(1)***	***Proceeds to Company***
Per Share	*$*	*$*	*$*
Total	*$*	*$*	*$*

(1) We have agreed to reimburse the underwriters for certain FINRA-related expenses. See "Underwriting" for additional information regarding the underwriters' compensation.

The underwriters have the option to purchase up to an aggregate of additional shares of common stock from us at the public offering price, less the underwriting discounts and commissions, for a period of 30 days after the date of this prospectus. The underwriters expect to deliver the shares against payment to the purchasers on or about , 2018.

Joint Book-Running Managers

MORGAN STANLEY *J.P. MORGAN*

Co-Managers

COWEN *CANACCORD GENUITY*

, 2018.

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We are responsible for the information contained in this prospectus. We have not, and the underwriters have not, authorized anyone to provide you with any information other than in, or incorporated by reference in, this prospectus. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you or any representation that others may make to you. We are not, and the underwriters are not, making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. The information in this prospectus is accurate only as of the date of this prospectus, regardless of the time of any sale of the common stock. Our business, liquidity position, financial condition, prospects or results of operations may have changed since the date of this prospectus.

This prospectus contains forward-looking statements that are subject to a number of risks and uncertainties, many of which are beyond our control. See "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements."

The Corporate Reorganization

TransMedics Group, Inc., a recently formed Massachusetts corporation, or TransMedics Group, is currently a direct, wholly-owned subsidiary of TransMedics, Inc., a Delaware corporation. Immediately prior to or concurrently with the closing of this initial public offering, TMDX, Inc., a direct, wholly-owned subsidiary of TransMedics Group, will merge with and into TransMedics, Inc. with TransMedics, Inc. as the surviving corporation. As a result of the merger, each outstanding share of capital stock of TransMedics, Inc. will be converted into shares of common stock of TransMedics Group, each outstanding option to purchase shares of common stock of TransMedics, Inc. will be converted into an outstanding option to purchase shares of common stock of TransMedics Group and each outstanding warrant to purchase shares of preferred stock of TransMedics, Inc. will be converted into a warrant to purchase shares of common stock of TransMedics Group, pursuant to the terms of the Agreement and Plan of Merger and Reorganization filed as an exhibit to the Registration Statement of which this prospectus forms a part. We refer to this as the "Corporate Reorganization."

Immediately following the Corporate Reorganization, (1) TransMedics Group will be a holding company with no material assets other than 100% of the equity interests in TransMedics, Inc., (2) the holders of capital stock in TransMedics, Inc. will become shareholders of TransMedics Group and (3) the historical consolidated financial statements of TransMedics, Inc. will become the historical consolidated financial statements of TransMedics Group because the Corporate Reorganization will be accounted for as a reorganization of entities under common control. Prior to the Corporate Reorganization, TransMedics Group has not conducted any activities other than in connection with its formation and in preparation for this offering and has no material assets other than 100% of the equity interests in TMDX, Inc.

Except as otherwise noted or the context otherwise requires, all information in this prospectus gives effect to the Corporate Reorganization.

Presentation of Financial and Operating Data

Unless otherwise indicated, the historical financial and operating information presented in this prospectus as of and for the fiscal years ended December 31, 2016 and December 30, 2017 and as of and for the fiscal nine months ended September 30, 2017 and September 29, 2018 is that of TransMedics, Inc. References in this prospectus to "fiscal 2015" relate to the fiscal year ended December 26, 2015, references in this prospectus to "fiscal 2016" relate to the fiscal year ended December 31, 2016 and references in this prospectus to "fiscal 2017" relate to the fiscal year ended December 30, 2017.

Certain amounts and percentages included in this prospectus have been rounded. Accordingly, in certain instances, the sum of the numbers in a column of a table may not exactly equal the total figure for that column.

Industry and Market Data

The market data and certain other statistical information used throughout this prospectus are based on independent industry publications, government publications and other published sources. Some data are also based on our good faith estimates. Although we believe these third-party sources are reliable as of their respective dates, neither we nor the underwriters have independently verified the accuracy or completeness of this information. The industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the section entitled "Risk Factors." These and other factors could cause results to differ materially from those expressed in these publications.

Trademarks and Tradenames

This prospectus contains references to our trademarks and to trademarks belonging to other entities. "TransMedics" is a registered trademark of TransMedics. The TransMedics logo, Organ Care System and OCS are trademarks of TransMedics. Each of the other trademarks, trade names and service marks included in this

prospectus belongs to its respective holder. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork and other visual displays, may appear without the ® or ™ symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

PROSPECTUS SUMMARY

This summary highlights information included elsewhere in this prospectus. This summary does not contain all the information you should consider before investing in our common stock. You should read and consider this entire prospectus carefully, including the sections titled "Risk Factors," "Cautionary Note Regarding Forward-Looking Statements," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes included elsewhere in this prospectus, before making any investment decision. Unless the context otherwise requires, the terms "TransMedics," the "Company," "we," "us" and "our" relate, prior to the Corporate Reorganization, to TransMedics, Inc., together with its consolidated subsidiaries, and, following the Corporate Reorganization, to TransMedics Group, together with its consolidated subsidiaries.

Our Business

We are a commercial-stage medical technology company transforming organ transplant therapy for end-stage organ failure patients across multiple disease states. We developed the Organ Care System, or the OCS, to replace a decades-old standard of care that we believe is significantly limiting access to life-saving transplant therapy for hundreds of thousands of patients worldwide. Our innovative OCS technology replicates many aspects of the organ's natural living and functioning environment outside of the human body. As such, the OCS represents a paradigm shift that transforms organ preservation for transplantation from a static state to a dynamic environment that enables new capabilities, including organ optimization and assessment. We believe our substantial body of clinical evidence has demonstrated the potential for the OCS to significantly increase the number of organ transplants and improve post-transplant outcomes.

Incidence of end-stage organ failure has been rapidly rising worldwide due to demographic trends that contribute to chronic diseases. Organ transplantation is the treatment of choice for addressing end-stage organ failure due to its positive clinical outcomes and favorable health economics. However, transplant volumes have been significantly restricted by the limitations of cold storage, the standard of care for organ transplantation. Cold storage is a rudimentary approach to organ preservation in which a donor organ is flushed with cold pharmaceutical solutions, placed in a plastic bag on top of ice and transported in a cooler. Cold storage subjects organs to significant injury due to a lack of oxygenated blood supply, or ischemia, does not allow physicians to assess organ viability and lacks the ability to optimize an organ's condition once it has been retrieved from the donor. Time-dependent ischemic injury has been shown to result in short- and long-term post-transplant clinical complications and, together with the inability to assess or optimize organs, contributes to the severe underutilization of donor organs. While there are approximately 67,000 potential donors annually in the United States, Canada, the European Union and Australia, which we refer to as our key geographies, the majority of lungs and hearts donated after brain death, or DBD, go unutilized, and almost no available lungs and hearts donated after circulatory death, or DCD, are utilized.

We developed the OCS to comprehensively address the major limitations of cold storage. The OCS is a portable organ perfusion, optimization and monitoring system that utilizes our proprietary and customized technology to replicate near-physiologic conditions for donor organs outside of the human body. We designed the OCS technology platform to perfuse donor organs with warm, oxygenated, nutrient-enriched blood, while maintaining the organs in a living, functioning state; the lung is breathing, the heart is beating and the liver is producing bile. Because the OCS significantly reduces injurious ischemic time on donor organs as compared to cold storage and enables the optimization and assessment of donor organs, it has demonstrated improved clinical outcomes relative to cold storage and offers the potential to significantly improve donor organ utilization.

We designed the OCS to be a platform that allows us to leverage core technologies across products for multiple organs. To date, we have developed three OCS products, one for each of lung, heart and liver

transplantations, making the OCS the only multi-organ technology platform. Our OCS products have been used for over 1,100 human organ transplants. We have commercialized the OCS Lung and OCS Heart outside of the United States and received our first premarket approval, or PMA, from the U.S. Food and Drug Administration, or the FDA, in March 2018 for the use of the OCS Lung for donor lungs currently utilized for transplantation. We expect FDA action on additional applications for PMAs we submitted or that we expect to submit in connection with our other OCS products over the next 18 months. We submitted a PMA application to the FDA in August 2018 for the use of the OCS Lung for donor lungs currently unutilized for transplantation based on the results of our OCS Lung EXPAND Trial. As is typical for a PMA review process, in November 2018, we received a major deficiency letter, or MDL, for this PMA application for which we are currently in discussions with the FDA to address. We intend to respond to the MDL during the first half of 2019 by providing the requested supplemental data, such as clarification for subgroups, longer time frames and other analyses as described further herein. We also expect to submit a PMA application to the FDA during the first quarter of 2019 for the use of the OCS Heart for currently utilized and unutilized DBD donor hearts for transplantation based on the results of our OCS Heart EXPAND Trial and OCS Heart PROCEED II Trial.

We have developed a substantial body of global clinical evidence to support our PMA applications, potential PMA applications and other regulatory approvals for the OCS for lung, heart and liver transplantation. Many of these clinical trials and studies have been published in peer-reviewed clinical journals and several additional studies are ongoing. Our clinical trials have evaluated the use of the OCS for transplantation of organs that meet the current criteria for organ transplantation, as well as organs that would otherwise go unutilized. We believe the results of our clinical trials across lung, heart and liver transplantation support the potential of the OCS in improving clinical outcomes and increasing utilization of available donor organs.

We are focused on establishing the OCS as the standard of care for solid organ transplantation. Because we believe cold storage is the primary factor limiting donor organ utilization today, we estimate our opportunity based on the existing donor pools and the potential for significantly expanded utilization with the OCS. We estimate the potential pool of DBD and DCD donors in our key geographies to be approximately 67,000 annually, with each donor having the capacity to donate more than one organ, including lung, heart and liver. Based on the utilization rates in our clinical trials and our commercial experience outside the United States, we estimate the potential annual addressable commercial opportunity for the OCS to be approximately $8 billion for lung, heart and liver transplantation combined.

The vast majority of transplant procedures are performed at a relatively small number of hospitals that have specialized organ transplant centers. For example, we estimate that approximately 50 to 55 transplant centers in the United States perform over 70% of the lung, heart and liver transplant volume. During our clinical trials, we established relationships with over 55 leading transplant programs in our key geographies and have generated a substantial body of clinical evidence. Our commercial strategy is focused on leveraging these relationships to drive deeper adoption of the OCS at the leading, large-volume academic transplant institutions. As of October 27, 2018, our sales and clinical adoption team consisted of 24 sales and clinical professionals.

Our OCS products are reimbursed in the United States through existing, standard commercial transplant billing mechanisms. The Medicare program and private payors have been providing reimbursement for the OCS Lung, OCS Heart and OCS Liver during the U.S. pivotal trials and have been providing reimbursement for the OCS Lung following FDA approval in March 2018. We believe these established channels will continue to facilitate commercial reimbursement for the OCS Lung and, if they are approved by the FDA, for the OCS Heart and OCS Liver. We are also in the process of seeking long-term reimbursement for our products outside of the United States.

Our corporate headquarters, manufacturing and clinical training facilities are located in Andover, Massachusetts. We have additional distribution and commercial operations in Europe and Asia-Pacific. As of October 27, 2018, we employed 83 people globally. We generated $7.7 million of net revenue during the fiscal year ended December 30, 2017 and $9.5 million of net revenue during the fiscal nine months ended September 29, 2018, of which $4.0 million of net revenue was generated during the fiscal three months ended September 29, 2018, representing a 116% increase as compared to the fiscal three months ended September 30, 2017.

Current Standards for Organ Preservation and their Limitations

In recent years, significant innovations have been implemented in most aspects of organ transplantation surgery. However, organ preservation remains primarily limited to cold storage. Cold storage involves flushing the organs with cold pharmaceutical solutions designed to reduce organ temperature and arrest organ function. This process adversely impacts clinical outcomes and leads to underutilization of viable donor organs due to the following inherent challenges:

- ***Time-dependent ischemic injury:*** Cold storage subjects donor organs to significant injury due to a lack of oxygenated blood supply, or ischemia. Ischemia has been reported to be an independent predictor of mortality after heart transplantation and development of short-term severe primary graft dysfunction, or PGD, which is associated with long-term complications in lung transplantation. In addition to resulting in poor transplant outcomes, time-dependent ischemic injury limits the acceptable time that transplant centers permit between organ retrieval and transplantation to four to six hours, resulting in restrictions on geographical distance between donors and transplant recipients.
- ***Lack of diagnostic assessment of organ viability or function:*** Cold storage does not support the assessment of organ function or viability because the organs are not functioning or metabolically active during cold storage. This lack of diagnostic assessment largely limits the donor pool to DBD donors, whose organs can be assessed for viability prior to retrieval because their hearts continue to beat.
- ***Lack of therapeutic or optimization capabilities:*** Clinical studies have demonstrated the clinical benefits of replenishing donor organs with glucose, oxygen, hormones and electrolytes that are significantly altered or depleted during the donation process. Cold storage, however, does not allow for therapeutic intervention to optimize the condition of donor organs, which results in suboptimal post-transplant outcomes. In addition, transplant programs are less likely to accept organs that may appear compromised if they are unable to treat or optimize the organ, which prevents utilization of the vast majority of organs from DBD and DCD donors.

We believe the limitations of cold storage are directly responsible for the severe shortage in donor organ supply, which in 2016 resulted in approximately 77% of donated lungs and approximately 68% of donated hearts going unutilized in the United States. In addition, we believe the limitations of cold storage are the primary driver of the high rate of severe post-transplant complications that negatively impact both patients' clinical outcomes and transplant economics for payors and providers.

Our Commercial Opportunity

We believe organ transplantation is severely supply constrained by the limitations of cold storage. While there is a national transplant waiting list that represents a snapshot of demand, we believe this waiting list significantly underrepresents the true clinical demand for organ transplants. Incidences of end-stage organ failure have been rapidly rising worldwide resulting in significant growth in the number of patients that could benefit from life-saving organ transplants. However, because the supply of donor organs has historically been constrained, the waiting list is fairly static, with annual additions to the waiting list typically matching closely the number of transplants performed or patients otherwise removed from the list. We believe that with increased utilization of donor organs for transplant, the waiting list will grow to match any increase in global supply.

We estimate our commercial opportunity based on the existing donor pools and the potential for significantly improved utilization resulting from the use of our OCS technology. We estimate that the potential pool of donors in our key geographies includes approximately 67,000 DBD and DCD donors annually. Because the OCS reduces injurious ischemic time significantly, allows for therapeutic optimization of the organ's condition and enables diagnostic assessment, we believe the OCS could allow surgeons to utilize the vast majority of the donor pool that is currently unutilized due to the limitations of cold storage.

Our Technology and Solution

We developed the OCS to comprehensively address the major limitations of cold storage. The OCS is a portable organ perfusion, optimization and monitoring system that utilizes our proprietary and customized technology to replicate near-physiologic conditions for donor organs outside of the human body. The OCS was designed to perfuse donor organs with warm, oxygenated and nutrient-enriched blood, while maintaining the organs in a living, functioning state; the lung is breathing, the heart is beating and the liver is producing bile. As such, the OCS represents a paradigm shift that transforms organ preservation for transplantation from a static state to a dynamic environment that enables new capabilities, including organ optimization and assessment.

We developed the OCS, the first and only multi-organ platform, to leverage proprietary core technologies across multiple organs. For each OCS product, we supplement the platform with organ-specific, customized and proprietary technologies. To date, we have developed three OCS products, one for each of lung, heart and liver transplantation. OCS products for additional organs, including kidneys, are under development.

Each OCS product consists of three primary components customized for each organ:

- **OCS Console:** The OCS Console is a highly portable electromechanical medical device that houses and controls the function of the OCS and is designed to fit in the current workflow for organ transplantation.

- **OCS Perfusion Set:** The OCS Perfusion Set is a sterile, biocompatible single-use disposable set that stores the organ and circulates blood. The OCS Perfusion Set includes all accessories needed to place the organ on the system.

- **OCS Solutions:** The OCS Solutions are a set of nutrient-enriched solutions used with blood to replenish depleted nutrients and hormones needed to optimize the organ's condition outside of the human body.

Our single-use OCS Perfusion Sets and OCS Solutions, which we refer to collectively as a disposable set, are required for each organ transplant. As such, our business model is characterized by a high level of recurring revenue. We expect that greater than 90% of our revenue will be related to sales of our single-use OCS disposable sets.

The OCS technology platform is equipped with the following core technologies that we designed to comprehensively address the limitations of cold storage and improve transplant outcomes:

- **proprietary pulsatile blood pump** to simulate beating heart perfusion in organs outside of the human body;

- **proprietary software-controlled titanium blood warmer** to maintain blood at body temperature while maximizing portability;
- **gas exchanger** to maintain organ oxygenation outside of the human body;
- **customized hemodynamics sensors** to monitor and assess organ function outside of the human body;
- **proprietary software-controlled, miniaturized, electromechanical system with universal power supply and hot-swappable batteries** to maximize portability and travel distance for organ retrieval;
- **proprietary wireless monitor and control software** to provide an intuitive user interface for monitoring critical organ function; and
- **customized carbon fiber OCS console structure** to reduce the overall weight of the system and maximize portability.

For each organ product, the OCS core technologies are supplemented with additional customized and proprietary organ-specific features to meet each organ's requirements.

Key Advantages of the OCS Platform

We believe the OCS platform provides significant benefits relative to cold storage, including:

- ***Improved Clinical Outcomes:*** Use of the OCS has demonstrated a substantial reduction in injurious ischemic time in all of our clinical trials. The results of our OCS Lung INSPIRE Trial, which compared the use of the OCS Lung to cold storage, demonstrated a statistically significant reduction of approximately two hours in the amount of time the organ went without oxygenation, or ischemic time. These results were achieved while allowing for an average of 1.5 incremental hours between donor and recipient. This decrease in injurious ischemic time resulted in an approximately 50% reduction relative to cold storage in the most common and severe form of lung transplant complication called primary graft dysfunction grade 3, or PGD3. PGD3 is a dangerous and costly complication as patients with it typically experience longer time on mechanical ventilation and in the intensive care unit, as well as potential long-term negative consequences. We believe these results are consistent with those of our other clinical trials and will support adoption of the OCS.
- ***Increased Donor Organ Utilization:*** In our OCS Lung EXPAND Trial, we evaluated the use of the OCS Lung for donor organs from both DBD and DCD donors that would not otherwise have been utilized, and in our OCS Heart EXPAND Trial, we evaluated the use of the OCS Heart for donor organs from DBD donors that would not otherwise have been utilized. The lungs and hearts that were transplanted in these studies were rejected an average of 35 and 66 times, respectively, by other institutions using cold storage due to a variety of clinical and logistical reasons that may have included donor organ quality, donor age, expected injurious ischemic time or travel distance, or type of donor. In these trials, the use of the OCS resulted in an 87% utilization rate of donor lungs and an 81% utilization rate of donor hearts that otherwise would have been unutilized. The results of these trials support our belief that the OCS can significantly expand the number of organs that can be transplanted and better serve the large population of patients who need an organ transplant to survive.

Our Strategy

We are committed to transforming organ transplantation with our OCS platform by increasing the utilization of donor organs and improving clinical outcomes. We are targeting a large and highly concentrated opportunity that, we believe, currently lacks an effective solution for organ preservation, optimization and assessment. Our goal is to establish the OCS as the standard of care for organ transplantation and increase the number of organ transplants performed.

The key elements of our strategy are:

- **Target and drive deeper adoption of the OCS at leading transplant institutions**. We are focused on driving adoption at leading, high volume transplant programs where we have established strong relationships during our clinical trials. We plan to leverage these centers' familiarity with the value of the OCS to increase the number of transplants they perform and increase our penetration of their case volumes. We also plan to expand our reach to additional high volume transplant programs.
- **Continue to build clinical evidence to substantiate the benefits of the OCS and expand clinical transplant indications**. Surgeons affiliated with leading academic transplant centers rely primarily on clinical evidence to drive changes in their practice. We have developed a substantial body of clinical evidence to support our PMA applications, potential PMA applications and other regulatory approvals for the use of the OCS technology in the field of organ transplantation. We plan to expand this body of clinical evidence in the post-market setting.
- **Expand the existing pool of utilizable donor organs by securing additional FDA PMA Supplements and new PMAs for expanded indications**. We secured our first PMA approval for the OCS Lung in March 2018. We have several additional applications for PMAs in the pipeline, including for our expanded lung indications and for our heart products, and we also plan to seek PMA approval for our liver products. If we are successful in obtaining such FDA approvals, we believe we will significantly expand the available donor organ pool.
- **Leverage the established commercial reimbursement process and billing mechanisms to accelerate U.S. commercial traction**. Medicare and private payors provided reimbursement for the OCS Lung, OCS Heart and OCS Liver during our U.S. pivotal trials using existing commercial billing and reimbursement processes for organ transplant procedures and have provided reimbursement for the OCS Lung following FDA approval in March 2018. We believe these established methods will continue to facilitate commercial reimbursement for the OCS Lung and, if they are approved by the FDA, for the OCS Heart and OCS Liver. We are in the process of seeking long-term reimbursement for our OCS products in several other countries.
- **Develop the next generation OCS technology platform to improve user experience and expand OCS products**. We intend to invest in developing the next generation, multi-organ platform to improve the user experience. We also intend to develop and seek approval for additional OCS products for other organs, including kidneys.

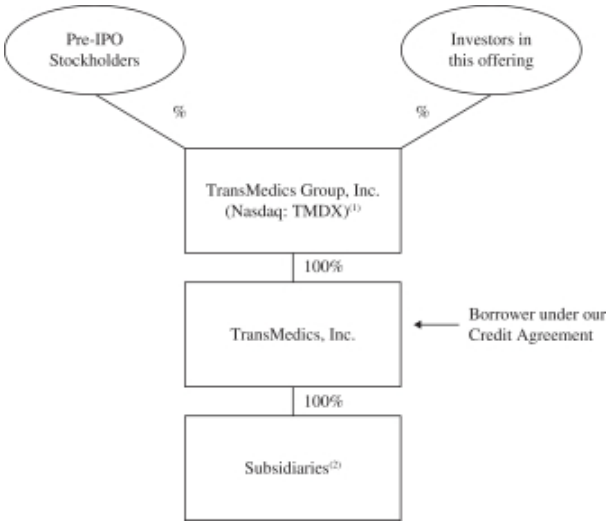
Corporate Reorganization

TransMedics Group, Inc., a recently formed Massachusetts corporation, or TransMedics Group, is currently a direct, wholly-owned subsidiary of TransMedics, Inc., a Delaware corporation. Immediately prior to or concurrently with the closing of this initial public offering, TMDX, Inc., a direct, wholly-owned subsidiary of TransMedics Group, will merge with and into TransMedics, Inc. with TransMedics, Inc. as the surviving corporation. As a result of the merger, each outstanding share of capital stock of TransMedics, Inc. will be converted into shares of common stock of TransMedics Group, each outstanding option to purchase shares of common stock of TransMedics, Inc. will be converted into an outstanding option to purchase shares of common stock of TransMedics Group and each outstanding warrant to purchase shares of preferred stock of TransMedics, Inc. will be converted into a warrant to purchase shares of common stock of TransMedics Group, pursuant to the terms of the Agreement and Plan of Merger and Reorganization filed as an exhibit to the Registration Statement of which this prospectus forms a part. We refer to this as the "Corporate Reorganization."

Immediately following the Corporate Reorganization, (1) TransMedics Group will be a holding company with no material assets other than 100% of the equity interests in TransMedics, Inc., (2) the holders of capital stock in TransMedics, Inc. will become shareholders of TransMedics Group and (3) the historical consolidated

financial statements of TransMedics, Inc. will become the historical consolidated financial statements of TransMedics Group because the Corporate Reorganization will be accounted for as a reorganization of entities under common control. Prior to the Corporate Reorganization, TransMedics Group has not conducted any activities other than in connection with its formation and in preparation for this offering and has no material assets other than 100% of the equity interests in TMDX, Inc. See "Corporate Reorganization" elsewhere in this prospectus.

The following chart illustrates our organizational structure upon completion of the Corporate Reorganization and this offering, assuming no exercise of the underwriters' option to purchase additional shares of common stock:



(1) Upon the consummation of this offering, TransMedics Group will become a guarantor under our credit agreement with OrbiMed Royalty Opportunities II, L.P., or the Credit Agreement.
(2) TransMedics B.V. is a guarantor under our Credit Agreement.

Risks Associated with Our Business

- We have incurred substantial losses since our inception, including a net loss of $16.1 million for the fiscal nine months ended September 29, 2018 and resulting in an accumulated deficit of $328.3 million as of September 29, 2018, and we anticipate that we will continue to incur losses in the future;
- We may need to raise additional funding, which might not be available on favorable terms, or at all;
- We depend heavily on the success of the OCS and achieving market acceptance, and if we are unable to successfully commercialize the OCS, our business may fail;
- The clinical trial process required to obtain regulatory approvals is lengthy and expensive, with uncertain outcomes;
- We must continue to educate surgeons, transplant centers and private payors and demonstrate the merits of the OCS compared with cold storage or new competing technologies, and surgeons, transplant centers and private payors may require additional clinical data prior to adopting or maintaining coverage of the OCS;

- Our long-term growth depends on our ability to improve the OCS platform, including to expand into new indications and to develop the next generation of our products;
- We depend on a limited number of customers for a significant portion of our net revenue and the loss of, or a significant shortfall in demand from, these customers could have a material adverse effect on our financial condition and operating results;
- Our business may not be successful if we are unable to protect, defend, maintain and enforce our intellectual property rights relating to the OCS and avoid allegations that our products infringe, misappropriate or otherwise violate the intellectual property rights of third parties; and
- Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern in its report on our audited financial statements included in this prospectus.

The foregoing is only a summary of some of our risks. For a more detailed discussion of these and other risks you should consider before making an investment in our common stock, see "Risk Factors."

Implications of Being an Emerging Growth Company and Smaller Reporting Company

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies, including:

- reduced disclosure about our executive compensation arrangements;
- exemption from the requirements to hold non-binding advisory votes on executive compensation and golden parachute payments; and
- exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We may take advantage of these exemptions until the last day of the fiscal year following the fifth anniversary of this offering or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company earlier if we have more than $1.07 billion in annual revenue, we have more than $700 million in market value of our stock held by non-affiliates (and we have been a public company for at least 12 months and have filed one annual report on Form 10-K with the Securities and Exchange Commission, or the SEC) or we issue more than $1 billion of non-convertible debt securities over a three-year period. For so long as we remain an emerging growth company, we are permitted, and intend, to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. We may choose to take advantage of some, but not all, of the available exemptions.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected not to "opt out" of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that we either (i) irrevocably elect to "opt out" of such extended transition period or (ii) no longer qualify as an emerging growth company. Therefore, the reported results of operations contained in our financial statements may not be directly comparable to those of other public companies.

We are also a "smaller reporting company," meaning that the market value of our stock held by non-affiliates plus the proposed aggregate amount of gross proceeds to us as a result of this offering is less than

$700 million and our annual revenue is less than $100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company after this offering if either (i) the market value of our stock held by non-affiliates is less than $250 million or (ii) our annual revenue is less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Our Corporate Information

Our predecessor TransMedics, Inc. was incorporated in Delaware in August 1998. We were incorporated in Massachusetts in October 2018. Our principal executive offices are located at 200 Minuteman Road, Andover, MA 01810, and our telephone number is (978) 552-0900. Our website address is www.transmedics.com. Information contained on, or that can be accessed through, our website is not part of this prospectus.

THE OFFERING

Common stock offered by us	shares.
Common stock outstanding after this offering	shares (shares if the underwriters exercise their option to purchase additional shares in full).
Underwriters' option to purchase additional shares of common stock from us	We have granted the underwriters an option to purchase up to an aggregate of additional shares of common stock from us at the public offering price, less the underwriting discounts and commissions, for a period of 30 days after the date of this prospectus.
Use of proceeds	We estimate that our net proceeds from the sale of our common stock in this offering will be approximately $ million, assuming an initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering to support commercialization of the OCS Lung and, if approved, the OCS Heart in the United States; to fund research and development to design and manufacture the next generation of OCS technology; for clinical trial expenditures, including those relating to our pre- and post-market clinical trials, including our Thoracic Organ Perfusion Post-Approval Study Registry, our OCS Liver PROTECT Trial and the use of the OCS Heart for DCD donor hearts; and for working capital and other general corporate purposes. See "Use of Proceeds."
Dividend policy	We do not anticipate declaring or paying any cash dividends on our capital stock in the foreseeable future. See "Dividend Policy."
Risk factors	You should carefully read the "Risk Factors" section of this prospectus and the other information included in this prospectus for a discussion of factors that you should consider before deciding to invest in our common stock.
Registration rights	Pursuant to an Investor Rights Agreement, certain existing holders of equity interests in TransMedics, Inc. will have registration rights with respect to shares of common stock of TransMedics Group upon completion of the Corporate Reorganization. See "Description of Capital Stock—Registration Rights."
Nasdaq Global Market trading symbol	"TMDX"

The number of shares of common stock to be outstanding after this offering is based on 4,877,288 shares of common stock outstanding as of October 27, 2018 and gives effect to the conversion of all outstanding shares of preferred stock into an aggregate of 45,918,010 shares of common stock, and excludes:

- 5,704,293 shares of common stock issuable upon the exercise of stock options outstanding as of October 27, 2018 under our 2004 Stock Incentive Plan, or our 2004 Plan, and our 2014 Stock Incentive Plan, or our 2014 Plan, at a weighted average exercise price of $0.50 per share;
- 225,544 shares of common stock issuable upon the exercise of warrants outstanding as of October 27, 2018 to purchase shares of preferred stock that will be converted into warrants to purchase shares of common stock, at a weighted average exercise price of $3.06 per share, in connection with the Corporate Reorganization;
- 253,860 shares of common stock available for future issuance as of October 27, 2018 under our 2014 Plan;
- shares of common stock that will become available for future issuance under our 2019 Stock Incentive Plan; and
- shares of common stock that will become available for future issuance under our 2019 Employee Stock Purchase Plan.

Except as otherwise noted or the context otherwise requires, all information in this prospectus assumes or gives effect to:

- the Corporate Reorganization, including (1) the conversion of all outstanding shares of preferred stock of TransMedics, Inc. into an aggregate of shares of common stock of TransMedics Group; (2) the conversion of all outstanding shares of common stock of TransMedics, Inc. into an aggregate of shares of common stock of TransMedics Group; (3) the conversion of all outstanding options to purchase shares of common stock of TransMedics, Inc. into options to purchase shares of common stock of TransMedics Group (as appropriately adjusted); and (4) the conversion of all outstanding warrants to purchase shares of preferred stock of TransMedics, Inc. into warrants to purchase shares of common stock of TransMedics Group (as appropriately adjusted);
- no exercise of the outstanding stock options described above;
- no exercise by the underwriters of their option to purchase additional shares; and
- the filing and effectiveness of our restated articles of organization and the adoption of our amended and restated bylaws upon the closing of this offering.

SUMMARY CONSOLIDATED FINANCIAL DATA

You should read the following summary consolidated financial data together with the sections titled "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes included elsewhere in this prospectus. The consolidated statement of operations data for the fiscal years ended December 31, 2016 and December 30, 2017 have been derived from our audited consolidated financial statements included elsewhere in this prospectus. The consolidated statement of operations data for the fiscal nine months ended September 30, 2017 and September 29, 2018 and the consolidated balance sheet data as of September 29, 2018 have been derived from our unaudited consolidated financial statements included elsewhere in this prospectus and have been prepared on the same basis as the audited consolidated financial statements. Our historical results are not necessarily indicative of the results that may be expected in the future.

	Fiscal Year Ended		Fiscal Nine Months Ended	
	December 31, 2016	December 30, 2017	September 30, 2017	September 29, 2018
	(in thousands, except per share data)			
Consolidated Statement of Operations Data:				
Net revenue	$ 6,209	$ 7,685	$ 5,579	$ 9,473
Cost of revenue	5,443	5,548	3,971	5,238
Gross profit	766	2,137	1,608	4,235
Operating expenses:				
Research, development and clinical trials	15,637	14,957	11,555	10,170
Selling, general and administrative	8,115	7,606	5,973	7,941
Total operating expenses	23,752	22,563	17,528	18,111
Loss from operations	(22,986)	(20,426)	(15,920)	(13,876)
Other income (expense):				
Interest expense	(979)	(1,072)	(804)	(1,647)
Change in fair value of preferred stock warrant liability	(105)	159	156	(423)
Other income (expense), net	5	548	421	(152)
Total other expense, net	(1,079)	(365)	(227)	(2,222)
Loss before income taxes	(24,065)	(20,791)	(16,147)	(16,098)
Provision for income taxes	—	(32)	(28)	(23)
Net loss	$ (24,065)	$ (20,823)	$ (16,175)	$ (16,121)
Net loss per share attributable to common stockholders, basic and diluted(1)	$ (5.35)	$ (4.48)	$ (3.48)	$ (3.42)
Weighted average common shares outstanding, basic and diluted(1)	4,502	4,647	4,647	4,714
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)(1)		$		$
Pro forma weighted average common shares outstanding, basic and diluted (unaudited)(1)				

(1) See Note 14 to our consolidated financial statements included elsewhere in this prospectus for details on the calculation of basic and diluted net loss per share attributable to common stockholders and unaudited basic and diluted pro forma net loss per share attributable to common stockholders.

	As of September 29, 2018		
	Actual	Pro Forma(2)	Pro Forma As Adjusted(3)
	(in thousands)		
Consolidated Balance Sheet Data:			
Cash and cash equivalents	$ 28,890	$ 28,890	$
Working capital(1)	31,722	31,722	
Total assets	48,397	48,397	
Long-term debt, net of discount	33,564	33,564	
Preferred stock warrant liability	776	—	
Convertible preferred stock	186,519	—	
Total stockholders' equity (deficit)	(184,697)	2,598	

(1) We define working capital as current assets less current liabilities.

(2) The pro forma consolidated balance sheet data give effect to the Corporate Reorganization, including (i) the conversion of all outstanding shares of preferred stock of TransMedics, Inc. into an aggregate of shares of common stock of TransMedics Group, (ii) the conversion of all outstanding shares of common stock of TransMedics, Inc. into an aggregate of shares of common stock of TransMedics Group and (iii) the conversion of all outstanding warrants to purchase shares of preferred stock of TransMedics, Inc. into warrants to purchase shares of common stock of TransMedics Group.

(3) The pro forma as adjusted balance sheet data give further effect to (i) our issuance and sale of shares of our common stock in this offering at an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, and (ii) our payment of $1.5 million to former financial advisors upon the closing of this offering in satisfaction of contractual obligations previously recorded.

The pro forma as adjusted information discussed above is illustrative only and will change based on the actual initial public offering price and other terms of this offering determined at pricing. A $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, working capital, total assets and total stockholders' equity by $ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase (decrease) of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, working capital, total assets and total stockholders' equity by $ million, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

RISK FACTORS

An investment in our common stock involves risks. You should consider carefully the following risks and all of the other information contained in this prospectus before investing in our common stock. The risks described below are those that we believe are the material risks that we face. If any of the following risks actually occurs, our business, prospects, operating results and financial condition could suffer materially, the trading price of our common stock could decline and you could lose all or part of your investment. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may also adversely affect our business. See "Cautionary Note Regarding Forward-Looking Statements" elsewhere in this prospectus.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred substantial losses since our inception and anticipate that we will continue to incur losses in the future.

Since our inception, we have incurred significant operating losses. Our ability to generate net revenue sufficient to achieve profitability will depend on the successful further development and commercialization of our Organ Care System, or the OCS, products. We generated net revenue of $6.2 million and $7.7 million for the fiscal years ended December 31, 2016 and December 30, 2017, respectively, and incurred net losses of $24.1 million and $20.8 million for those same years. We generated net revenue of $9.5 million and incurred a net loss of $16.1 million for the fiscal nine months ended September 29, 2018. As of September 29, 2018, we had an accumulated deficit of $328.3 million. To date, we have funded our operations primarily with proceeds from sales of preferred stock and borrowings under loan agreements, as well as revenue from clinical trials and commercial sales outside of the United States. Our losses have resulted principally from costs incurred in connection with our research and development, clinical trials, manufacturing and commercialization activities.

We expect to continue to incur net losses for the foreseeable future as we focus on growing commercial sales of our products in both the U.S. and select non-U.S. markets, including growing our sales and clinical adoption team, which will pursue increasing commercial sales and clinical adoption of our OCS products; scaling our manufacturing operations; continuing research, development and clinical trial efforts; and seeking regulatory clearance for new products and product enhancements, including new indications, in both the U.S. and select non-U.S. markets. Further, following the closing of this offering, we expect to incur additional costs associated with operating as a public company. As a result, we will need substantial additional funding for expenses related to our operating activities, including selling, general and administrative expenses and research, development and clinical trials expenses. Because of the numerous risks and uncertainties associated with product development and commercialization, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve or maintain profitability. Until such time, if ever, as we can generate substantial net revenue sufficient to achieve profitability, we expect to finance our operations through a combination of equity offerings, debt financings and strategic alliances. We may be unable to raise additional funds or enter into such other agreements or arrangements, when needed, on favorable terms, or at all. If we are unable to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back or discontinue the further development and commercialization efforts of one or more of our products, or may be forced to reduce or terminate our operations.

We may need to raise additional funding, which might not be available on favorable terms, or at all. Raising additional capital may cause dilution to our shareholders.

As we continue to pursue and increase commercial sales of our OCS products, we expect our costs and expenses to increase in the future, particularly as we expand our sales and clinical adoption team, scale our manufacturing operation, continue research, development and clinical trial efforts, and seek regulatory clearance for new products and product enhancements, including new indications, both in the United States and in

select non-U.S. markets. In addition, upon the closing of this offering, we expect to incur additional costs associated with operating as a public company. The timing and amount of our operating and capital expenditures will depend on many factors, including:

- the amount of net revenue generated by sales of our OCS Consoles, OCS Perfusion Sets and OCS Solutions and other products that may be approved in the United States and select non-U.S. markets;
- the costs and expenses of expanding our U.S. and non-U.S. sales and marketing infrastructure and our manufacturing operations;
- the extent to which our OCS products are adopted by the transplant community;
- the ability of our customers to obtain adequate reimbursement from third-party payors for procedures performed using the OCS products;
- the degree of success we experience in commercializing our OCS products for additional indications;
- the costs, timing and outcomes of any future clinical studies and regulatory reviews, including to seek and obtain approvals for new indications for our OCS products;
- the emergence of competing or complementary technologies;
- the number and types of future products we develop and commercialize;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims; and
- the level of our selling, general and administrative expenses.

Additional capital might not be available when we need it, and our actual cash requirements might be greater than anticipated. If we require additional capital at a time when investment in our industry or in the marketplace in general is limited, we might not be able to raise funding on favorable terms, if at all. If we are not able to obtain financing on terms favorable to us, we may need to cease or reduce development or commercialization activities, sell some or all of our assets or merge with another entity, which could result in a loss of all or part of your investment.

In addition, if we raise additional funds through the issuance of equity or convertible securities, the issuance of these securities could dilute your percentage ownership in our company. Furthermore, newly issued securities may have rights, preferences or privileges senior to those of common shareholders. If we raise additional funds through additional debt financing, we may need to dedicate a substantial additional portion of any operating cash flows to the payment of principal and interest on such indebtedness. The terms of any debt financing also could impose significant restrictions on our operations.

Our existing and any future indebtedness could adversely affect our ability to operate our business.

As of September 29, 2018, we had $35.0 million of outstanding long-term debt under our credit agreement with OrbiMed Royalty Opportunities II, LP, or OrbiMed, which we refer to as the Credit Agreement. We could incur additional indebtedness in the future. Our payment obligations under the Credit Agreement reduce cash available to fund working capital, capital expenditures, research and development and general corporate needs. In addition, indebtedness under the Credit Agreement bears interest at a variable rate, making us vulnerable to increases in market interest rates. If market rates increase substantially, we will have to pay additional interest on this indebtedness, which would further reduce cash available for our other business needs.

Our obligations under the Credit Agreement are secured by substantially all of our assets and the assets of our wholly-owned subsidiaries. The security interest granted over our assets could limit our ability to obtain additional debt financing. In addition, the Credit Agreement contains negative covenants restricting our activities, including limitations on dispositions, mergers or acquisitions; encumbering our intellectual property; incurring

indebtedness or liens; paying dividends or redeeming stock or making other distributions; making certain investments; liquidating our company; modifying our organizational documents; entering into sale-leaseback arrangements and engaging in certain other business transactions. In addition, we are required to maintain a minimum liquidity amount of $3.0 million. Failure to comply with the covenants in the Credit Agreement, including the minimum liquidity covenant, could result in the acceleration of our obligations under the Credit Agreement, and, if such acceleration were to occur, it would materially and adversely affect our business, financial condition, operating results, cash flows and prospects.

We may not have sufficient funds, and may be unable to arrange for additional financing, to pay the amounts due under our debt arrangements. The obligations under the Credit Agreement are subject to acceleration upon the occurrence of specified events of default, including payment default, change in control, bankruptcy, insolvency, certain defaults under other material debt, certain events with respect to regulatory approvals and a material adverse change in our business, operations or other financial condition. If an event of default (other than certain events of bankruptcy or insolvency) occurs and is continuing, OrbiMed may declare all or any portion of the outstanding principal amount of the borrowings plus accrued and unpaid interest to be due and payable. Upon the occurrence of certain events of bankruptcy or insolvency, all of the outstanding principal amount of the borrowings plus accrued and unpaid interest will automatically become due and payable.

Our outstanding indebtedness and any future indebtedness, combined with our other financial obligations, could increase our vulnerability to adverse changes in general economic, industry and market conditions, limit our flexibility in planning for, or reacting to, changes in our business and the industry and impose a competitive disadvantage compared to our competitors that have less debt or better debt servicing options. See “Description of Certain Indebtedness.”

Our financial results may fluctuate from quarter to quarter, which makes our results difficult to predict and may cause our results to fall short of expectations.

Our financial results may fluctuate from quarter to quarter due to a number of factors, including the timing of our clinical trials, the availability of donor organs for transplantation, which is unpredictable and could impact the volume of transplant procedures performed at transplant centers using the OCS, and foreign currency exchange rates. We expect that revenue from sales will fluctuate significantly from quarter to quarter, and our future quarterly and annual expenses as a percentage of our revenue may be significantly different from those we have recorded in the past. Our financial results in some quarters may fall below expectations. Comparing our financial results on a period-to-period basis may not be meaningful, and you should not rely on our past results as an indication of our future performance. Because the timing of organ transplant procedures is generally unpredictable, we have not experienced seasonality in our business from quarter to quarter and do not expect to do so in the foreseeable future.

Our ability to use our net operating losses and research and development credit carryforwards to offset future taxable income may be subject to limitations.

As of December 30, 2017, we had U.S. federal and state net operating loss, or NOL, carryforwards of $215.2 million and $148.5 million, respectively, which may be available to offset future taxable income and begin to expire in 2018 and 2030, respectively. As of December 30, 2017, we also had U.S. federal and state research and development tax credit carryforwards of $6.0 million and $4.0 million, respectively, which may be available to offset future tax liabilities and begin to expire in 2020 and 2024, respectively. These NOL and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. In addition, in general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an “ownership change,” generally defined as a greater than 50% change by value in its equity ownership over a three-year period, is subject to limitations on its ability to utilize its pre-change NOLs, its research and development credit carryforwards and its disallowed interest expense carryovers to offset future taxable income. Our existing NOLs and research and development credit carryforwards may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change in connection with or after this offering, our ability to utilize NOLs and research and development credit carryforwards could be

further limited by Sections 382 and 383 of the Code. In addition, future changes in our stock ownership, some of which might be beyond our control, could result in an ownership change under Section 382 of the Code. Our NOLs and credits may also be impaired under state law. For these reasons, if we determine that an ownership change has occurred or in the event we experience a change of control, we may not be able to utilize a material portion of the NOLs, research and development credit carryforwards or disallowed interest expense carryovers incurred prior to 2018. Furthermore, our ability to utilize our NOLs or credits is conditioned upon our attaining profitability and generating U.S. federal and state taxable income. As described above we have incurred significant net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future; and therefore, we do not know whether or when we will generate the U.S. federal or state taxable income necessary to utilize our NOL or credit carryforwards. Under the Tax Cuts and Jobs Act, or TCJA, NOLs arising in taxable years beginning after December 31, 2017 will not be subject to expiration. In addition, the deduction for NOLs in any taxable year is limited to 80% of current year taxable year income in respect of NOLs generated during or after 2018. The TCJA also reduced the corporate income tax rate to 21%, from a prior rate of 35%. This may cause a reduction in the potential economic benefit of our NOLs and other available deferred tax assets.

Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern in its report on our audited financial statements included in this prospectus.

Our recurring losses from operations raise substantial doubt about our ability to continue as a going concern. As a result, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements for the fiscal year ended December 30, 2017 with respect to this uncertainty. Our ability to continue as a going concern will require us to obtain additional funding. We believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will enable us to fund our operating expenses, capital expenditure requirements and debt service payments through , without considering potential additional borrowings that may become available to us upon our achievement of specified revenue thresholds and a regulatory milestone under the Credit Agreement. Without giving effect to the net proceeds from this offering, we expect that our existing cash and cash equivalents as of September 29, 2018 will be sufficient to fund our operating expenses, capital expenditure requirements and debt service payments through September 2019, without considering potential additional borrowings that may become available to us under the Credit Agreement. We have based these estimates on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. If we are unable to raise capital when needed or on acceptable terms, we would be forced to delay, or discontinue the further development and commercialization efforts of one or more of our products, or may be forced to reduce or terminate our operations.

Risks Related to Research and Development and Commercialization

We depend heavily on the success of the OCS and achieving market acceptance. If we are unable to successfully commercialize the OCS, our business may fail.

We have invested all of our efforts and financial resources in the development of the OCS. While the OCS Lung received premarket approval, or PMA, from the U.S. Food and Drug Administration, or the FDA, for the preservation of donor lungs currently utilized for double-lung transplantation, and our OCS products have received the Conformité Européenne, or CE Mark, and several other international regulatory approvals for lung, heart and liver for sales outside the United States, we might not be able to commercialize successfully the OCS for the approved indications or obtain approvals for additional indications or in additional jurisdictions on our planned timing, or at all. Our ability to generate product revenue and become profitable depends solely on sales of OCS Perfusion Sets and OCS Solutions, which we refer to collectively as disposable sets, and OCS Consoles. Our assumptions regarding demographic trends, donor organ availability and the use of transplantation as a treatment for end-stage organ failure may prove to be incorrect.

In order to achieve market acceptance for the OCS, we expect that we will need to demonstrate to surgeons, transplant center program directors and private payors that the OCS potentially results in some or all of the

following: improvements in post-transplant clinical outcomes, increases in the utilization of donor organs, expansion of the pool of potential donors and reduction in the total cost of care as compared to available alternatives. Data from our ongoing or future clinical trials may not demonstrate that the OCS provides these benefits. In addition, the medical community might not consider data collected from our patient registry meaningful or compelling, or the data collected from our patient registry or any clinical or commercial experience could indicate that the OCS is unsafe, which would substantially undermine our commercialization efforts.

Surgeons, transplant centers and private payors often are slow to adopt new products, technologies and treatment practices that require additional upfront costs and training. We expect that the cost of the OCS will significantly exceed the cost of cold storage preservation. In addition, surgeons may not be willing to undergo training to use the OCS, may decide the OCS is too complex to adopt without appropriate training and may choose not to use the OCS. Based on these and other factors, transplant center program directors and private payors may decide that the benefits of the OCS do not outweigh its costs. In addition, adoption of the OCS may be constrained by the capacity of individual transplant centers to perform transplants due to factors such as the number of its surgeons trained on the use of the OCS. As a result, demand for the OCS could be materially lower than we expect it to be, which would materially and adversely affect our business, financial condition, operating results, cash flows and prospects.

The clinical trial process required to obtain regulatory approvals is lengthy and expensive, with uncertain outcomes.

We have obtained PMA approval for the OCS Lung for certain lung transplants in the United States. In order to obtain PMA approval for a device, the sponsor must conduct clinical trials, often well-controlled clinical studies, designed to assess the safety and effectiveness of the product. Conducting clinical trials is a complex and expensive process, can take many years and outcomes are inherently uncertain. We incur substantial expense for, and devote significant time to, clinical trials but cannot be certain that the product tested will ever generate revenue sufficient to cover the costs of trials. We may experience significant setbacks in clinical trials, even after earlier clinical trials showed promising results, and failure can occur at any time during the clinical trial process. Any of our products may malfunction or may produce undesirable adverse effects that could cause us or regulatory authorities to interrupt, delay or halt clinical trials. We, the FDA or another regulatory authority may suspend or terminate clinical trials at any time.

Successful results in early studies do not assure positive results in subsequent clinical trials. The data we collect from our preclinical studies and clinical trials may not be sufficient to support FDA or other regulatory clearance or approval. Additionally, the FDA may disagree with our interpretation of the data from our studies and trials. The FDA may conclude that the clinical trial design, conduct or results are inadequate to prove safety or effectiveness, and the FDA may require us to undertake expensive and lengthy additional trials, either of which may delay clearance or approval of products.

Clinical trials are necessary to support PMA applications and may be necessary to support PMA supplements for modified versions of our marketed device products. Trials often require enrollment of large numbers of subjects, who may be difficult to identify, recruit and maintain as participants in the clinical trial. For example, the clinical trials supporting the PMA application for the OCS Lung involved 349 randomized and transplanted patients. As a condition of our PMA approval for the OCS Lung, we are required to conduct two post-market studies. Adverse outcomes in post-approval studies can result in withdrawal of approval of a PMA or restrictions on the approval. We will need to conduct additional clinical studies to support use of the OCS in, and development of OCS products for, new organs, like kidney, and for commercialization of our products in additional foreign jurisdictions. Clinical trials in organ transplant are difficult to design and implement, take substantial time to conduct and are expensive. The results of clinical trials are inherently uncertain. The initiation and completion of any studies may be prevented, delayed or halted for numerous reasons. The following could adversely affect the costs, timing or successful completion of our clinical trials:

- we have been required and, prior to collecting clinical data in the future to support new PMA applications, will be required again to submit an IDE application to the FDA, which must become effective prior to commencing human clinical trials, and the FDA may reject our IDE application and notify us that we may not begin investigational trials;
- regulators and other comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical trials;
- regulators and/or institutional review boards, or IRBs, or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site;
- we may not reach agreement on acceptable terms with prospective clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different trial sites;
- clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of subjects or patients required for clinical trials may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, and the number of clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors, including those manufacturing products or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical trials for various reasons, including a finding that the subjects are being exposed to unacceptable health risks;
- we may have to amend clinical trial protocols or conduct additional studies to reflect changes in regulatory requirements or guidance, which we may be required to submit to an IRB and/or regulatory authorities for re-examination;
- regulators, IRBs or other reviewing bodies may require or recommend that we or our investigators suspend or terminate clinical research for various reasons, including safety signals or noncompliance with regulatory requirements;
- the cost of clinical trials may be greater than we anticipate;
- we may be unable to recruit a sufficient number of clinical trial sites;
- regulators, IRBs or other reviewing bodies may fail to approve or subsequently find fault with our manufacturing processes or facilities of third-party manufacturers with which we enter into agreement for clinical and commercial supplies, the supply of devices or other materials necessary to conduct clinical trials may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply;

- approval policies or regulations of FDA or applicable foreign regulatory agencies may change in a manner rendering our clinical data insufficient for approval; and
- our current or future products may have undesirable side effects or other unexpected characteristics.

Patient enrollment in clinical trials and completion of patient follow-up depend on many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial, patient compliance, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the product being studied in relation to other available products or services. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and effectiveness of a product, or they may be persuaded to participate in contemporaneous clinical trials of a competitor's product. In addition, patients participating in our clinical trials may drop out before completion of the trial or experience adverse medical events unrelated to our products. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may delay commencement or completion of the clinical trial, cause an increase in the costs of the clinical trial and delays, or result in the failure of the clinical trial.

Clinical trials must be conducted in accordance with the regulations of the FDA and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and IRBs at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with supplies of our devices produced under certain requirements of the Quality System Regulation, or QSR, and other regulations. Furthermore, we rely on clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities, we have limited influence over their actual performance. We depend on transplant centers to conduct our clinical trials in compliance with good clinical practice, or GCP, requirements. To the extent that transplant centers fail to enroll participants for our clinical trials, fail to conduct the study to GCP standards or are delayed for a significant time in the execution of trials, including achieving full enrollment, we may be affected by increased costs, program delays or both. In addition, clinical trials that are conducted in countries outside the United States may subject us to further delays and expenses as a result of increased shipment costs, additional regulatory requirements and the engagement of non-U.S. institutions, as well as expose us to risks associated with clinical investigators who are unknown to the FDA, and different standards of diagnosis, screening and medical care.

Failure can occur at any stage of clinical testing. Our clinical studies may produce negative or inconclusive results, and, in the future, we may decide, or regulators may require us, to conduct additional clinical and non-clinical testing in addition to those we have planned. For example, in a November 2018 major deficiency letter for our PMA supplement to our OCS Lung PMA, as described further below, the FDA asked us for additional available data and supplemental analyses and, in the future, could ask us to conduct additional clinical trials or submit additional evidence to support our PMA application for use of the OCS Lung for currently unutilized DBD and DCD donor lungs if the FDA does not believe the data we have already submitted is sufficient. Our failure to adequately demonstrate the safety and effectiveness of the OCS or any product we may develop in the future would prevent receipt of regulatory clearance or approval and, ultimately, the commercialization of that product or indication for use. Even if our future products are cleared or approved in the United States, commercialization of our products in foreign countries would require approval by regulatory authorities in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials. Any of these occurrences could materially and adversely affect our business, financial condition, operating results, cash flows and prospects.

We must continue to educate surgeons, transplant centers and private payors and demonstrate the merits of the OCS compared with cold storage or new competing technologies. Surgeons, transplant centers and private payors may require additional clinical data prior to adopting or maintaining coverage of the OCS.

Directors of transplant programs are key decision-makers in the adoption of novel medical devices used in organ transplantation. An important part of our commercialization efforts is to educate transplant center program directors and other surgeons on the relative merits of the OCS. Our success depends, in large part, on effectively marketing and educating program directors and other surgeons about the benefits of the OCS. Acceptance of the OCS also depends on educating program directors, other surgeons and private payors as to the distinctive characteristics, perceived medical and economic benefits, safety and ease of use and cost-effectiveness of the OCS. If program directors, other surgeons and private payors do not find our body of published clinical evidence and data compelling or wish to wait for additional studies, they may choose not to use or provide coverage and reimbursement for our products. Currently, national healthcare systems do not reimburse transplant centers for the use of the OCS and reimbursement in international markets may require us to undertake additional clinical studies.

In addition, the long-term effects of our OCS beyond one to two years following transplantation are not yet known. Certain surgeons, transplant centers and private payors may prefer to see longer-term safety and efficacy data than we have produced. We cannot provide assurance that any data that we or others may generate in the future will be consistent with that observed in our existing clinical studies.

Our long-term growth depends on our ability to improve the OCS platform, including by expanding into new indications and developing the next generation of our products.

Our business plan contemplates that we will continue to improve the OCS platform, including by expanding into additional organs and developing the next generation of our products. Developing such new or modified products is expensive and time-consuming and diverts management's attention away from current operations. The success of any new product offering or product enhancements to our OCS platform will depend on several factors, including our ability to:

- properly identify and anticipate surgeon and patient needs;
- develop and introduce new products and product modifications in a timely manner;
- avoid infringing upon, misappropriating or otherwise violating the intellectual property rights of third parties;
- demonstrate the safety and efficacy of new products and product modifications;
- obtain necessary regulatory clearances or approvals;
- comply with regulations regarding the marketing of new products or product modifications;
- provide adequate training to potential users of our products;
- receive adequate coverage and reimbursement for procedures performed with our products; and
- develop an effective sales and marketing effort.

In addition, issues pertaining to the core technology of the OCS could negatively affect adoption of the OCS across the OCS platform. If we are not successful in expanding our indications and developing the next generation of our products, our ability to increase our revenue may be impaired, which could materially and adversely affect our business, financial condition, operating results, cash flows and prospects.

We depend on a limited number of customers for a significant portion of our net revenue and the loss of, or a significant shortfall in demand from, these customers could have a material adverse effect on our financial condition and operating results.

We generate a significant amount of our net revenue from a limited number of customers. For the fiscal year ended December 30, 2017 and the fiscal nine months ended September 29, 2018, Harefield Hospital accounted

for 16% and 11%, respectively, of our net revenue. We expect that sales to relatively few customers will continue to account for a significant percentage of our net revenue in future periods. However, these customers or any of our other customers may not continue to utilize our products at current levels, pricing, or at all, and our revenue could fluctuate significantly due to changes in economic conditions, the use of other methods for organ preservation, such as cold storage, or the loss of, reduction of business with, or less favorable terms with any of our largest customers. Our future success will depend upon the timing and volume of business from our largest customers and the financial and operational success of these customers. If we were to lose one of our key customers or have a key customer significantly reduce its volume of business with us, our revenue may be materially reduced, which would materially and adversely affect our business, financial condition, operating results, cash flows and prospects.

We depend on single-source suppliers and, in a few cases, sole-source suppliers for many of the components used in the OCS.

We rely on single-source suppliers and, in a few cases, sole-source suppliers for many of the components used in the OCS. A single-source supplier is a supplier from which we make all purchases of a particular component used in the OCS even though other suppliers of the component exist. A sole-source supplier is a supplier from which we make all purchases of a particular component used in the OCS, and the supplier is the only source of that particular component in the market. For example, each of Fresenius Kabi Austria GmbH and Fresenius Kabi AB, which we refer to collectively as Fresenius, is our single-source supplier of OCS Solutions for the OCS Lung and the OCS Heart, respectively. While we have manufacturing and supply agreements with certain of our suppliers, for most of our suppliers, we place purchase orders on an as-needed basis. Our suppliers could discontinue the manufacturing or supply of these components at any time. We do not carry a significant inventory of these components. Our suppliers may not be able to meet our demand for their products, either because of acts of nature, the nature of our agreements with those manufacturers or our relative importance to them as a customer, and our manufacturers may decide in the future to discontinue or reduce the level of business they conduct with us. We might not be able to identify and qualify additional or replacement suppliers for any of these components quickly or at all or without incurring significant additional costs. We cannot guarantee that we will be able to establish alternative relationships on similar terms, without delay or at all. We may also face regulatory delays or be required to seek additional regulatory clearances or approvals if we experience any delay or deficiency in the quality of products obtained from suppliers or if we have to replace our suppliers. In addition, many of the components used in the OCS are specifically designed for use in the OCS, which means that off-the-shelf components may not be available as substitutes.

Establishing additional or replacement suppliers for any of these materials or components, if required, or any supply interruption from our suppliers, could limit our ability to manufacture our products, result in production delays and increased costs and adversely affect our ability to deliver products to our customers on a timely basis. Our inability to obtain sufficient quantities of components for the OCS also could adversely affect clinical development of the OCS. If we are not able to identify alternate sources of supply for the components, we might have to modify our product to use substitute components, which could cause delays in shipments, increase design and manufacturing costs and increase prices for our products. Any such modified product might not be as effective as the predecessor product or might not gain market acceptance. This could lead to customer dissatisfaction and damage to our reputation and could materially and adversely affect our business, financial condition, operating results, cash flows and prospects.

We have limited experience in manufacturing the OCS on a commercial scale and may encounter problems at our manufacturing facility or otherwise.

We have limited experience in manufacturing the OCS on a commercial scale. In order to manufacture the OCS in quantities sufficient to meet our anticipated commercial opportunity, we will need to increase our manufacturing capabilities. We may encounter technical challenges to increasing the scale at which we manufacture the OCS, including with respect to material procurement and quality control and assurance. An increase in production could make it more difficult for us to comply with quality system regulations or other

applicable requirements that are currently enforced by the FDA and other regulatory authorities, or that may be introduced in the future, in both the United States and in other countries. Commercial scale production of the OCS on a continuing basis also will require us to hire and retain additional management and technical personnel who have the necessary manufacturing experience and skills. We might not successfully identify, hire or retain qualified personnel on a timely basis or at all. Our inability to increase the scale of our manufacturing of the OCS could impair our ability to generate revenue and adversely affect market acceptance of our product.

In addition, all of our manufacturing operations are conducted at a single facility in Andover, Massachusetts. Any interruption in operations at this location could result in our inability to satisfy product demand. Despite our efforts to safeguard this facility, including acquiring insurance on commercially reasonable terms, adopting environmental health and safety protocols and utilizing off-site storage of computer data, a number of factors could damage or destroy our manufacturing equipment or our inventory of component supplies or finished goods, cause substantial delays in our operations, result in the loss of key information, and cause us to incur additional expenses, including relocation expense, including:

- operating restrictions, partial suspension or total shutdown of production imposed by regulatory authorities;
- equipment malfunctions or failures;
- technology malfunctions;
- work stoppages;
- damage to or destruction of the facility due to natural disasters or other events; or
- regional or local power shortages.

Our insurance may not cover our losses in any particular case, or insurance may not be available on commercially reasonable terms to cover certain of these catastrophic events. In addition, regardless of the level of insurance coverage, damage to our facilities or any disruption that impedes our ability to manufacture the OCS in a timely manner could materially and adversely affect our business, financial condition, operating results, cash flows and prospects.

Risks Related to Our Business and Industry

Failure to maintain an ethical and inclusive corporate culture, or damage to our reputation, could have a material adverse effect on our business.

We strive to create a culture in which our employees act with integrity, treat each other with respect and consider themselves empowered to report suspected misconduct. Our ability to attract and retain a high-quality workforce depends upon our commitment to a diverse and inclusive environment, along with our perceived trustworthiness and ethics. Allegations of misconduct by employees, particularly leaders, erode trust and confidence and cause reputational damage. Negative public opinion can result from actual or alleged conduct by the Company or those currently or formerly associated with the Company. Issues can arise in any number of circumstances, including employment-related offenses such as workplace harassment and discrimination, regulatory noncompliance, and failure to properly use and protect data and systems, as well as from actions taken by regulators or others in response to such conduct. Addressing allegations of misconduct detracts focus from business operations and is expensive. In 2018, for example, we resolved a claim based on allegations by a former employee relating to our Chief Executive Officer. Our board of directors, assisted by outside counsel, concluded that our Chief Executive Officer had exhibited poor personal judgment but had not violated state or federal employment discrimination laws (or engaged in any other illegal conduct). Allegations may be made against us and our executives in the future, and we may incur costs defending or settling such claims. We have adopted policies to promote compliance with laws and regulations as well as to foster a respectful workplace for all employees. These policies, which include a code of business conduct and ethics, an insider trading policy, a

Regulation FD policy, a sexual harassment policy, a regulated fraternization policy, and a whistleblower policy, are a component of our effort to minimize employee misconduct as well as activities that frequently result in allegations of misconduct, but our employees may fail to abide by these policies. In addition to damaging our reputation, actual or alleged misconduct could affect the confidence of our shareholders, regulators and other parties and could have a material adverse effect on our business, financial condition and operating results.

Our failure to compete effectively will harm our business and operating results.

A broad range of medical device, pharmaceutical and biotechnology companies offer products, procedures and therapies that have the potential to limit the demand for organ transplantation. Companies within this group vary depending on the type of organ. New therapies for chronic obstructive pulmonary disease, or COPD, which includes emphysema and chronic bronchitis, could limit the demand for lung transplants. For heart transplants, these alternative products, procedures and therapies include ventricular assist devices, cardiac rhythm management products, total artificial hearts, drug therapies for the heart and surgical procedures. Improved treatments for chronic diseases or conditions affecting the liver as well as efforts to develop artificial livers could limit the need for liver transplants. If demand for organ transplants decreases, sales of the OCS and its components will suffer.

Other companies may develop technologies and products that result in improved patient outcomes or are safer, easier to use, less expensive or more readily accepted than the OCS. Their products or technologies could make the OCS obsolete or noncompetitive. Other companies may also obtain FDA or other regulatory approval or clearance for their products sooner than we may obtain approval or clearance for the OCS. Many of these providers of alternative products, procedures and therapies have greater name recognition, significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and clearances and marketing and selling products than we do. Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Third parties may also compete with us in recruiting and retaining qualified medical, engineering and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to or necessary for our products or development programs or otherwise advantageous to our business. Our failure to compete effectively will harm our business and operating results.

Failure to protect our information technology infrastructure against cyber-based attacks, network security breaches or data corruption could materially disrupt our operations and adversely affect our business and operating results.

The efficient operation of our business depends on our information technology systems. We rely on our information technology systems to effectively manage sales and marketing data, accounting and financial functions, inventory management, product development tasks, clinical data, donor and patient data, customer service and technical support functions. Our information technology systems are vulnerable to damage or interruption from earthquakes, fires, floods and other natural disasters; terrorist attacks; cyber-based attacks; attacks by computer viruses or hackers; power losses, computer system or data network failures; security breaches and data corruption. Federal, state and international laws and regulations, such as the European Union’s General Data Protection Regulation, or the GDPR, which took effect in May 2018, can expose us to enforcement actions and investigations by regulatory authorities, and potentially result in regulatory penalties and significant legal liability, if our information technology security efforts fail. In addition, our software systems include cloud-based applications that are hosted by third-party service providers with security and information technology systems subject to similar risks.

The failure of either our or our service providers’ information technology could disrupt our entire operation or result in decreased sales, increased overhead costs and product shortages, all of which could materially and adversely affect our business, financial condition, operating results, cash flows and prospects.

Economic, political and other risks associated with foreign operations could adversely affect our international sales and our results of operations.

Because we market the OCS in countries in Europe, the Asia-Pacific, Central Asia and Canada and plan to market it in other international markets, we are subject to risks associated with doing business internationally. During the fiscal nine months ended September 30, 2017 and September 29, 2018, 66% and 54%, respectively, of our net revenue was generated from customers located outside of the United States. Even if we are successful in commercializing the OCS in the United States, we anticipate that international sales will represent a substantial portion of our total sales. In addition, some of our employees and suppliers are located outside of the United States. Accordingly, our results of operations could be harmed by a variety of factors, including:

- changes in a country's or region's political or economic conditions, including any potential impact resulting from the U.K.'s decision to exit the European Union, commonly referred to as "Brexit";
- longer payment cycles of foreign customers and difficulty of collecting receivables in foreign jurisdictions;
- different or changing regulatory or insurance practices regarding reimbursement for transplant procedures;
- difficulties in developing effective marketing campaigns in unfamiliar foreign countries;
- trade protection measures, import or export licensing requirements or customs clearance and shipping delays;
- fluctuations in foreign currency exchange rates;
- differing tax laws and changes in those laws in the countries in which we are subject to tax, or potentially adverse tax consequences, including the complexities of foreign value-added tax systems, tax inefficiencies related to our corporate structure, and restrictions on the repatriation of earnings;
- changes in international legislation or regulations governing the approval or clearance process for the OCS or ongoing compliance requirements;
- differing business practices associated with foreign operations;
- difficulties in staffing and managing our international operations;
- political, social, and economic instability abroad, terrorist attacks, and security concerns in general;
- the burdens of complying with a wide variety of foreign laws and different legal standards, such as anti-bribery laws, including the U.S. Foreign Corrupt Practices Act and U.K. Bribery Act of 2010, or the Bribery Act, data privacy requirements, labor laws and anti-competition regulations;
- differing protection of intellectual property; and
- increased financial accounting and reporting burdens and complexities.

We rely on shipping providers to deliver products to our customers globally. Labor, tariff or World Trade Organization-related disputes, piracy, physical damage to shipping facilities or equipment caused by severe weather or terrorist incidents, congestion at shipping facilities, inadequate equipment to load, dock and offload our products, energy-related tie-ups or other factors could disrupt or delay shipping or off-loading of our products domestically and internationally. Such disruptions or delays could materially and adversely affect our business, financial condition, operating results, cash flows and prospects.

If one or more of these risks are realized, our business, financial condition, operating results, cash flows and prospects could be materially and adversely affected.

Our success depends on our ability to retain our founder and President and Chief Executive Officer and other members of our management team and to attract, retain and motivate qualified personnel.

Our success depends on our continued ability to attract, retain and motivate highly qualified clinicians, surgeons, scientists, engineers, managers and sales personnel. Dr. Waleed H. Hassanein, our founder and President and Chief Executive Officer, and other members of our management team are important to the success of our operations and to our efforts to develop and commercialize the OCS. All of these key employees, including Dr. Hassanein, are at-will employees and can terminate their employment with us at any time. The loss of any of these key members of our management team and, in particular, Dr. Hassanein, could impede our achievement of our research, development and commercialization objectives. In addition, it will be an event of default under our Credit Agreement if Dr. Hassanein ceases to be our President and Chief Executive Officer and we do not hire a replacement that is reasonably acceptable to OrbiMed within 120 days. We maintain $1.0 million of "key person" insurance policy on the life of Dr. Hassanein, but we do not maintain such insurance on any of our other employees.

In addition, our expected growth will require us to hire a significant number of qualified personnel, including clinical development, regulatory, sales, marketing, engineering, scientific, clinical support and administrative personnel. There is intense competition from other companies and research and academic institutions for qualified personnel in the areas of our activities. If we cannot continue to attract and retain, on acceptable terms, the qualified personnel necessary for the continued development of our business, we might not be able to sustain our operations or become profitable.

The failure to manage our growth effectively could harm our business.

To manage our anticipated future growth effectively, we must enhance our manufacturing capabilities, information technology infrastructure and financial and accounting systems and controls. Our growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of the OCS for transplants involving additional indications or other organs, such as kidney. If we are unable to effectively manage our growth, our expenses may increase more than expected, our revenue could grow more slowly than expected and we might not be able to achieve our research and development and commercialization goals, which in turn could materially and adversely affect our business, financial condition, operating results, cash flows and prospects.

Risks Related to Our Intellectual Property

If we fail to maintain our license to patents covering the OCS, we will lose the right to manufacture, market and sell the OCS and our business would be harmed.

Our business depends, in part, on our license from the Department of Veterans Affairs, or VA, that covers the OCS. We have a license under certain patent rights relevant to our right to manufacture, market and sell the OCS, including the OCS Perfusion Sets and OCS Solutions specific to the lung, heart, liver and kidney for use in the OCS, pursuant to a license agreement with the VA. For more information, see "Business—Intellectual Property—Department of Veterans Affairs License". Our license agreement requires us, among other things, to pay royalties, determined as a percentage of our net sales of products covered by the licensed patents. If we fail to make these payments or otherwise fail to comply with the terms of our license agreement, the VA would have the right to terminate our license, in which case we would lose our right to manufacture, market and sell products covered by the licensed patents, which would materially and adversely affect our business, financial condition, operating results, cash flows and prospects.

The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the agreement. If disputes over intellectual property that we have licensed

prevent or impair our ability to maintain our license agreement with the VA or any other licensing arrangements on acceptable terms, or are insufficient to provide us the necessary rights to use the intellectual property, we may be unable to successfully develop and commercialize the OCS or other affected products. If we or our licensors fail to adequately protect our licensed intellectual property, our ability to commercialize our products could suffer. Any disputes with our licensor or any termination of the licenses on which we depend could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we infringe or are alleged to infringe the intellectual property rights of third parties or are otherwise subject to litigation or other proceedings regarding our intellectual property rights, our business or competitive position could be adversely affected.

Our commercial success will depend in part on not infringing, misappropriating or otherwise violating the patents or other intellectual property or proprietary rights of others. Significant litigation regarding patent and other intellectual property rights occurs in the medical device industry. Third parties may claim that the OCS or aspects or uses of the OCS infringe intellectual property rights for which we do not hold licenses or other rights in the United States and abroad. Third parties in both the United States and abroad may have applied for or obtained, or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our products.

Given the vast number of patents in our field of technology, we cannot be certain that we do not infringe existing patents or that we will not infringe patents that may be granted in the future. For example, patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived, so there may be applications of others now pending or recently revived patents of which we are unaware. These applications may later result in issued patents, or the revival of previously abandoned patents, that will prevent, limit or otherwise interfere with our ability to make, use or sell our products. Third parties may, in the future, assert claims that we are employing their proprietary technology without authorization, including claims from competitors or from non-practicing entities that have no relevant product revenue and against whom our own patent portfolio may have no deterrent effect. As we continue to commercialize our products in their current or updated forms, launch new products and enter new markets, competitors may claim that one or more of our products infringe their intellectual property rights as part of business strategies designed to impede our successful commercialization and entry into new markets. The large number of patents, the rapid rate of new patent applications and issuances, the complexities of the technology involved, and the uncertainty of litigation may increase the risk of business resources and management’s attention being diverted to patent litigation.

If any third-party patents were asserted against us, even if we believe such claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability, or priority. A court of competent jurisdiction could hold that the asserted third-party patents are valid, enforceable, and infringed, which could materially and adversely affect our ability to commercialize our products. In order to successfully challenge the validity of any U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. We may choose or, if we are found to infringe a third party’s patent rights and we are unsuccessful in demonstrating that such patents are invalid or unenforceable, we could be required to obtain a license from such third party to continue developing, manufacturing, and marketing any of our products. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We also could be forced, including by court order, to cease developing, manufacturing, and commercializing the infringing technology or products. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys’ fees if we are found to have willfully infringed a patent or other intellectual property right. There could also be public announcements of the results of hearing,

motions, or other interim developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar material adverse effect on our business, financial condition, results of operations and prospects.

Our industry has experienced substantial litigation and other proceedings regarding patent and other intellectual property rights and lawsuits to protect or enforce our patents and other intellectual property rights could be expensive, time-consuming and unsuccessful.

In addition to infringement claims against us, we may become a party to other types of patent litigation and other proceedings, including post-grant proceedings declared by the United States Patent and Trademark Office, or USPTO, and opposition proceedings in the European Patent Office, regarding intellectual property rights with respect to the OCS. For example, we may be subject to a third-party preissuance submission of prior art to the USPTO, or become involved in post-grant review procedures, oppositions, derivations, reexaminations, *inter partes* review or interference proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete. Patent litigation and other proceedings may also absorb significant management time.

In addition, competitors and other third parties may infringe, misappropriate or otherwise violate our patents and other intellectual property rights. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming and divert the time and attention of our management. In addition, many of our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can.

A court may disagree with our allegations and may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the third-party technology in question. Furthermore, the other party could counterclaim that we infringe their intellectual property or counterclaim that a patent we have asserted against them is invalid or unenforceable, or both. In patent litigation in the United States, counterclaims challenging the validity, enforceability or scope of asserted patents are commonplace. Similarly, third parties may initiate legal proceedings against us seeking a declaration that certain of our intellectual property rights are non-infringed, invalid, or unenforceable. The outcome of any such proceeding is generally unpredictable.

An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. If a defendant were to prevail on a legal assertion of invalidity or unenforceability of our patents covering one of our products, we would lose at least part, and perhaps all, of the patent protection covering such product. Competing products may also be sold in other countries in which our patent coverage might not exist or be as strong. Any of these outcomes would have a material adverse effect on our business.

Because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearing, motions, or other interim developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Even if we ultimately prevail, a court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may not be an adequate

remedy. Furthermore, the monetary cost of such litigation and the diversion of the attention of our management could outweigh any benefit we receive as a result of the proceedings. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our business.

If we are unable to establish, maintain or adequately protect our intellectual property rights relating to the OCS, the commercial value of the OCS will be adversely affected and our competitive position could be harmed.

Our success and ability to compete depend in part upon our ability to establish and maintain intellectual property rights covering the OCS in the United States and other countries. We own or have an exclusive license under several patents and patent applications in the United States and corresponding patents and patent applications in a number of foreign jurisdictions. All but one of the issued United States patents under the VA license expired in 2017 and the issued international patents expired in 2018. With respect to the unexpired, issued U.S. patent licensed from the VA, we have filed an application for patent term extension that, if granted, would extend the term of that patent until 2022. With respect to the patents and patent applications that we own, any patents that have or may issue from our currently issued or pending patent applications would be expected to expire between 2023 and 2036, assuming all required fees are paid.

However, we cannot provide any assurances that any of our patents have, or that any of our pending patent applications that mature into issued patents will include, claims with a scope sufficient to protect our OCS technology, any additional features we develop for our OCS technology or any new products. Other parties may have developed technologies that may be related to or competitive with our system, may have filed or may file patent applications and may have received or may receive patents that overlap or conflict with our patent applications, either by claiming the same methods or devices or by claiming subject matter that could dominate our patent position. The patent positions of medical device companies, including our patent position, may involve complex legal and factual questions, and, therefore, the scope, validity and enforceability of any patent claims that we may obtain cannot be predicted with certainty. Our pending and future patent applications may not issue as patents or, if issued, may not issue in a form that will be advantageous to us. Even if issued, our patents may be challenged, narrowed, held unenforceable, invalidated or circumvented, or others could challenge the inventorship, ownership or enforceability of our patents and patent applications, any of which could limit our ability to stop competitors from marketing similar products or limit the term of patent protection we may have for our products, or cause us to lose our right to manufacture, market and sell the OCS products or components of the OCS products. Proceedings challenging our patents could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. Furthermore, an adverse decision in an interference proceeding can result in a third party receiving the patent right sought by us, which in turn could affect our ability to commercialize our products.

Changes in either patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection, which in turn could diminish the commercial value of the OCS. The laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the United States, and we may encounter significant problems in protecting our proprietary rights in these countries.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- any of our patents, or any of our pending patent applications, if issued, will include claims having a scope sufficient to protect the OCS;
- any of our pending patent applications will issue as patents;
- we will be able to successfully commercialize our products on a substantial scale, if approved, before any relevant patents we may have expire;
- we were the first to make the inventions covered by each of our patents and pending patent applications;

- we were the first to file patent applications for these inventions;
- others will not develop similar or alternative technologies that do not infringe our patents; any of our patents will be found to ultimately be valid and enforceable;
- any patents issued to us will provide a basis for an exclusive market for our commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties;
- we will develop additional proprietary technologies or products that are separately patentable; or
- our commercial activities or products will not infringe upon the patents of others.

If we are unable to obtain patent term extension under the Hatch-Waxman Amendments our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of our products, one or more of the U.S. patents we own or license may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. For example, we currently have a pending patent term extension request based on the recently approved OCS Lung that, if granted, would increase the term of one of our patents by up to five years. The Hatch-Waxman Amendments permit a patent restoration term of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, even if, at the relevant time, we have an issued patent covering our product, we may not be granted an extension if we were, for example, to fail to exercise due diligence during the testing phase or regulatory review process, to fail to apply within applicable deadlines or prior to expiration of relevant patents or otherwise to fail to satisfy applicable requirements. Moreover, the time period of the extension or the scope of patent protection afforded could be less than we request. Only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval and only those claims covering the approved product, a method for using it or a method for manufacturing it may be extended. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable product will be shortened and our competitors may obtain approval of competing products following our patent expiration. As a result, our ability to generate revenues could be materially adversely affected. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. If we do not have adequate patent protection or other exclusivity for our products, our business, financial condition or results of operations could be materially adversely affected.

Recent changes in U.S. patent laws may limit our ability to obtain, defend and/or enforce our patents.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith America Invents Act, or the Leahy-Smith Act, includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. In addition, the Leahy-Smith Act has transformed the U.S. patent system into a first-to-file system. The first-to-file provisions, however, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business.

However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the enforcement and defense of our issued patents. For example, the Leahy-Smith Act provides that an administrative tribunal known as the Patent Trial and Appeals Board, or PTAB, provides a venue for challenging the validity of patents at a cost that is much lower than district court litigation and on timelines that are much faster. Although it is not clear what, if any, long-term impact the PTAB proceedings will have on the operation of our business, the initial results of patent challenge proceedings before the PTAB since its inception

in 2013 have resulted in the invalidation of many U.S. patent claims. The availability of the PTAB as a lower-cost, faster and potentially more potent tribunal for challenging patents could increase the likelihood that our own patents will be challenged, thereby increasing the uncertainties and costs of maintaining and enforcing them.

We may be unable to enforce our intellectual property rights throughout the world.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. This could make it difficult for us to stop infringement of our foreign patents, if obtained, or the misappropriation of our other intellectual property rights. For example, some foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, some countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries.

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of our intellectual property.

If we are unable to protect the confidentiality of our trade secrets, the value of the OCS and our business and competitive position could be harmed.

In addition to patent protection, we also rely upon trade secret protection, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants and third parties, to protect our confidential and proprietary information. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using commonly accepted physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. Even though we use commonly accepted security measures, trade secret violations are often a matter of state law, and the criteria for protection of trade secrets can vary among different jurisdictions. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. We also have agreements with our employees, consultants and third parties that obligate them to assign inventions made in the course of their work for us to us, however these agreements may not be self-executing, not all employees or consultants may enter into such agreements, or employees or consultants may breach or violate the terms of these agreements, and we may not have adequate remedies for any such breach or violation. If any of our intellectual property or confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, the value of the OCS and our business and competitive position could be harmed.

We may be subject to claims that we or our employees have misappropriated the intellectual property of a third party, including trade secrets or know-how, or are in breach of non-competition or non-solicitation agreements with our competitors and third parties may claim an ownership interest in intellectual property we regard as our own.

Many of our employees and consultants were previously employed at or engaged by other medical device, biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants and contractors may have executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may be subject to claims that we or these individuals have, inadvertently or otherwise, misappropriated the intellectual property or disclosed the alleged trade secrets or other proprietary information, of these former employers, competitors or other third parties. Additionally, we may be subject to claims from third parties challenging our ownership interest in or inventorship of intellectual property we regard as our own, based on claims that our agreements with employees or consultants obligating them to assign intellectual property to us are ineffective or in conflict with prior or competing contractual obligations to assign inventions to another employer, to a former employer, or to another person or entity. Litigation may be necessary to defend against claims, and it may be necessary or we may desire to enter into a license to settle any such claim; however, there can be no assurance that we would be able to obtain a license on commercially reasonable terms, if at all. If our defense to those claims fails, in addition to paying monetary damages or a settlement payment, a court could prohibit us from using technologies, features or other intellectual property that are essential to our products, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. An inability to incorporate technologies, features or other intellectual property that are important or essential to our products could have a material adverse effect on our business and competitive position, and may prevent us from selling our products. In addition, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. Any litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our products, which could materially and adversely affect our business, financial condition, operating results, cash flows and prospects.

Risks Related to Government Regulation

If we fail to adequately respond to FDA follow-up inquiries or to obtain or maintain necessary FDA approval for each use of the OCS, or if such approval is delayed, or if we fail to maintain the CE Mark in the European Union, we will not be able to commercially sell and market the OCS.

The OCS products are medical devices subject to extensive regulation in the United States by the FDA and other federal, state and local authorities. The FDA regulates the design, development, testing, manufacturing, labeling, selling, promoting, distributing, importing, exporting and shipping of the OCS. We have obtained PMA approval for the OCS Lung for the preservation of donor lungs currently utilized for double-lung transplantation, but the OCS has not yet attained PMA approval for preservation of heart and liver donor organs, as well as for certain donor lungs that are currently unutilized for transplantation. In the European Union, we have the right to affix a CE Mark for the sale of the OCS Lung, OCS Heart and OCS Liver for lung, heart and liver transplants, respectively. Following the U.K.'s withdrawal from the European Union, certificates issued by U.K. notified bodies will no longer be recognized. Our notified body, British Standards Institution, or BSI, is currently headquartered in the U.K., but it is in the process of applying for designation as a Medical Device Notified Body in the Netherlands to ensure that CE marks are transferred without interruption, or minimal delay. If BSI is unable to issue certificates from its office in the Netherlands, we may be unable to sell products in the European Union and the U.K. following Brexit until we are able to obtain an authorized notified body.

In the United States, before we can market the OCS products for each organ, we must first receive PMA approval from the FDA. This process can be expensive and lengthy and entail significant costs. The process of

obtaining PMA approval requires significant clinical trial data. It generally takes from one to three years, or even longer, from the time the PMA application is submitted to the FDA until an approval is obtained. Despite the time, effort and cost involved in this process, the FDA might not approve the OCS products for use in preservation of donor lungs currently unutilized for transplantation or of donor hearts, livers, or other organs.

Furthermore, unforeseen requirements or delays in obtaining clearances or approvals from the FDA for any future products could result in unexpected and significant costs for us and consume management's time and other resources. The FDA could ask us to supplement our submissions, collect additional non-clinical data, conduct additional clinical trials or engage in other costly and time-consuming actions, or it could simply deny our PMA application or, if we were to seek any 510(k) clearance for a product, issue a not substantially equivalent determination for a 510(k) device. For example, in 2015, we voluntarily withdrew our original PMA for OCS Heart in an effort to expand our data to include OCS Heart EXPAND Trial results as well as to supplement our OCS Heart PROCEED II Trial results with long-term follow-up data that was not collected as part of the original trial protocol. In addition, even if we obtain PMA approval, the approval could be withdrawn or other restrictions imposed if post-market data demonstrate safety issues or inadequate performance. For 510(k) cleared devices, FDA can use its enforcement authorities to require removal of a device from the market in case of safety issues. Even if the FDA grants PMA approval for the OCS Lung for preservation of donor lungs currently unutilized for transplantation and for the OCS Heart and OCS Liver for preservation of donor hearts and livers for transplantation, respectively, the claims approved by the FDA may be significantly narrower than those we are seeking.

We are currently investigating the safety and effectiveness of the OCS in multiple IDE investigations. Specifically, pivotal trials are being initiated or under IDEs that investigate the safety and effectiveness of the OCS Lung for the preservation of donor lungs that are currently unutilized for transplantation, the safety and effectiveness of the OCS Heart for the preservation of donor hearts that are currently unutilized for transplantation and the safety and effectiveness of the OCS Liver for the preservation of donor livers that are currently utilized and currently unutilized for transplantation. In addition, we completed an IDE pivotal trial of the OCS Heart for donor hearts and received conditional approval for the Continued Access Protocol to the OCS Heart Trial for the preservation of certain donor hearts that are currently unutilized for transplantation. We have also submitted an IDE for a study of OCS Heart for donor hearts that are donated after circulatory death. We intend to use data from the pivotal clinical trials we are conducting under IDEs to support our applications for PMA approvals for the OCS Heart and OCS Liver, and recently submitted a panel track supplement to the OCS Lung PMA for the indication of the preservation of certain donor lungs that are currently unutilized for transplantation.

As is typical to the PMA review process, during the course of its initial PMA review and within 90 calendar days of the company's PMA filing date, the FDA communicates deficiencies it has identified through a substantive interaction, which in most cases is a letter that is referred to as a major deficiency letter, or MDL, and provides the applicant with an opportunity to address the FDA's questions. After completing its review of a PMA application, the FDA will take one of the following actions: an approval, an approvable letter, a not approvable letter, or, in rare instances, a denial. As anticipated, in November 2018, we received an MDL for our PMA supplemental application for the OCS Lung EXPAND Trial. In our subsequent Day-100 meeting with the FDA, we discussed the FDA's requests in the MDL, as described below, and we intend to formally respond to all of the requests in the MDL during the first half of 2019.

The requests in the MDL for the OCS Lung PMA supplement are primarily focused on: (1) additional sub-group and other analyses of the existing OCS Lung EXPAND Trial clinical data, given that the objective performance goal for the primary effectiveness composite endpoint was not met and the lack of a prospective control arm for these type of donor lungs; (2) submission of available longer-term data on survival and bronchiolitis obliterans syndrome, or BOS, which is a common long-term complication of lung transplantation, for OCS Lung EXPAND Trial patients and analyses of these data; (3) recommended changes to our proposed post-approval study; and (4) clarifications regarding OCS Lung EXPAND Trial clinical data, data analyses and information about the OCS Lung submitted in the PMA supplement. In the MDL, the FDA also requested an explanation regarding the dual roles of a physician serving as our medical monitor for the OCS Lung EXPAND

Trial, who is also a member of the data safety monitoring board overseeing this trial. The FDA also indicated its continued interest in the OCS Lung INSPIRE Trial's long-term results beyond two years that are currently being collected under the OCS Lung INSPIRE Continuation Post-Approval Study. Although the OCS Lung EXPAND Trial and the OCS Lung INSPIRE Trial are separate studies, we plan to include in our upcoming MDL response any OCS Lung INSPIRE Trial long-term BOS and survival data that are available at the time of the response. However, it is possible that the data from our clinical studies and trials might not support PMAs or any of the claims we wish to make, or the FDA could require us to gather significant additional clinical data, including longer term outcome data.

The approval process involving the OCS for each organ is subject to many of the same risks and uncertainties as for the lungs. If we are not able to obtain the necessary regulatory approvals for the OCS, or approvals or clearances for future products on a timely basis or at all, our financial condition and results of operations would suffer, possibly materially, and our business might fail.

We have been able to affix the CE Mark to the OCS Heart since September 2006, the OCS Lung since December 2010 and the OCS Liver since November 2016. These CE Marks were renewed in September 2017 and are valid for five years, so they will expire in September 2022. In order to be able to continue to use the CE Mark in the same manner after May 2020, we will have to meet the conditions set out in the transitional provisions in the Medical Devices Regulation (Regulation 2017/745), or the Medical Devices Regulation. Before expiry of these certificates, we will need to apply for their re-certification under the new Medical Devices Regulation. We might not be able to continue to use the CE Mark for any current use of the OCS. If:

- we are not able to obtain re-certification of our products for their current use;
- we are not able to do so in time before the certificates expire;
- our technical files for our products do not meet the new (and more stringent) requirements under the Medical Devices Regulation; or
- any variation in the uses for which the CE Mark has been affixed to the OCS requires us to perform further research or to modify the technical documentation required to affix the CE mark, our revenues and operating results could be adversely affected and our reputation could be harmed.

If we fail to obtain and maintain regulatory approval in foreign jurisdictions, our market opportunities will be limited.

FDA clearance or approval or a CE mark does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries. However, the failure to obtain clearance or approval in one jurisdiction may have a negative impact on our ability to obtain clearance or approval elsewhere. If we do not obtain or maintain necessary market authorizations to commercialize our products in markets outside the United States, it would negatively affect our overall market penetration. For example, if, as a result of manufacturing error, the efficacy of our products does not meet the standards claimed in the accompanying instructions for use, regulatory authorities could prevent our products from being placed on the market in the European Union.

Additionally, we may need to obtain additional regulatory approval in the U.K. following Brexit. Failure to do so may mean that we will be unable to sell our products in the U.K.

If transplant centers and hospitals cannot obtain adequate reimbursement or funding from governments or third-party payors for purchases of the OCS, and additional disposable sets and for costs associated with procedures that use the OCS, our prospects for generating revenue and achieving profitability will suffer materially.

Our prospects for generating revenue and achieving profitability depend heavily upon the availability of adequate reimbursement or funding in both the United States and other markets for purchases of the OCS and for organ transplant procedures that use the OCS.

In the United States, Medicare generally reimburses the facilities in which transplant procedures are performed based upon prospectively determined amounts. For hospital inpatient treatment, the Medicare prospective payment generally is determined by the patient's condition and other patient data and procedures performed during the patient's hospital stay, using a classification system known as Medicare severity diagnosis-related groups, or MS-DRGs. Prospective rates are adjusted for, among other things, regional differences and whether the hospital is a teaching hospital. Because prospective payments are based on predetermined rates and may be less than a hospital's actual costs in furnishing care, hospitals have incentives to lower their inpatient operating costs by utilizing products, devices and supplies that will reduce the length of patients' hospital stays, decrease labor or otherwise lower their costs.

In addition to these MS-DRG-based payments, Medicare reimburses transplant centers for "reasonable and necessary" organ acquisition costs, which are considered "pass-through" costs from the prospective payment system, and are not based on the payments for the applicable MS-DRG. Pass-through organ acquisition costs include services required for the acquisition of an organ, such as tissue typing, organ preservation, transport of organs, donor evaluation and other acquisition costs. The separate payments for these costs are determined on a reasonable cost basis established through the transplant center's Medicare cost report. During OCS clinical trials, even before the OCS had been approved by the FDA, the Medicare program reimbursed transplant centers for their use of the OCS for lung, heart and liver transplantation. We believe, though cannot be assured, that the costs incurred by transplant centers for the organ-specific OCS Console, OCS Perfusion Sets and OCS Solutions will be classified as organ acquisition costs for which Medicare will provide additional reimbursement. However, Medicare does not reimburse for items determined not to be reasonable and necessary for diagnosis or treatment of an illness or injury. The Centers for Medicare & Medicaid Services, or CMS, and Medicare contractors who administer Medicare around the country have substantial discretion in determining whether the OCS is reasonable and necessary in this context. Either CMS or a Medicare contractor might determine that Medicare will not cover and reimburse for the cost of the OCS in the absence of reliable clinical data evidencing the benefits to patients of the use of the OCS. The data we collect from our prior, ongoing and planned clinical studies and patient registry may not be sufficient for this purpose in a coverage determination by CMS or a Medicare contractor. Accordingly, Medicare might not reimburse transplant centers for all or a portion of the cost of the OCS. We believe that private insurers and other public insurers in the United States generally will follow the coverage and payment policies of Medicare.

Outside of the United States, reimbursement and funding systems vary significantly by country, and within some countries, by region. Many foreign markets have government managed healthcare systems that govern reimbursement and funding for medical devices and procedures. In the European Union member states, the costs associated with organ transplant procedures may be paid for by national insurance and in some cases private insurers or by both national insurance and private insurers, depending on the priorities established by individual programs. These reimbursement arrangements are subject to complex rules and regulations at the national and regional levels that can vary between member states of the European Union and are likely to require that we demonstrate that the OCS is superior to existing preservation methods. We have no studies currently planned to collect such clinical data, and any studies of this kind likely would be expensive and lengthy and may not ultimately produce results adequate to secure reimbursement. In some cases, we might not be able to secure adequate reimbursement for the OCS at all or until we have collected additional clinical data supporting the benefits associated with the use of the OCS in transplant procedures. Hospitals or surgeons in countries or regions where separate additional reimbursement or funding for the OCS is not available may determine that the benefits of the OCS do not or will not outweigh the cost of the OCS. Adoption of our products in the European Union may be hindered if they impede our customer's compliance with the requirements of Directive 2010/53/EU (formerly Directive 2010/45/EU), which imposes certain standards on procurement, preservation and transport of organs intended for transplantation. Even where reimbursement or funding is available, in some foreign countries, particularly in the European Union, the pricing of medical devices is subject to governmental control. In these countries, reimbursement and pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. For example, some foreign reimbursement systems provide for limited payments in a given period and, therefore, result in extended payment periods, which could hinder adoption

of the OCS for use in transplantation, limiting sales. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, it may not be profitable to sell our products in certain foreign countries, which could negatively affect the long-term growth of our business.

Even if existing reimbursement and funding arrangements of governmental programs and other third-party payors provide for sufficient payments to make purchases of the OCS cost-effective for hospitals, the laws and regulations governing these arrangements are subject to change. The continuing efforts of governments, insurance companies and other payors of healthcare costs to contain or reduce these costs could lead to legislative or regulatory reform of the United States or foreign reimbursement and funding systems in a manner that significantly reduces or eliminates reimbursement for the OCS or for transplant procedures.

If hospitals in the United States or the European Union are not able to obtain reimbursement or funding for the cost of the OCS and additional disposable sets or for transplant procedures generally, they may not have sufficient economic incentives to purchase the OCS. If hospitals or surgeons determine that the benefits of the OCS do not or will not outweigh the initial cost and ongoing expense of the OCS, we might fail to achieve significant sales and may never become profitable.

Reimbursement in international markets is likely to require us to undertake country-specific reimbursement activities, including additional clinical studies, which could be time-consuming and expensive and may not yield acceptable reimbursement rates.

In international markets, market acceptance of our products will likely depend in large part on the availability of reimbursement within prevailing healthcare payment systems. Reimbursement and healthcare payment systems in international markets vary significantly by country, and by region in some countries, and include both government-sponsored healthcare and private insurance. We may not obtain international reimbursement approvals in a timely manner, if at all. In addition, even if we do obtain international reimbursement approvals, the level of reimbursement may not be enough to commercially justify expansion of our business into the approving jurisdiction. To the extent we or our customers are unable to obtain reimbursement for products in major international markets in which we seek to market and sell our products, our international revenue growth would be harmed, and our business and results of operations would be adversely affected.

If we modify our products, we may be required to obtain approval of new PMAs or PMA supplements, vary existing CE Marking, and may be required to cease marketing or recall any modified products until the required approvals are obtained.

Certain modifications to a PMA-approved device require approval of a new PMA or a PMA supplement, while other modifications can be reported in an annual report or through a 30-day Notice. The FDA may not agree with our decisions regarding whether a new PMA or PMA supplement is necessary. We may make modifications to our approved devices and manufacturing processes in the future that we believe do not require approval of a new PMA application or PMA supplement, or submission of a 30-day Notice. If the FDA disagrees with our determination and requires us to submit a new PMA, PMA supplement or 30-day Notice for modifications to our previously approved products or manufacturing processes, we may be required to cease marketing or to recall the modified product until we obtain approval or submit the 30-day Notice, and we may be subject to significant regulatory fines or penalties. In addition, the FDA may not approve our products for the indications that are necessary or desirable for successful commercialization or could require clinical trials to support any modification to the device or our modified indications or claims. Any delay or failure in obtaining required approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

Additionally, any significant change to the quality system or the product range in relation to a CE Marked device will require notification to the notified body which certified the product. The notified body will assess the proposed change. We might not be able to have the CE Mark varied without taking additional steps, or at all. For

example, we might need to conduct additional clinical trials and provide additional technical information to the appropriate notified body before the CE Mark can be affixed to the changed product.

Even after approval for the OCS, we are subject to continuing regulation by regulatory authorities and entities in the United States and other countries, and if we fail to comply with any of these regulations, our business could suffer.

Even after approval of the OCS for a specific indication, we are subject to extensive continuing regulation by the FDA and other regulatory authorities and entities. We are subject to Medical Device Reporting, or MDR, regulations, which require us to report to the FDA if we become aware of information that reasonably suggests our product may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device we market would likely cause or contribute to a death or serious injury if the malfunction were to recur. We must report corrections and removals to the FDA where the correction or removal was initiated to reduce a risk to health posed by the device or to remedy a violation of the Federal Food, Drug, and Cosmetic Act, or FDCA, caused by the device that may present a risk to health, and maintain records of other corrections or removals. The FDA closely regulates promotion and advertising and all claims that we make for the OCS. If the FDA determines that our promotional materials, training or advertising activities constitute promotion of an unapproved use of the OCS, it could request that we cease or modify our training or promotional materials or subject us to regulatory enforcement actions.

The FDA and state authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement actions by the FDA or state agencies, which may include any of the following sanctions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- recall, termination of distribution, administrative detention, injunction or seizure of organ-specific OCS Consoles or disposable sets;
- customer notifications or repair, replacement or refunds;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for 510(k) clearance or premarket approval of new products or for modifications to existing products, and refusing or delaying our requests for PMAs for new intended uses of the OCS.
- withdrawing or suspending PMA approvals that have already been granted, resulting in prohibitions on sales of our products;
- FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries; and
- criminal prosecution.

Any corrective action, whether voluntary or involuntary, as well as potentially defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

We are currently required to comply with strict post-marketing obligations that accompany the affixing of the CE Mark to medical devices in the European Union. These include the obligation to report serious adverse events within a specified time period and to provide periodic safety reports and updates. Authorities in the European Union also closely monitor the marketing programs implemented by device companies. The obligations that companies must fulfill concerning premarketing approval of promotional material vary among member states of the European Union. A failure to comply with our obligations in marketing and promoting the OCS in the European Union could harm our business and results of operations.

For our currently marketed OCS Lung, as part of the conditions of approval, we must complete two PMA post-approval studies, the INSPIRE Continuation Post-Approval Study, which is a two-arm observational study intended to evaluate long-term outcomes of the OCS Lung INSPIRE Trial patients, and our OCS Lung Thoracic Organ Perfusion Post-Approval Study Registry, or TOP Registry, which is a prospective, single-arm, multi-center, observational study designed to evaluate short- and long-term safety and effectiveness of the OCS Lung. Both the INSPIRE Continuation Post-Approval Study and the TOP Registry entail submission of regular reports to the FDA. Failure to comply with the conditions of approval can result in material adverse enforcement action, including withdrawal of the approval.

In addition, certain changes and other events with respect to regulatory approvals may cause an event of default under our Credit Agreement. See "Description of Certain Indebtedness."

If we fail to comply with the FDA's QSR, or FDA or EU requirements that pertain to clinical trials or investigations, the FDA or the competent EU authority could take various enforcement actions, including halting our manufacturing operations, and our business would suffer.

In the United States, as a manufacturer of a medical device, we are required to demonstrate and maintain compliance with the FDA's QSR. The QSR is a complex regulatory scheme that covers the methods and documentation of the design, testing, control, manufacturing, labeling, quality assurance, packaging, storage and shipping of medical devices. The FDA enforces the QSR through periodic inspections and unannounced "for cause" inspections.

We are subject to periodic FDA inspections to determine compliance with QSR and pursuant the Bioresearch Monitoring Program, which have in the past and may in the future result in the FDA issuing Form 483s, including during the conduct of clinical trials. Outside the United States, our products and operations are also often required to comply with standards set by industrial standards bodies, such as the International Organization for Standardization. Foreign regulatory bodies may evaluate our products or the testing that our products undergo against these standards. The specific standards, types of evaluation and scope of review differ among foreign regulatory bodies. Our failure to comply with FDA or local requirements that pertain to clinical trials/investigations, including GCP requirements, and the QSR (in the United States), or failure to take satisfactory and prompt corrective action in response to an adverse inspection, could result in enforcement actions, including a warning letter, adverse publicity, a shutdown of or restrictions on our manufacturing operations, delays in approving or clearing our products, refusal to permit the import or export of our product, prohibition on sales of our product, a recall or seizure of our products, fines, injunctions, civil or criminal penalties, or other sanctions, any of which could cause our business and operating results to suffer.

Our products have been and may in the future be subject to product recalls that could harm our reputation and could materially and adversely affect our business, financial condition, operating results, cash flows and prospects.

The OCS must be manufactured in accordance with federal and state regulations, and we or any of our suppliers or third-party manufacturers could be forced to recall our installed systems or terminate production if we fail to comply with these regulations. The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design, manufacture or labeling. In the case of the FDA, the recall order must be based on an FDA finding that there is a reasonable probability that the device would cause serious adverse health consequences or death. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us could occur as a result of component failures, security failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. The FDA requires that recalls initiated to

reduce a risk to health posed by the device or to remedy a violation of the FDCA caused by the device that may present a risk to health be reported to the FDA within 10 working days after the recall is initiated. Companies are required to maintain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, we could be required to report those actions as recalls. A recall announcement could harm our reputation with customers and negatively affect our sales. Additionally, any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device approval, seizure of our products or delay in clearance or approval of future products.

We have voluntarily removed certain products from customer sites in the past, and may need to take similar actions in the future, which may result in notices to regulatory agencies in other jurisdictions. For example, in July 2018, we implemented a correction to the OCS Heart and Liver Consoles to address a loss of connection between the OCS Console and Perfusion Sets that was caused by incomplete cleaning, and issued a Product Information Bulletin to all customers and filed corrective action reports with European and Australian authorities. In March 2018, we identified a defect in one of the parts of the OCS Liver organ chamber. As a result, we temporarily suspended enrollment in the OCS Liver PROTECT Trial and removed all potentially affected units from customer sites. Additionally, in March 2018, after identifying out-of-specification plastic components used in the manufacturing of the OCS Lung Console, we removed the affected units from customer sites and replaced them with known, good product. All affected customers were notified of the issue, and regulatory bodies in Italy, Lithuania and Netherlands were notified. In September 2017, we removed the OCS Heart units from customer sites in the United States and U.K. that were not displaying the programmed settings for certain parameters and replaced them with properly labeled products. We also notified the FDA as well as regulatory bodies in the U.K. and Netherlands. In addition, in January 2017, a heart was rejected for transplantation in the U.K. due to exposure to elevated temperatures beyond the set point due to incorrect reading of the temperature sensor offsets. We notified all OCS Heart users of the issue, and provided steps to help avoid a similar event. We also notified the FDA as well as regulatory bodies in the U.K., Netherlands, Germany, Italy, Denmark, Lithuania and Australia.

Internationally, the approaches to product defects will vary. A product may be recalled in one country but not in others. However, within the European Union, competent authorities are known to communicate with each other, therefore a recall in one EU member state may lead to recalls in the rest of the European Union.

We may not be able to obtain or maintain regulatory qualifications outside the United States, which could harm our business.

Sales of the OCS outside the United States are subject to foreign regulatory requirements that vary widely from country to country. The foreign regulatory approval process generally includes all of the risks associated with obtaining FDA clearance or approval in addition to other risks. Complying with international regulatory requirements can be an expensive and time-consuming process, and approval is not certain. The time required to obtain foreign clearances or approvals may exceed the time required for FDA clearance or approval, and requirements for such clearances or approvals may differ significantly from FDA requirements. Foreign regulatory authorities may not clear or approve our product for the same uses cleared or approved by the FDA. Although we have been able to affix the CE Mark to the OCS Lung, OCS Heart and OCS Liver in the European Union, we may not be able to maintain such CE Marking, including as a result of the need to re-certify our products, under the new Medical Devices Regulation. We may not be able to affix the CE Mark to new or modified products. In addition, we may fail to obtain any additional regulatory qualifications, clearances or approvals or to comply with additional legal obligations required by the individual member states of the European Union or other countries in which we seek to market the OCS. The FDA also regulates the export of

medical devices from the United States. If we are not successful in obtaining and maintaining foreign regulatory approvals or complying with U.S. export regulations, our business will be harmed.

Foreign regulatory agencies periodically inspect manufacturing facilities both in the United States and abroad. Our most recent inspection by our EU Notified Body was in July 2018, which resulted in observations. While we have implemented corrective and preventive actions to address these observations, these previous observations may not be closed out. Additionally, we may fail to pass future inspections of our facility by applicable regulatory authorities or entities both in the United States and in other countries. Delays in receiving necessary qualifications, clearances or approvals to market our product outside the United States, or the failure to receive those qualifications, clearances or approvals, or to comply with other foreign regulatory requirements, could limit or prevent us from marketing our products or enhancements in international markets. Additionally, the imposition of new requirements could significantly affect our business and our product and we might not be able to adjust to such new requirements. If we fail to comply with applicable foreign regulations, we could face substantial penalties and our business, financial condition, operating results, cash flows and prospects could be adversely affected.

We could face product liability suits or regulatory delays due to defects in the OCS, which could be expensive and time-consuming and result in substantial damages payable by us and increases in our insurance rates.

If our products are deemed to be defectively designed, manufactured or labeled, contain defective components, suffer security failures or are hacked, or are counterfeited, we could face substantial and costly litigation by transplant centers that purchase or use the OCS or by their patients or others claiming damages on their behalf. Moreover, transplantations are complex and inherently risky medical procedures. For example, most recipients of heart transplants experience one or more serious adverse events during their transplant and post-operative care, including in some cases, death. In our OCS Lung INSPIRE Trial of donor lungs, 24% of patients experienced serious lung graft related adverse events and in our OCS Heart PROCEED II Trial of donor hearts, 13% of patients experienced serious heart graft related adverse events. Many of the patients currently on a waiting list for a lung, heart or liver transplant already are very sick, with some of them receiving intensive care. All of these patients have a significant risk of death if they do not receive a transplant. Thus, we may incur substantial liability if the OCS fails to perform as expected and, as a result of this failure, patients do not receive the intended transplants or receive transplants that are not successful.

Additionally, if the number of adverse events experienced by patients in clinical trials of the OCS is greater than expected, our clinical trials could be delayed or terminated by us or regulatory authorities. In our OCS Lung INSPIRE Trial of currently utilized donor lungs, 5.3% of patients died within 30 days of transplant, and in our OCS Heart PROCEED II Trial of currently utilized donor hearts, 6% of patients died within 30 days of transplant. Additionally, in a post-hoc observational analysis of all-cause mortality measured at 39 months post transplant for OCS Heart PROCEED II Trial patients, overall deaths were higher in the OCS group compared to the standard of care group. Although death is an anticipated adverse event of the organ transplant population, if the rate of deaths or other serious adverse events using the OCS is greater than expected using conventional transplant procedures, the study could be delayed or halted, which could materially and adversely affect our business, financial condition, operating results, cash flows and prospects.

Because the OCS represents a novel approach to organ transplantation, a patient or transplant center may choose to name us as a party to a lawsuit relating to the use of the OCS in connection with a planned or completed transplant procedure regardless of whether the OCS caused or contributed to a serious adverse event or death of a patient. Any claim, whether or not we are ultimately successful, could divert management’s attention from our core business, be expensive to defend and result in sizable damage awards against us.

Currently, we maintain product liability insurance covering damages of up to $10 million per occurrence for both the human clinical and commercial use of our product. We also maintain local insurance policies in

Belgium, Germany, Australia and the U.K. with coverage ranging from €2.5 million to €10.0 million per occurrence as required by the applicable country. Our current insurance coverage might not be sufficient to cover future claims and is subject to deductibles. Moreover, in the future, we may not be able to obtain insurance in amount or scope sufficient to provide us with adequate coverage against potential liabilities. Any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, could harm our reputation in the industry, impair our current or future preclinical studies or clinical trials, hinder acceptance of our products in the market and reduce product sales. Furthermore, we would need to pay any product liability losses in excess of our insurance coverage or within the deductibles provided under our insurance policies applicable to the claim out of cash reserves, which could materially and adversely affect our business, financial condition, operating results, cash flows and prospects.

The FDA has warned that the threat of cyberattacks on medical devices is no longer theoretical. Hackers and other third parties may try to circumvent security controls on an OCS to gain access to information on the OCS, alter the way an OCS operates, to act as a trojan horse or other entry point to other systems that could lead to those systems suffering cybersecurity breaches or attacks, or to cause harms to transplanted organs or individuals. If our security controls fail to fully protect the OCS and the information on it, we could suffer reputational harm, could undergo regulatory investigations and enforcement, or could have claims brought against us.

Third parties may attempt to produce counterfeit versions of our products and which may harm our ability to sell the OCS and its components, negatively affect our reputation or harm patients and subject us to product liability.

Counterfeit medical devices are an increasing presence on the market. Third parties may seek to develop, manufacture, distribute and sell systems that we believe infringe our proprietary rights, which would compete against the OCS and impair our ability to sell the OCS in jurisdictions in which our proprietary rights are not upheld. In addition, counterfeit products may be promoted in a way that misleads consumers into believing they are affiliated with us. If a counterfeit version of the OCS were to appear on the market, we would expect to be obliged to verify all OCS products currently on the market, and possibly to withdraw all OCS products from the market while verifications are made. We also might be named in a lawsuit relating to any side effects or fatalities allegedly related to the use of a counterfeit OCS irrespective of whether the counterfeit device in fact contributed to such an adverse event or whether we were aware of the existence of the counterfeit device.

Improper marketing or promotion of our products or misuse or off-label use of the OCS may harm our reputation in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business.

Certain OCS products have been approved by regulatory authorities in the United States, European Union and other jurisdictions for specific indications, and our promotional materials and training methods must comply with regulatory requirements in the countries where they are sold. We train our sales and clinical adoption team to not promote the OCS for uses outside of the approved indications for use, known as “off-label uses.” We cannot, however, prevent a surgeon from using the OCS off-label, when in the surgeon’s independent professional medical judgment he or she deems it appropriate. There may be increased risk of injury to patients if surgeons attempt to use the OCS off-label. Furthermore, the use of the OCS for indications other than those approved by the FDA or approved by any foreign regulatory body may not effectively treat such conditions, which could harm our reputation in the marketplace among surgeons and patients.

If the FDA or any foreign regulatory body determines that our promotional materials or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance or imposition of an untitled letter, which is used for violators that do not necessitate a warning letter, injunction, seizure, civil fine or criminal penalties. It is also

possible that other federal, state or foreign enforcement authorities might take action under other regulatory authority, such as false claims laws, if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment of our operations.

In addition, surgeons may misuse the OCS or use improper techniques if they are not adequately trained, potentially leading to unsatisfactory patient outcomes, patient injuries, negative publicity and an increased risk of product liability. If the OCS is misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. Similarly, in an effort to decrease costs, surgeons may also reuse the component and accessories of the OCS that are intended for a single use or may purchase reprocessed OCS components from third-party reprocessors in lieu of purchasing new components from us, which could result in product failure and liability. As described above, product liability claims could divert management's attention from our core business, be expensive to defend and result in sizeable damage awards against us that may not be covered by insurance.

Legislative or regulatory reforms in the United States or other jurisdictions may make it more difficult and costly for us to obtain regulatory clearances or approvals for our products or to manufacture, market or distribute our products after clearance or approval is obtained.

From time to time, legislation is drafted and introduced in the U.S. Congress that could significantly change the statutory provisions governing the regulation of medical devices. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new statutes, regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of any future products or make it more difficult to obtain approval for, manufacture, market or distribute our products. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require additional testing prior to obtaining clearance or approval; changes to manufacturing methods; recall, replacement or discontinuance of our products; or additional record keeping.

On April 5, 2017, the European Parliament passed the Medical Devices Regulation, which repeals and replaces the European Union Medical Devices Directive and the Active Implantable Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the European Economic Area, or EEA, member states, regulations would be directly applicable, (i.e., without the need for adoption of EEA member state laws implementing them) in all EEA member states and are intended to eliminate current differences in the regulation of medical devices among EEA member states. The Medical Devices Regulation, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices and ensure a high level of safety and health while supporting innovation.

The Medical Devices Regulation will become applicable three years after publication, which is in 2020. Once applicable, the new regulations will, among other things:

- strengthen the rules on placing devices on the market and reinforce surveillance once they are available;
- establish explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- improve the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- set up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the European Union; and

- strengthen rules for the assessment of certain high-risk devices, such as implants, which may have to undergo an additional check by experts before they are placed on the market.

Our products may be affected by these rules, which may mean longer or more burdensome assessment of our products. These modifications may have an effect on the way we conduct our business in the EEA.

We recognize that our products will have to be re-certified under the Medical Devices Regulation and we are in the process of updating internal procedures to ensure compliance with the new Medical Devices Regulation and have added international regulatory personnel to assist with the transition.

In addition, there are significant concerns associated with whether EU Notified Bodies will be able to re-certify all devices in their care in time. If we do not manage to re-certify our products under this new regulation or cannot rely on the transitional provisions, we may have to take our products off the EU market until this is the case.

We are subject to certain federal, state and foreign fraud and abuse laws, health information privacy and security laws and transparency laws, which, if violated, could subject us to substantial penalties. Additionally, any challenge to or investigation into our practices under these laws could cause adverse publicity and be costly.

There are numerous U.S. federal and state, as well as foreign, laws pertaining to healthcare fraud and abuse, including anti-kickback, false claims and physician transparency laws. Our business practices and relationships with providers are subject to scrutiny under these laws. We may also be subject to privacy and security regulation related to patient, customer, employee and other third-party information by both the federal government and the states and foreign jurisdictions in which we conduct our business. The healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual or furnishing or arranging for a good or service, for which payment may be made, in whole or in part, under federal healthcare programs, such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. The U.S. government has interpreted this law broadly to apply to the marketing and sales activities of manufacturers. Moreover, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Violations of the federal Anti-Kickback Statute may result in substantial civil monetary and criminal penalties. Similarly, violations can result in exclusion from participation in government healthcare programs, including Medicare and Medicaid;
- the federal civil and criminal false claims laws and civil monetary penalties laws, including the federal civil False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other federal healthcare programs that are false or fraudulent. These laws can apply to manufacturers who provide information on coverage, coding, and reimbursement of their products to persons who bill private payors. Private individuals can bring False Claims Act “qui tam” actions, on behalf of the government and such individuals, commonly known as “whistleblowers,” may share in amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the federal civil False Claims Act, the government may impose substantial civil fines and penalties, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;
- the federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary’s decision to order or receive items or services reimbursable by the government from a particular provider or supplier;

- the Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- the federal Physician Sunshine Act under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the Affordable Care Act, which require certain applicable manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to CMS information related to payments and other transfers of value to physicians and teaching hospitals. Applicable manufacturers are required to submit annual reports to CMS. Failure to submit required information may result in substantial civil monetary penalties;
- many countries in which we operate have laws with extra-territorial effect—those laws apply to our operations outside the relevant country, to the extent they are breached. Examples of such laws include: U.S. Foreign Corrupt Practices Act, Bribery Act and the GDPR. The extra-territorial effect of those laws affects our sales and marketing strategy, since in many countries healthcare professionals are officers of the state. This is particularly important in the context of bribery offences, which in the U.K. and in the United States include the offence of bribing a foreign public official. Failure by our sales staff to comply with those laws may result in criminal and civil penalties and damage our reputation; and
- analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any private payor, including commercial insurers or patients; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm customers, foreign and state laws, including the GDPR, governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; and state laws related to insurance fraud in the case of claims involving private insurers.

These laws and regulations, among other things, constrain our business, marketing and other promotional activities by limiting the kinds of financial arrangements, including sales programs, we may have with customers, physicians or other potential purchasers of our products. In particular, these laws will influence, among other things, how we structure our sales offerings, including discount and rebate practices, customer support, education and training programs, and physician consulting and other service arrangements. Due to the breadth of these laws, the narrowness of statutory exceptions and regulatory safe harbors available, and the range of interpretations to which they are subject, it is possible that some of our current or future practices might be challenged under one or more of these laws.

To enforce compliance with the healthcare regulatory laws, certain enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. For example, the member states of the European Union closely monitor perceived unlawful marketing activity by companies, including inducement to prescribe and the encouragement of off-label use of devices. Responding to investigations can be time-and resource-consuming and can divert management's attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may have to agree to additional

compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity, and be costly to respond to. If our operations are found to be in violation of any of the healthcare laws or regulations described above or any other healthcare regulations that apply to us, we may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, imprisonment, contractual damages, reputational harm, disgorgement and the curtailment or restructuring of our operations. Moreover, industry associations closely monitor the activities of their member companies. If these organizations or national authorities were to name us as having breached our obligations under their laws, regulations, rules or standards, our reputation would suffer and our business, financial condition, operating results, cash flows and prospects could be adversely affected.

Failure to comply with anti-bribery, anti-corruption, and anti-money laundering laws, including the U.S. Foreign Corrupt Practices Act, as well as export control laws, customs laws, sanctions laws and other laws governing our operations could result in civil or criminal penalties, other remedial measures and legal expenses.

As we grow our international presence, we are increasingly exposed to trade and economic sanctions and other restrictions imposed by the United States, the European Union and other governments and organizations. The U.S. Departments of Justice, Commerce, State and Treasury and other federal agencies and authorities have a broad range of civil and criminal penalties they may seek to impose against corporations and individuals for violations of economic sanctions laws, export control laws, the U.S. Foreign Corrupt Practices Act, or FCPA, and other federal statutes and regulations, including those established by the Office of Foreign Assets Control, or OFAC. In addition, the Bribery Act prohibits both domestic and international bribery, as well as bribery across both private and public sectors, where a business or personnel engaged by it have a connection with the U.K. An organization with that connection and that “fails to prevent bribery” by anyone associated with the organization can be found guilty under the Bribery Act unless the organization can establish the defense of having implemented “adequate procedures” to prevent bribery. Under these laws and regulations, as well as other anti-corruption laws, anti-money laundering laws, export control laws, customs laws, sanctions laws and other laws governing our operations, various government agencies may require export licenses, may seek to impose modifications to business practices, including cessation of business activities in sanctioned countries or with sanctioned persons or entities and modifications to compliance programs, which may increase compliance costs, and may subject us to fines, penalties and other sanctions. A violation of these laws or regulations would negatively affect our business, financial condition and results of operations. Due to sales of our products to government or government-affiliated entities, we may be exposed to heightened risk of potential violations of the FCPA, the Bribery Act, or other relevant law.

We have implemented policies and procedures designed to ensure compliance by us and our directors, officers, employees, representatives, consultants and agents with the FCPA, OFAC restrictions, the Bribery Act and other export control, anti-corruption, anti-money-laundering and anti-terrorism laws and regulations. We cannot assure you, however, that our policies and procedures are or will be sufficient or that directors, officers, employees, representatives, consultants and agents have not engaged and will not engage in conduct for which we may be held responsible, nor can we assure you that our business partners have not engaged and will not engage in conduct that could materially affect their ability to perform their contractual obligations to us or even result in our being held liable for such conduct. Violations of the FCPA, OFAC restrictions, the Bribery Act or other export control, anti-corruption, anti-money laundering and anti-terrorism laws or regulations may result in severe criminal or civil sanctions, and we may be subject to other liabilities, which could have a material adverse effect on our business, financial condition and results of operations.

We are subject to, and may in the future become subject to additional, U.S., state and foreign laws and regulations imposing obligations on how we collect, store, process or share information concerning individuals. Our actual or perceived failure to comply with such obligations could harm our business. Complying with such laws could also impair our efforts to maintain and expand our customer base, and thereby decrease our revenue.

In the conduct of our business, we may at times collect, process or share data concerning individuals, including health-related personal data. The U.S. federal government and various states have adopted or proposed laws, regulations, guidelines and rules for the collection, distribution, use and storage of personal information of individuals. We may also be subject to U.S. federal rules, regulations and guidance concerning cybersecurity for medical devices, including guidance from the FDA. State privacy and cybersecurity laws vary and, in some cases, can impose more restrictive requirements than U.S. federal law. Where state laws are more protective, we must comply with the stricter provisions. In addition to fines and penalties that may be imposed for failure to comply with state law, some states also provide for private rights of action to individuals for misuse of personal information.

The European Union also has laws and regulations dealing with the collection, use and processing of personal data concerning individuals who are located in the European Union, which are often more restrictive than those in the United States. Data laws in the European Union are under reform and since May 25, 2018, we have been and will be subject to the requirements of the GDPR because we are processing personal data in the European Union. or offering goods to, or monitoring the behavior of, individuals who are located in the European Union. The GDPR implements more stringent administrative requirements for controllers and processors of personal data, including, for example, shortened timelines for data breach notifications, limitations on retention of information, increased requirements pertaining to health data and pseudonymised (i.e., key-coded) data, additional obligations when we contract with service providers, and more robust rights for individuals over their personal data. The GDPR provides that EU member states may make their own further laws and regulations limiting the processing of genetic, biometric or health data, which could limit our ability to use and share personal data or to cause our costs could increase, and harm our business and financial condition. If we do not comply with our obligations under the GDPR, we could be exposed to substantial fines and litigation. In addition, EU law restricts transfers of personal data to the United States unless certain requirements are met. These rules are under flux. For example, following a decision of the Court of Justice of the European Union in October 2015, transferring personal data to U.S. companies that had certified as members of the U.S. Safe Harbor Scheme was declared invalid. In July 2016, the European Commission adopted the U.S.-EU Privacy Shield Framework which replaces the Safe Harbor Scheme. However, this Framework is under review and there is currently litigation challenging it and other mechanisms for transferring personal data from the EU (e.g., through standard contractual clauses). It is uncertain whether the Privacy Shield Framework and/or the standard contractual clauses will be similarly invalidated by the European courts. We rely on a mixture of mechanisms to transfer personal data from our EU business to the United States, and could be impacted by changes in law as a result of a future review of these transfer mechanisms by European regulators under the GDPR, as well as current challenges to these mechanisms in the European courts.

Any actual or perceived failure by us or the third parties with whom we work to comply with data privacy or security laws, policies, legal obligations or industry standards, or any security incident that results in the unauthorized release or transfer of information concerning individuals, may result in governmental enforcement actions and investigations, including by European data protection authorities and U.S. federal and state regulatory authorities, fines and penalties, litigation and/or adverse publicity, including by consumer advocacy groups, and could cause our customers, their patients and other healthcare professionals to lose trust in us, which could harm our reputation and have a material adverse effect on our business, financial condition and results of operations.

Healthcare policy changes, including recently enacted legislation reforming the U.S. healthcare system, could harm our business, financial condition and results of operations.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. In March 2010, the Affordable Care Act was enacted in the United States, which made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. Among other ways in which it may affect our business, the Affordable Care Act:

- imposed an annual excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the United States, with limited exceptions, although the effective rate paid may be lower. Through a series of legislative amendments, the tax was suspended for 2016 through 2019. Absent further legislative action, the device excise tax will be reinstated on medical device sales starting January 1, 2020;
- established a new Patient-Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical effectiveness research in an effort to coordinate and develop such research;
- implemented payment system reforms, including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models; and
- expanded the eligibility criteria for Medicaid programs.

We do not yet know the full impact that the Affordable Care Act, and more recent measures impacting the healthcare system, will have on our business. The taxes imposed by the Affordable Care Act may result in decreased profits to us, lower reimbursement by payors to hospitals and transplant centers, and/or reduced medical procedure volumes, all of which may have a material adverse effect on our business, financial condition and results of operations. The Trump Administration and the U.S. Congress may take further action regarding the Affordable Care Act, including, but not limited to, repeal or replacement. Most recently, the TCJA was enacted which, among other things, removes penalties for not complying with the individual mandate to carry health insurance. Additionally, all or a portion of the Affordable Care Act and related subsequent legislation may be modified, repealed or otherwise invalidated through judicial challenge, which could result in lower numbers of insured individuals, reduced coverage for insured individuals and adversely affect our business.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, reduced Medicare payments to providers by 2% per fiscal year, effective on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2027 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, enacted on April 16, 2015, repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates and a new system of incentive payments scheduled to begin in 2019 that are based on various performance measures and physicians' participation in alternative payment models such as accountable care organizations. It is unclear what effect new quality and payment programs, such as MACRA, may have on our business, financial condition, results of operations or cash flows.

We expect additional state and federal healthcare policies and reform measures to be adopted in the future, any of which could limit reimbursement for healthcare products and services or otherwise result in reduced demand for the OCS or additional pricing pressure and have a material adverse effect on our industry generally and on our customers. Any changes of, or uncertainty with respect to, future reimbursement to hospitals and transplant centers could affect demand for the OCS, which in turn could have a material adverse effect on our business, financial condition and results of operations.

Our business activities involve the use of hazardous materials, which require compliance with environmental and occupational safety laws regulating the use of such materials. If we violate these laws, we could be subject to significant fines, liabilities or other adverse consequences.

Our research and development programs involve the controlled use of hazardous materials. Accordingly, we are subject to international, federal, state and local laws governing the use, handling and disposal of these materials. Although we believe that our safety procedures for handling and disposing of these materials comply in all material respects with applicable regulations, we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of an accident or failure to comply with environmental laws, we could be held liable for damages that result, and any such liability could exceed our assets and resources. Our general liability and umbrella insurance policies provide for coverage up to annual aggregate limits of $2 million per occurrence, but exclude coverage for liabilities relating to the release of pollutants. The insurance that we currently hold may not be adequate to cover all liabilities relating to accidental contamination or injury due to pollution conditions or other extraordinary or unanticipated events. Furthermore, an accident could damage or force us to shut down our operations.

Risks Related to Our Common Stock and this Offering

An active trading market for our common stock may not develop, and you may not be able to resell your shares of our common stock at or above the initial offering price.

Before this offering, there was no public trading market for our common stock. If a market for our common stock does not develop or is not sustained, it may be difficult for you to sell your shares of common stock at an attractive price, at the time that you would like to sell them, or at all. The initial public offering price of our common stock will be determined through negotiations between us and the underwriters. This initial public offering price may not be indicative of the market price of our common stock after the offering. We cannot predict the prices at which our common stock will trade. Consequently, you may not be able to sell our common stock at prices equal to or greater than the price you paid in this offering, or at all.

The market price of our common stock may be volatile, which could result in substantial losses for investors purchasing shares in this offering and could subject us to securities class action litigation.

The market price of our common stock could be subject to significant fluctuations after this offering, and it may decline below the initial public offering price. Some of the factors that may cause the market price of our common stock to fluctuate include:

- price and volume fluctuations in the overall stock market;
- volatility in the market price and trading volume of comparable companies;
- actual or anticipated changes in our earnings or fluctuations in our operating results or in the expectations of securities analysts;
- results of clinical trials relating to the OCS or competing products;
- failure or discontinuation of any of our product development and research programs;
- regulatory or legal developments in the United States and other countries, including changes in the healthcare payment systems;
- results of applications for regulatory approvals or clearances for the OCS or competing products;
- our announcements or our competitors’ announcements of new products, procedures or therapies;
- departure of key personnel;
- litigation involving us or that may be perceived as having an adverse effect on our business;

- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- market conditions in the medical device and biotechnology sectors;
- changes in general economic, industry and market conditions and trends;
- investors' general perception of us; and
- sales of large blocks of our stock.

The market for medical device and biotechnology companies, in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Because of the potential volatility of our stock price, we may become the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management's attention and resources from our business.

We will have broad discretion in the use of our net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of our net proceeds from the sale of our shares in this offering, and you will be relying on the judgment of our management regarding the application of these proceeds. The timing and amount of our actual expenditures will be based on many factors, including cash flows from operations, the occurrence and timing of regulatory approvals and clinical trials, the anticipated growth of our business and the availability and terms of alternative financing sources to fund our growth. Because we will have broad discretion in the application of our net proceeds from this offering, our management may fail to apply these funds effectively, which could materially and adversely affect our ability to operate and grow our business.

Purchasers in this offering will incur immediate and substantial dilution in the book value of their investment as a result of this offering.

The initial public offering price will be substantially higher than the pro forma as adjusted net tangible book value per share of our common stock after this offering. Investors purchasing common stock in this offering will pay a price per share that substantially exceeds the pro forma as adjusted net tangible book value per share after this offering. If you purchase shares of our common stock in this offering, you will incur immediate dilution of $ per share as of September 29, 2018, based on an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, representing the difference between our pro forma as adjusted net tangible book value per share after giving effect to this offering and the assumed initial public offering price. Further, investors purchasing common stock in this offering will contribute approximately % of the total amount invested by stockholders since our inception, but will own only approximately % of the shares of common stock outstanding after this offering. You will experience additional dilution upon the exercise of options to purchase shares of our common stock, including those options currently outstanding and those granted in the future, and the issuance of restricted stock or other equity awards under our stock incentive plans. To the extent we raise additional capital by issuing equity securities, our shareholders will experience substantial additional dilution. See "Dilution."

Because we do not expect to pay any dividends on our common stock for the foreseeable future, investors in this offering may never receive a return on their investment.

You should not rely on an investment in our common stock to provide dividend income. We do not anticipate that we will pay cash dividends to holders of our common stock in the foreseeable future. Instead, we plan to retain any earnings to maintain and expand our existing operations. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, to realize a return on their investment.

A significant portion of our total outstanding shares may be sold into the public market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

Following completion of this offering, we will have shares of common stock outstanding (or shares of common stock if the underwriters exercise their option to purchase additional shares in full). Of the shares of our common stock to be outstanding following completion of this offering, the shares offered by this prospectus will be eligible for immediate sale in the public market without restriction by persons other than our affiliates. Our remaining outstanding shares will become available for resale in the public market as shown in the chart below, subject to the provisions of Rule 144 and Rule 701.

Number of Shares	Date Available for Resale
	On the date of this offering
	180 days after this offering, subject to certain exceptions

In addition, each of our officers and directors and certain holders of our common stock have entered into a lock-up agreement with Morgan Stanley & Co. LLC and J.P. Morgan Securities LLC, as representatives of the underwriters, which regulates their sales of our common stock for a period of 180 days after the date of this prospectus, subject to certain exceptions. Morgan Stanley & Co. LLC and J.P. Morgan Securities LLC may, in their sole discretion, release all or some portion of the shares subject to lock-up agreements at any time and for any reason.

Sales of substantial amounts of our common stock in the public market after this offering, the perception that such sales will occur, or early release of these lock-up agreements could adversely affect the market price of our common stock and make it difficult for us to raise funds through securities offerings in the future. For more information, see the “Shares Eligible for Future Sale” and “Underwriting” sections of this prospectus.

We will adopt anti-takeover provisions in our restated articles of organization and amended and restated bylaws and are subject to provisions of Massachusetts law that may frustrate any attempt to remove or replace our current board of directors or to effect a change of control or other business combination involving our company.

Our restated articles or organization and amended and restated bylaws and certain provisions of Massachusetts law may discourage certain types of transactions involving an actual or potential change of control of our company that might be beneficial to us or our security holders. For example, our amended and restated bylaws will grant our directors the right to adjourn any meetings of shareholders. Our board of directors also may issue shares of any class or series of preferred stock in the future without shareholder approval and upon such terms as our board of directors may determine. The rights of the holders of our common stock will be subject to, and may be harmed by, the rights of the holders of any class or series of preferred stock that may be issued in the future. Massachusetts state law also prohibits us from engaging in specified business combinations unless the combination is approved or consummated in a prescribed manner. These provisions, alone or together, could delay hostile takeovers and changes in control of our company or changes in our management.

Our restated articles of organization will designate the state and federal courts located within the Commonwealth of Massachusetts as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our shareholders, which could discourage lawsuits against us and our directors and officers.

Our restated articles of organization will designate the state and federal courts located within the Commonwealth of Massachusetts as the sole and exclusive forum for any derivative action or proceeding brought

on our behalf, any action asserting a claim of breach of a fiduciary duty owed by any of our directors or officers to us or our shareholders, creditors or other constituents, any action asserting a claim arising pursuant to any provision of the Massachusetts Business Corporation Act or any action asserting a claim governed by the internal affairs doctrine, in all cases subject to the court's having personal jurisdiction over the indispensable parties named as defendants. In addition, our articles of organization provide that unless our board of directors consents in writing to the selection of an alternative forum, the U.S. federal district courts shall be the exclusive forum for the resolutions of any complaint asserting a cause of action arising under the U.S. federal securities laws. This exclusive forum provision may limit the ability of our shareholders to bring a claim in a judicial forum that such shareholders find favorable for disputes with us or our directors or officers, which may discourage such lawsuits against us and our directors and officers. Alternatively, if a court outside of Massachusetts were to find this exclusive forum provision inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings described above, we may incur additional costs associated with resolving such matters in other jurisdictions, which could materially and adversely affect our business, financial condition, operating results, cash flows and prospects.

Our management team has limited experience managing a public company.

Most members of our management team have limited experience managing a publicly-traded company, interacting with public company investors and complying with the increasingly complex laws pertaining to public companies. Our management team may not successfully or efficiently manage our transition to being a public company subject to significant regulatory oversight and reporting obligations under the federal securities laws and the scrutiny of securities analysts and investors. These new obligations and constituents will require significant attention from our management team and could divert their attention away from the day-to-day management of our business, which could materially and adversely affect our business, financial condition, operating results, cash flows and prospects.

Our directors, officers and principal shareholders have significant voting power and may take actions that may not be in the best interests of our other shareholders.

Following completion of this offering, our directors, officers and principal shareholders each holding more than 5% of our common stock will collectively control approximately % of our outstanding common stock (approximately % if the underwriters exercise their option to purchase additional shares in full). As a result, these shareholders, if they act together, will be able to control the management and affairs of our company and most matters requiring shareholder approval, including the election of directors and approval of significant corporate transactions. The interests of these shareholders may not be the same as or may even conflict with your interests. For example, these shareholders could attempt to delay or prevent a change in control of the Company, even if such change in control would benefit our other shareholders. As a result, this concentration of ownership may not be in the best interests of our other shareholders.

As a public company, we will become subject to additional laws, regulations and stock exchange listing standards, which will impose additional costs on us and may strain our resources and divert our management's attention.

Prior to this offering, we operated on a private basis. After this offering, we will be subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the listing requirements of Nasdaq and other applicable securities laws and regulations. Compliance with these laws and regulations will increase our legal and financial compliance costs and make some activities more difficult, time-consuming or costly, which may strain our resources or divert management's attention.

If we fail to maintain effective internal control over financial reporting and effective disclosure controls and procedures, we may not be able to accurately report our financial results in a timely manner or prevent fraud, which may adversely affect investor confidence in our company.

We are not currently required to comply with the rules of the SEC implementing Section 404 of the Sarbanes-Oxley Act and, therefore, we are not required to make a formal assessment of the effectiveness of our internal control over financial reporting for that purpose. Upon becoming a public company, we will be required to comply with the SEC's rules implementing Sections 302 and 404 of the Sarbanes-Oxley Act, which require management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of controls over financial reporting. Although we will be required to disclose changes made in our internal controls and procedures on a quarterly basis, we are not required to make our first annual assessment of our internal control over financial reporting pursuant to Section 404 until the year following our first annual report required to be filed with the SEC. As an emerging growth company, our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 until the later of the year following our first annual report required to be filed with the SEC or the date we are no longer an emerging growth company. At such time, our independent registered public accounting firm may issue a report that is adverse in the event it is not satisfied with the level at which our controls are documented, designed or operating.

To comply with the requirements of being a public company, we may need to undertake actions, such as implementing new internal controls and procedures and hiring additional accounting or internal audit staff. Testing and maintaining internal control can divert our management's attention from other matters that are important to the operation of our business. In addition, when evaluating our internal control over financial reporting, we may identify material weaknesses that we may not be able to remediate in time to meet the applicable deadline imposed upon us for compliance with the requirements of Section 404. If we identify any material weaknesses in our internal controls over financial reporting or we are unable to comply with the requirements of Section 404 in a timely manner or assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting once we are no longer an emerging growth company, investors may lose confidence in the accuracy and completeness of our financial reports. As a result, the market price of our common stock could be materially adversely affected.

We are an "emerging growth company" and "smaller reporting company," and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and may remain an emerging growth company until the last day of our fiscal year following the fifth anniversary of this offering, subject to specified conditions. We would cease to be an emerging growth company prior to such date if we have more than $1.07 billion in annual revenue, we have more than $700 million in market value of our stock held by non-affiliates (and we have been a public company for at least 12 months and have filed one annual report on Form 10-K) or we issue more than $1 billion of non-convertible debt securities over a three-year period. For so long as we remain an emerging growth company, we are permitted, and intend, to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include reduced disclosure obligations regarding executive compensation and no requirements to hold non-binding advisory votes on executive compensation and golden parachute payments, to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and to comply with certain requirements of Auditing Standard 3101 relating to providing a supplement to the auditor's report regarding critical audit matters. In this prospectus, we have not included all of the executive compensation-related information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We intend to avail ourselves of this exemption, and the reported results of operations contained in our financial statements may not be directly comparable to those of other public companies. Accordingly, we will incur additional costs in connection with complying with the accounting standards applicable to public companies at such time or times as they become applicable to us.

We are also a "smaller reporting company," meaning that the market value of our stock held by non-affiliates plus the proposed aggregate amount of gross proceeds to us as a result of this offering is less than $700 million and our annual revenue is less than $100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company after this offering if either (i) the market value of our stock held by non-affiliates is less than $250 million or (ii) our annual revenue is less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Changes in accounting standards and subjective assumptions, estimates and judgments by management related to complex accounting matters could significantly affect our financial condition and results of operations.

Accounting principles and related pronouncements, implementation guidelines and interpretations we apply to a wide range of matters that are relevant to our business, including, but not limited to, revenue recognition, leases and stock-based compensation, are complex and involve subjective assumptions, estimates and judgments by our management. Changes in accounting pronouncements or their interpretation or changes in underlying assumptions, estimates or judgments by our management could significantly change our reported or expected financial performance.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the sections entitled “Prospectus Summary,” “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business”, contains forward-looking statements. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future results of operations and financial position, business strategy and plans and our objectives for future operations, are forward-looking statements. The words “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “expect,” “should,” “could,” “target,” “predict,” “seek” and similar expressions are intended to identify forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy, short- and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in “Risk Factors.” Moreover, we operate in a very competitive and rapidly changing environment and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this prospectus may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

Some of the key factors that could cause actual results to differ from our expectations include:

- our anticipation that we will continue to incur losses in the future;
- our potential need to raise additional funding;
- our existing and any future indebtedness, including our ability to comply with affirmative and negative covenants under the Credit Agreement to which we will remain subject to until maturity;
- the fluctuation of our financial results from quarter to quarter;
- our ability to use NOLs and research and development credit carryforwards;
- our dependence on the success of the OCS;
- the rate and degree of market acceptance of the OCS;
- our ability to educate patients, surgeons, transplant centers and private payors of benefits offered by the OCS;
- our ability to improve the OCS platform;
- our dependence of limited number of customers for a significant portion of our net revenue;
- the timing of and our ability to obtain and maintain regulatory approvals or clearances;
- our ability to adequately respond to FDA follow-up inquiries in a timely manner;
- the performance of our third-party suppliers and manufacturers;
- the timing or results of clinical trials for the OCS;
- our manufacturing, sales, marketing and clinical support capabilities and strategy;
- attacks against our information technology infrastructure;
- the economic, political and other risks associated with our foreign operations;
- our ability to attract and retain key personnel;
- our ability to protect, defend, maintain and enforce our intellectual property rights relating to the OCS and avoid allegations that our products infringe, misappropriate or otherwise violate the intellectual property rights of third parties;

- the ability to obtain and maintain regulatory approvals or clearance for our OCS products;
- our expectations for the pricing of the OCS, as well as the reimbursement coverage for the OCS in the United States and internationally;
- regulatory developments in the United States, European Union and other jurisdictions;
- the extent and success of competing products that are or may become available;
- the impact of any product recalls or improper use of our products;
- our use of proceeds for this offering; and
- our estimates regarding revenues, expenses and needs for additional financing.

The forward-looking statements included in this prospectus are made only as of the date hereof. You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Moreover, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this prospectus to conform these statements to actual results or to changes in our expectations.

You should read this prospectus with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect.

USE OF PROCEEDS

We estimate that our net proceeds from the sale of our common stock in this offering will be approximately $ million, or approximately $ million if the underwriters exercise in full their option to purchase additional shares from us in this offering, assuming an initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

A $1.00 increase (decrease) in the assumed initial public offering price of $ per share would increase (decrease) the net proceeds to us from this offering by approximately $ million, assuming that the number of shares offered, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase (decrease) of 1,000,000 shares in the number of shares offered by us in this offering, as set forth on the cover page of this prospectus, would increase (decrease) the net proceeds to us from this offering by approximately $ million, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

We intend to use the net proceeds from this offering as follows:

- approximately $ million to support commercialization of the OCS Lung and, if approved, the OCS Heart in the United States;
- approximately $ million to fund research and development to design and manufacture the next generation of OCS technology;
- approximately $ million for clinical trial expenditures, including those relating to our pre- and post-market clinical trials, including our TOP Registry, our OCS Liver PROTECT Trial and the use of the OCS Heart for DCD donor hearts; and
- the balance for working capital and other general corporate purposes.

In addition, we believe that opportunities may exist from time to time to expand our current business through acquisitions of or investments in complementary products, technologies or businesses. While we have no current agreements, commitments or understandings for any specific acquisitions or in-licenses at this time, we may use a portion of our net proceeds for these purposes.

Based on our current plans, we believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will enable us to fund our operating expenses, including completing the clinical trials specifically identified above, capital expenditure requirements and debt service payments through , without considering potential additional borrowings that may become available to us upon our achievement of specified revenue thresholds and a regulatory milestone under our Credit Agreement. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—Funding Requirements” and “Risk Factors—Risks Related to Our Financial Position and Need for Additional Capital—We have incurred substantial losses since our inception and anticipate that we will continue to incur losses in the future” and “—We may need to raise additional funding, which might not be available on favorable terms, or at all. Raising additional capital may cause dilution to our shareholders.”

Our management will have broad discretion in the application of the net proceeds we receive from this offering, and investors will be relying on the judgment of our management regarding the application of our net proceeds. The timing and amount of our actual expenditures will be based on many factors, including cash flows from operations, the occurrence and timing of regulatory approvals and clinical trials, the anticipated growth of our business and the availability and terms of alternative financing sources to fund our growth. Pending their use as described above, we intend to invest the net proceeds we receive from this offering in saving, certificate of deposit and money market accounts as well as short-term and intermediate investment-grade interest-bearing securities and obligations, such as money market funds, commercial paper and obligations of the United States government and its agencies.

DIVIDEND POLICY

We have never declared or paid any dividends on our capital stock. We do not anticipate declaring or paying any cash dividends on our capital stock in the foreseeable future. Any future determination to declare and pay cash dividends, if any, will be made at the discretion of our board of directors and will depend on a variety of factors, including applicable laws, our financial condition, results of operations, contractual restrictions, capital requirements, business prospects, general business or financial market conditions and other factors our board of directors may deem relevant. In addition, our Credit Agreement contains covenants that restrict our ability to pay cash dividends. See “Description of Certain Indebtedness—Credit Agreement.” Investors should not purchase our common stock with the expectation of receiving cash dividends.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and our capitalization as of September 29, 2018:

- on an actual basis, before giving effect to the Corporate Reorganization;
- on a pro forma basis to give effect to the Corporate Reorganization, including (i) the conversion of all outstanding shares of preferred stock of TransMedics, Inc. into an aggregate of shares of common stock of TransMedics Group, Inc., or TransMedics Group, (ii) the conversion of all outstanding shares of common stock of TransMedics, Inc. into an aggregate of shares of common stock of TransMedics Group, (iii) the conversion of all outstanding warrants to purchase shares of preferred stock of TransMedics, Inc. into warrants to purchase shares of common stock of TransMedics Group and (iv) the filing and effectiveness of our restated articles of organization; and
- on a pro forma as adjusted basis to give further effect to (i) our issuance and sale of shares of our common stock in this offering at an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, and (ii) our payment of $1.5 million to former financial advisors upon the closing of this offering in satisfaction of contractual obligations previously recorded.

The pro forma as adjusted information below is illustrative only, and our capitalization following the closing of this offering will change based on the actual initial public offering price and other terms of this offering determined at pricing. You should read the information in this table together with our consolidated financial statements and the related notes included elsewhere in this prospectus and the "Corporate Reorganization," "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of this prospectus.

	As of September 29, 2018		
	Actual	Pro Forma	Pro Forma As Adjusted
	(in thousands, except share and per share data)		
Cash and cash equivalents	$ 28,890	$ 28,890	$
Preferred stock warrant liability	$ 776	$ —	$
Long-term debt, net of discount	33,564	33,564	
Convertible preferred stock (Series A-1, B, B-1, C, D, E and F), $0.0001 par value; 50,776,054 shares authorized, 50,404,140 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	186,519	—	
Stockholders' equity (deficit):			
Preferred stock, no par value; no shares authorized, issued or outstanding, actual; shares authorized and no shares issued or outstanding, pro forma and pro forma as adjusted	—	—	
Common stock, $0.0001 par value; 60,000,000 shares authorized, 4,878,364 shares issued and 4,877,288 shares outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	1	—	
Common stock, no par value; no shares authorized, issued or outstanding, actual; shares authorized, shares issued and outstanding, pro forma; shares authorized, shares issued and outstanding, pro forma as adjusted	—	331,037	
Additional paid-in capital	143,741	—	
Accumulated other comprehensive loss	(138)	(138)	
Accumulated deficit	(328,301)	(328,301)	
Total stockholders' equity (deficit)	(184,697)	2,598	
Total capitalization	$ 36,162	$ 36,162	$

A $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, common stock, total stockholders' equity and total capitalization by $ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase (decrease) of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, common stock, total stockholders' equity and total capitalization by $ million, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The table above does not include:

- 5,386,293 shares of common stock issuable upon the exercise of stock options outstanding as of September 29, 2018 under our 2004 Plan and our 2014 Plan, at a weighted average exercise price of $0.39 per share;
- 225,544 shares of common stock issuable upon the exercise of warrants outstanding as of September 29, 2018 to purchase shares of preferred stock that will be converted into warrants to purchase shares of common stock at a weighted average exercise price of $3.06 per share, in connection with the Corporate Reorganization;
- 571,860 shares of common stock available for future issuance as of September 29, 2018 under our 2014 Plan;
- shares of common stock that will become available for future issuance under our 2019 Stock Incentive Plan, or our 2019 Plan; and
- shares of common stock that will become available for future issuance under our 2019 Employee Stock Purchase Plan, or our 2019 ESPP.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted immediately to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock after this offering.

Our historical net tangible book value (deficit) as of September 29, 2018 was $(186.2) million, or $(38.17) per share of common stock. Our historical net tangible book value (deficit) is the amount of our total tangible assets less our total liabilities and the carrying value of our preferred stock, which is not included within stockholders' equity (deficit). Historical net tangible book value (deficit) per share represents historical net tangible book value (deficit) divided by the 4,877,288 shares of common stock outstanding as of September 29, 2018, before giving effect to the Corporate Reorganization.

Our pro forma net tangible book value as of September 29, 2018 was $1.1 million, or $ per share of common stock. Pro forma net tangible book value represents the amount of our total tangible assets less our total liabilities, after giving effect to the Corporate Reorganization, including (i) the conversion of all outstanding shares of preferred stock of TransMedics, Inc. into an aggregate of shares of common stock of TransMedics Group, (ii) the conversion of all outstanding shares of common stock of TransMedics, Inc. into an aggregate of shares of common stock of TransMedics Group and (iii) the conversion of all outstanding warrants to purchase shares of preferred stock of TransMedics, Inc. into warrants to purchase shares of common stock of TransMedics Group. Pro forma net tangible book value per share represents pro forma net tangible book value divided by the total number of shares outstanding as of September 29, 2018, after giving effect to the pro forma adjustments described above.

After giving further effect to (i) our issuance and sale of shares of our common stock in this offering at an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us and (ii) our payment of $1.5 million to former financial advisors upon the closing of this offering in satisfaction of contractual obligations previously recorded, our pro forma as adjusted net tangible book value as of September 29, 2018 would have been $ million, or $ per share. This represents an immediate increase in pro forma as adjusted net tangible book value per share of $ to existing stockholders and immediate dilution of $ in pro forma as adjusted net tangible book value per share to new investors purchasing common stock in this offering. Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the assumed initial public offering price per share paid by new investors. The following table illustrates this dilution on a per share basis:

Assumed initial public offering price per share		$
Historical net tangible book value (deficit) per share as of September 29, 2018	$(38.17)	
Increase per share attributable to the pro forma adjustments described above		
Pro forma net tangible book value per share as of September 29, 2018		
Increase in pro forma as adjusted net tangible book value per share attributable to new investors purchasing common stock in this offering		
Pro forma as adjusted net tangible book value per share after this offering		
Dilution per share to new investors purchasing common stock in this offering		$

The dilution information discussed above is illustrative only and will change based on the actual initial public offering price and other terms of this offering determined at pricing. A $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) our pro forma as adjusted net tangible book value per share after this offering by $ and dilution per share to new investors purchasing common stock in this offering by $, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and

estimated offering expenses payable by us. An increase of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase our pro forma as adjusted net tangible book value per share after this offering by $ and decrease the dilution per share to new investors purchasing common stock in this offering by $, assuming no change in the assumed initial public offering price per share and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. A decrease of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would decrease our pro forma as adjusted net tangible book value per share after this offering by $ and increase the dilution per share to new investors purchasing common stock in this offering by $, assuming no change in the assumed initial public offering price and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters exercise their option to purchase additional shares in full, our pro forma as adjusted net tangible book value per share after this offering would be $, representing an immediate increase in pro forma as adjusted net tangible book value per share of $ to existing stockholders and immediate dilution in pro forma as adjusted net tangible book value per share of $ to new investors purchasing common stock in this offering, assuming an initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The following table summarizes, as of September 29, 2018, on the pro forma as adjusted basis described above, the total number of shares of common stock purchased from us on an as converted to common stock basis, the total consideration paid or to be paid and the average price per share paid or to be paid by existing stockholders and by new investors in this offering at an assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. As the table shows, new investors purchasing common stock in this offering will pay an average price per share substantially higher than our existing stockholders paid.

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percentage	
Existing stockholders		%	$	%	$
New investors					$
Total		100.0%	$	100.0%	

A $1.00 increase (decrease) in the assumed initial public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the total consideration paid by new investors by $ million and, in the case of an increase, would increase the percentage of total consideration paid by new investors by percentage points and, in the case of a decrease, would decrease the percentage of total consideration paid by new investors by percentage points, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. An increase (decrease) of 1,000,000 shares in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the total consideration paid by new investors by $ million and, in the case of an increase, would increase the percentage of total consideration paid by new investors by percentage points and, in the case of a decrease, would decrease the percentage of total consideration paid by new investors by percentage points, assuming no change in the assumed initial public offering price.

If all of the outstanding options and warrants noted below were exercised, (i) the number of shares of our common stock held by existing stockholders would be increased to shares, or % of the total number of shares of our common stock outstanding after this offering, and the percentage of shares of common stock held by new investors purchasing common stock in this offering would be decreased to % of the total

number of shares of our common stock outstanding after this offering, (ii) the consideration paid by existing stockholders would be increased to $ million, or % of the total consideration paid by stockholders after this offering, and the percentage of consideration paid by new investors purchasing common stock in this offering would be decreased to % of the total consideration paid by stockholders after this offering, and (iii) the average price per share paid by existing stockholders would decrease to $ per share.

The table above assumes no exercise of the underwriters' option to purchase additional shares in this offering. If the underwriters' option to purchase additional shares is exercised in full, the number of shares of our common stock held by existing stockholders would be reduced to % of the total number of shares of our common stock outstanding after this offering, and the number of shares of common stock held by new investors purchasing common stock in this offering would be increased to % of the total number of shares of our common stock outstanding after this offering.

The tables and discussion above are based on the number of shares of our common stock outstanding as of September 29, 2018, and exclude:

- 5,386,293 shares of common stock issuable upon the exercise of stock options outstanding as of September 29, 2018 under our 2004 Plan and our 2014 Plan, at a weighted average exercise price of $0.39 per share;
- 225,544 shares of common stock issuable upon the exercise of warrants outstanding as of September 29, 2018 to purchase shares of preferred stock that will be converted into warrants to purchase shares of common stock, at a weighted average exercise price of $3.06 per share, in connection with the Corporate Reorganization;
- 571,860 shares of common stock available for future issuance as of September 29, 2018 under our 2014 Plan;
- shares of common stock that will become available for future issuance under our 2019 Plan; and
- shares of common stock that will become available for future issuance under our 2019 ESPP.

To the extent that new stock options or warrants are issued, or we issue additional shares of common stock in the future, there will be further dilution to new investors. In addition, we may choose to raise additional capital because of market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our shareholders.

SELECTED CONSOLIDATED FINANCIAL DATA

You should read the following selected consolidated financial data together with the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes included elsewhere in this prospectus. The consolidated statement of operations data for the fiscal years ended December 31, 2016 and December 30, 2017 and the consolidated balance sheet data as of December 31, 2016 and December 30, 2017 have been derived from our audited consolidated financial statements included elsewhere in this prospectus. The consolidated statement of operations data for the fiscal nine months ended September 30, 2017 and September 29, 2018 and the consolidated balance sheet data as of September 29, 2018 have been derived from our unaudited consolidated financial statements included elsewhere in this prospectus and have been prepared on the same basis as the audited consolidated financial statements. Our historical results are not necessarily indicative of the results that may be expected in the future.

	Fiscal Year Ended		Fiscal Nine Months Ended	
	December 31, 2016	December 30, 2017	September 30, 2017	September 29, 2018
	(in thousands, except per share data)			
Consolidated Statement of Operations Data:				
Net revenue	$ 6,209	$ 7,685	$ 5,579	$ 9,473
Cost of revenue	5,443	5,548	3,971	5,238
Gross profit	766	2,137	1,608	4,235
Operating expenses:				
Research, development and clinical trials	15,637	14,957	11,555	10,170
Selling, general and administrative	8,115	7,606	5,973	7,941
Total operating expenses	23,752	22,563	17,528	18,111
Loss from operations	(22,986)	(20,426)	(15,920)	(13,876)
Other income (expense):				
Interest expense	(979)	(1,072)	(804)	(1,647)
Change in fair value of preferred stock warrant liability	(105)	159	156	(423)
Other income (expense), net	5	548	421	(152)
Total other expense, net	(1,079)	(365)	(227)	(2,222)
Loss before income taxes	(24,065)	(20,791)	(16,147)	(16,098)
Provision for income taxes	—	(32)	(28)	(23)
Net loss	$ (24,065)	$ (20,823)	$ (16,175)	$ (16,121)
Net loss per share attributable to common stockholders, basic and diluted(1)	$ (5.35)	$ (4.48)	$ (3.48)	$ (3.42)
Weighted average common shares outstanding, basic and diluted(1)	4,502	4,647	4,647	4,714
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)(1)		$		$
Pro forma weighted average common shares outstanding, basic and diluted (unaudited)(1)				

(1) See Note 14 to our consolidated financial statements included elsewhere in this prospectus for details on the calculation of basic and diluted net loss per share attributable to common stockholders and unaudited basic and diluted pro forma net loss per share attributable to common stockholders.

	As of December 31, 2016	As of December 30, 2017	As of September 29, 2018
		(in thousands)	
Consolidated Balance Sheet Data:			
Cash, cash equivalents and marketable securities	$ 47,838	$ 24,663	$ 28,890
Working capital(1)	46,392	23,137	31,722
Total assets	58,104	37,001	48,397
Long-term debt, net of discount, including current portion	8,407	8,652	33,564
Preferred stock warrant liability	512	353	776
Convertible preferred stock	186,519	186,519	186,519
Total stockholders' deficit	(148,242)	(168,724)	(184,697)

(1) We define working capital as current assets less current liabilities.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with the "Selected Consolidated Financial Data" section of this prospectus and our consolidated financial statements and related notes included elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this prospectus, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a commercial-stage medical technology company transforming organ transplant therapy for end-stage organ failure patients across multiple disease states. We developed the OCS to replace a decades-old standard of care that we believe is significantly limiting access to life-saving transplant therapy for hundreds of thousands of patients worldwide. Our innovative OCS technology replicates many aspects of the organ's natural living and functioning environment outside of the human body. As such, the OCS represents a paradigm shift that transforms organ preservation for transplantation from a static state to a dynamic environment that enables new capabilities, including organ optimization and assessment. We believe our substantial body of clinical evidence has demonstrated the potential for the OCS to significantly increase the number of organ transplants and improve post-transplant outcomes.

We developed the OCS to comprehensively address the major limitations of cold storage. The OCS is a portable organ perfusion, optimization and monitoring system that utilizes our proprietary and customized technology to replicate near-physiologic conditions for donor organs outside of the human body. We designed the OCS technology platform to perfuse donor organs with warm, oxygenated, nutrient-enriched blood, while maintaining the organs in a living, functioning state; the lung is breathing, the heart is beating and the liver is producing bile. Because the OCS significantly reduces injurious ischemic time on donor organs as compared to cold storage and enables the optimization and assessment of donor organs, it has demonstrated improved clinical outcomes relative to cold storage and offers the potential to significantly improve donor organ utilization.

We designed the OCS to be a platform that allows us to leverage core technologies across products for multiple organs. To date, we have developed three OCS products, one for each of lung, heart and liver transplantations, making the OCS the only multi-organ technology platform. Our OCS products have been used for over 1,100 human organ transplants. During our clinical trials, we established relationships with over 55 leading transplant programs worldwide. We have commercialized the OCS Lung and OCS Heart outside of the United States and received our first PMA approval from the FDA in March 2018 for the use of the OCS Lung for donor lungs currently utilized for transplantation. We expect FDA action on additional applications for PMAs we submitted or that we expect to submit in connection with our other OCS products over the next 18 months.

Since our inception, we have focused substantially all of our resources on designing, developing and building our proprietary OCS technology platform and organ-specific OCS products; obtaining clinical evidence for the safety and effectiveness of our OCS products through clinical trials; securing regulatory approval; organizing and staffing our company; planning our business; raising capital; and providing general and administrative support for these operations. To date, we have funded our operations primarily with proceeds from sales of preferred stock and borrowings under loan agreements.

Since our inception, we have incurred significant operating losses. Our ability to generate net revenue sufficient to achieve profitability will depend on the successful further development and commercialization of our products. We generated net revenue of $6.2 million and $7.7 million for the fiscal years ended December 31,

2016 and December 30, 2017, respectively, and incurred net losses of $24.1 million and $20.8 million for those same years. We generated net revenue of $9.5 million and incurred a net loss of $16.1 million for the fiscal nine months ended September 29, 2018. As of September 29, 2018, we had an accumulated deficit of $328.3 million. We expect to continue to incur net losses for the foreseeable future as we focus on growing commercial sales of our products in both the U.S. and select non-U.S. markets, including growing our sales and clinical adoption team, which will pursue increasing commercial sales and clinical adoption of our OCS products; scaling our manufacturing operations; continuing research, development and clinical trial efforts; and seeking regulatory clearance for new products and product enhancements, including new indications, in both the U.S. and select non-U.S. markets. Further, following the closing of this offering, we expect to incur additional costs associated with operating as a public company. As a result, we will need substantial additional funding for expenses related to our operating activities, including selling, general and administrative expenses and research, development and clinical trials expenses.

Because of the numerous risks and uncertainties associated with product development and commercialization, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve or maintain profitability. Until such time, if ever, as we can generate substantial net revenue sufficient to achieve profitability, we expect to finance our operations through a combination of equity offerings, debt financings and strategic alliances. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we are unable to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back or discontinue the further development and commercialization efforts of one or more of our products, or may be forced to reduce or terminate our operations.

We believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will enable us to fund our operating expenses, capital expenditure requirements and debt service payments through , without considering potential additional borrowings that may become available to us upon our achievement of specified revenue thresholds and a regulatory milestone under our credit agreement with OrbiMed. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See "—Liquidity and Capital Resources."

Without giving effect to the net proceeds from this offering, we expect that our existing cash and cash equivalents as of September 29, 2018 will be sufficient to fund our operating expenses, capital expenditure requirements and debt service payments through September 2019, without considering potential additional borrowings that may become available to us under our credit agreement with OrbiMed. Beyond that point, we will need to raise additional capital to finance our operations, which cannot be assured. We have concluded that this circumstance raises substantial doubt about our ability to continue as a going concern within one year after the October 19, 2018 issuance date of our annual consolidated financial statements for the fiscal year ended December 30, 2017 and the December 12, 2018 issuance date of our interim consolidated financial statements for the fiscal nine months ended September 29, 2018. See Note 1 to our consolidated financial statements included elsewhere in this prospectus for additional information on our assessment.

Similarly, in its report on our financial statements for the fiscal year ended December 30, 2017, our independent registered public accounting firm included an explanatory paragraph stating that our recurring losses from operations since inception and required additional funding to finance our operations raise substantial doubt about our ability to continue as a going concern.

Corporate Reorganization

TransMedics Group, Inc., a recently formed Massachusetts corporation, is currently a direct, wholly-owned subsidiary of TransMedics, Inc., a Delaware corporation. Immediately prior to or concurrently with the closing of this offering, TMDX, Inc., a direct, wholly-owned subsidiary of TransMedics Group, will merge with and into TransMedics, Inc. with TransMedics, Inc. as the surviving corporation. As a result of the merger, each outstanding share of capital stock of TransMedics, Inc. will be converted into shares of common stock of

TransMedics Group, each outstanding option to purchase shares of common stock of TransMedics, Inc. will be converted into an outstanding option to purchase shares of common stock of TransMedics Group and each outstanding warrant to purchase shares of preferred stock of TransMedics, Inc. will be converted into a warrant to purchase shares of common stock of TransMedics Group, pursuant to the terms of the Agreement and Plan of Merger and Reorganization filed as an exhibit to the Registration Statement of which this prospectus forms a part.

Immediately following the Corporate Reorganization, (1) TransMedics Group will be a holding company with no material assets other than 100% of the equity interests in TransMedics, Inc., (2) the holders of capital stock in TransMedics, Inc. will become shareholders of TransMedics Group and (3) the historical consolidated financial statements of TransMedics, Inc. will become the historical consolidated financial statements of TransMedics Group because the Corporate Reorganization will be accounted for as a reorganization of entities under common control. Prior to the Corporate Reorganization, TransMedics Group has not conducted any activities other than in connection with its formation and in preparation for its initial public offering and has no material assets other than 100% of the equity interests in TMDX, Inc.

Components of Our Results of Operations

Net Revenue

We generate revenue primarily from sales of our single-use, organ-specific disposable sets (i.e., our organ-specific OCS Perfusion Sets sold together with our organ-specific OCS Solutions) used on our organ-specific OCS Consoles, each being a component of our OCS products. To a lesser extent, we also generate revenue from the sale of OCS Consoles to customers and from the implied rental of OCS Consoles loaned to customers at no charge. For each new transplant procedure, customers purchase an additional disposable set for use on the customer's existing organ-specific OCS Console.

All of our revenue has been generated by sales to transplant centers in the United States, Europe and Asia-Pacific, or, in some cases, to distributors selling to transplant centers in select countries. Substantially all of our customer arrangements are multiple-element arrangements that contain deliverables consisting of OCS Perfusion Sets and OCS Solutions. In some of those multiple-element arrangements, the deliverables also include an OCS Console, whether sold or loaned to the customer.

Some of our revenue has been generated from products sold in conjunction with the clinical trials conducted for our OCS products, under arrangements referred to as customer clinical trial agreements. Under most of these customer clinical trial agreements, we place an organ-specific OCS Console at the customer site for its use free of charge for the duration of the clinical trial, and the customer separately purchases from us the OCS disposable sets used in each transplant procedure during the clinical trial. When we loan the OCS Console to the customer, we retain title to the console at all times and do not require minimum purchase commitments from the customer related to any OCS products. In such cases, we invoice the customer for OCS disposable sets based on customer orders received for each new transplant procedure and the prices set forth in the customer agreement. Over time, we typically recover the cost of the loaned OCS Console through the customer's continued purchasing and use of additional disposable sets. For these reasons, we have determined that part of the arrangement consideration for the disposable set is an implied rental payment for use of the OCS Console. We intend to continue to loan OCS Consoles to some of our customers during commercialization of our OCS products.

Because all elements of a customer order are delivered and recognized as revenue at the same time and because revenue allocated to elements other than OCS disposable sets, such as implied rental income and service revenue, is insignificant, all elements of revenue from customer arrangements are classified as a single category of revenue in our consolidated statement of operations.

For customer clinical trial agreements, we make payments to our customers for reimbursements of clinical trial materials and for specified clinical documentation related to their use of our OCS products. Because these

payments do not provide us with a separately identifiable benefit, we record such payments as a reduction of revenue from the customer, resulting in our net revenue presentation.

Through September 29, 2018, all of our net revenue in the United States has been generated from sales of OCS disposable sets sold in conjunction with clinical trials conducted for our OCS products. In March 2018, we received our first FDA PMA approval for the OCS Lung, and we began commercial sales of this product in the fourth quarter of 2018. We expect to continue to have U.S. clinical trial sales for our OCS Heart and OCS Liver products until we receive similar FDA PMAs for those products.

Historically, our net revenue in the United States fluctuated from period to period as a result of the timing of patient enrollment in our clinical trials. Our net revenue during periods of patient enrollment has been higher due to the sale of OCS disposable sets for use during these clinical trials, as compared to periods during which our clinical trials were not actively enrolled. Our OCS Lung EXPAND Trial began patient enrollment in January 2014 and completed patient enrollment in October 2016. Our OCS Heart EXPAND Trial began patient enrollment in September 2015 and completed patient enrollment in March 2018. Our Liver PROTECT Trial began enrollment in January 2016 and is currently enrolling patients. Our OCS Lung EXPAND II Trial began patient enrollment in March 2018 and is currently enrolling patients. Our net revenue may continue to fluctuate from period to period as a result of the timing of ongoing clinical trials in which our OCS products are used.

Through September 29, 2018, all of our sales outside of the United States have been commercial sales (unrelated to any clinical trials) and our net revenue has been generated from sales of OCS disposable sets and, to a much lesser extent, sales of OCS Consoles. Commercial sales of OCS disposable sets generally have a higher average selling price than clinical trial sales of OCS disposable sets.

We expect that our net revenue will increase in the future as a result of receiving our first FDA PMA approval for the OCS Lung in the United States in March 2018 and any potential future FDA approvals in the United States for additional indications on OCS Lung and, eventually, OCS Heart and OCS Liver. We also expect that our net revenue will increase as a result of anticipated growth in non-U.S. sales if national healthcare systems begin to reimburse transplant centers for the use of the OCS, if transplant centers utilize the OCS in more transplant cases, and if more transplant centers adopt the OCS in their programs.

Cost of Revenue, Gross Profit and Gross Margin

Cost of revenue consists primarily of costs of components of our OCS Consoles and disposable sets, costs of direct materials, labor and the manufacturing overhead that directly supports production, and costs related to the depreciation of OCS Consoles loaned to customers. When we loan an OCS Console to a customer for its use free of charge, we capitalize as property and equipment the cost of our OCS Console and depreciate these assets over the five-year estimated useful life of the console. Included in the cost of disposable sets is the cost of our OCS Lung, OCS Heart and OCS Liver Solutions. If we do not meet our obligation to purchase minimum quantities annually from our supplier of OCS Lung Solution, we are obligated to pay a premium equal to the order shortfall multiplied by a specified price. We capitalize any estimated premium we expect to pay at the end of the year as an adjustment to the inventory cost of OCS Lung Solution. If the number of OCS disposable sets purchased by us increases over time, the allocated cost of the premium per disposable set sold will decrease during that time.

We expect that cost of revenue will increase in absolute dollars primarily as, and to the extent that, our net revenue increases.

Gross profit is the amount by which our net revenue exceeds our cost of revenue in each reporting period. We calculate gross margin as gross profit divided by net revenue. Our gross margin has been and will continue to be affected by a variety of factors, primarily production volumes, the cost of components and direct materials, manufacturing costs, headcount, the selling price of our OCS products and fluctuations in amounts paid by us to customers related to reimbursements of their clinical trial expenses.

We expect that cost of revenue as a percentage of net revenue will decrease and gross margin and gross profit will increase over the long term as our sales and production volumes increase and our cost per unit of our disposable sets decreases due to efficiencies of scale. We intend to use our design, engineering and manufacturing capabilities to further advance and improve the efficiency of our manufacturing processes, which we believe will reduce costs and increase our gross margin. As utilization by customers of our OCS products increases, we expect that a greater number of OCS disposable sets will be used per year on the same OCS Console, thereby driving overall gross margin improvement. Because we expect that the number of OCS disposable sets sold over time will be significantly greater than the number of OCS Consoles sold or loaned to customers over that same period, we expect that our gross margin improvement will not be significantly affected by the number of OCS Consoles that we sell or loan to customers. While we expect gross margin to increase over the long term, it will likely fluctuate from quarter to quarter.

Operating Expenses

Research, Development and Clinical Trials Expenses

Research, development and clinical trials expenses consist primarily of costs incurred for our research activities, product development, hardware and software engineering, clinical trials to develop clinical evidence of our products' safety and effectiveness, regulatory expenses, testing, consultant services and other costs associated with our OCS technology platform and OCS products, which include:

- employee-related expenses, including salaries, related benefits and stock-based compensation expense for employees engaged in research, hardware and software development, regulatory and clinical trial functions;
- expenses incurred in connection with the clinical trials of our products, including under agreements with third parties, such as consultants, contractors and data management organizations;
- the cost of maintaining and improving our product designs, including the testing of materials and parts used in our products;
- laboratory supplies and research materials; and
- facilities, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities and insurance.

We expense research, development and clinical trials costs as incurred. In the future, we expect that research, development and clinical trials expenses will increase due to ongoing product development and approval efforts. We expect to continue to perform activities related to obtaining additional regulatory approvals for expanded indications in the United States and to developing the next generation of our OCS technology platform.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of salaries and related costs, including stock-based compensation, for personnel in our sales and clinical adoption team and personnel in executive, marketing, finance and administrative functions. Selling, general and administrative expenses also include direct and allocated facility-related costs, promotional activities, marketing, conferences and trade shows as well as professional fees for legal, patent, consulting, investor and public relations, accounting and audit services. We expect to continue to increase headcount in our sales and clinical adoption team and increase marketing efforts as we continue to grow commercial sales of our OCS products in both U.S. and select non-U.S. markets.

We expect that our selling, general and administrative expenses will increase as we increase our headcount to support the expected continued sales growth of our OCS products. We also anticipate that we will incur increased accounting, audit, legal, regulatory, compliance and director and officer insurance costs as well as investor and public relations expenses associated with operating as a public company.

Other Income (Expense)

Interest Expense

Interest expense consists of interest expense associated with outstanding borrowings under a prior loan agreement and our existing loan agreement as well as the amortization of debt discount associated with such agreements. We expect our interest expense will increase in connection with our credit agreement with OrbiMed, under which we borrowed $35.0 million in June 2018. At that time, we repaid the remaining $6.7 million of principal that had been outstanding under our prior loan and security agreement with Hercules Technology Growth Capital, or Hercules, thereby increasing our total debt by $28.3 million.

Change in Fair Value of Preferred Stock Warrant Liability

In connection with our prior loan and security agreement, as amended, with Hercules, we issued warrants to purchase shares of Series B, Series D and Series F preferred stock. We classify these warrants as a liability on our consolidated balance sheet that we remeasure to fair value at each reporting date, and we recognize changes in the fair value of the warrant liability as a component of other income (expense) in our consolidated statements of operations. We will continue to recognize changes in the fair value of each warrant comprising the warrant liability until each respective warrant is exercised, expires or qualifies for equity classification.

In connection with the Corporate Reorganization, the warrants to purchase preferred stock will be converted into warrants to purchase common stock, and the fair value of the warrant liability at that time will be reclassified to common stock. As a result, subsequent to the closing of this offering, we will no longer remeasure the fair value of the warrant liability at each reporting date.

Other Income (Expense), Net

Other income (expense), net includes interest income, foreign currency transaction gains and losses and other non-operating income and expense items unrelated to our core operations, including the loss on extinguishment of debt that we recognized in June 2018 in connection with our repayment of borrowings under our loan and security agreement with Hercules.

Interest income consists of interest earned on our invested cash balances. We expect our interest income to increase as we invest the net proceeds from this offering. Foreign currency transaction gains and losses result from intercompany transactions of a short-term nature as well as transactions with customers or vendors denominated in currencies other than the functional currency of the legal entity in which the transaction is recorded.

Provision for Income Taxes

Since our inception, we have not recorded any U.S. federal or state income tax benefits for the net operating losses we have incurred in each year or for the research and development tax credits we generated in the United States, as we believe, based upon the weight of available evidence, that it is more likely than not that all of our net operating loss carryforwards and tax credits will not be realized. In reporting periods subsequent to 2016, we have recorded provisions for foreign income taxes of an insignificant amount related to the operations of one of our foreign subsidiaries.

As of December 30, 2017, we had U.S. federal and state net operating loss carryforwards of $215.2 million and $148.5 million, respectively, which may be available to offset future taxable income and begin to expire in 2018 and 2030, respectively. As of December 30, 2017, we also had U.S. federal and state research and development tax credit carryforwards of $6.0 million and $4.0 million, respectively, which may be available to offset future tax liabilities and begin to expire in 2020 and 2024, respectively. As of December 30, 2017, we had no foreign net operating loss carryforwards. We have recorded a full valuation allowance against our net deferred tax assets at each balance sheet date.

On December 22, 2017, the TCJA was signed into United States law. The TCJA includes a number of changes to existing tax law, including, among other things, a permanent reduction in the federal corporate income tax rate from a top marginal tax rate of 35% to a flat rate of 21%, effective as of January 1, 2018, as well as limitation of the deduction for net operating losses to 80% of annual taxable income and elimination of net operating loss carrybacks, in each case, for losses arising in taxable years beginning after December 31, 2017 (though any such net operating losses may be carried forward indefinitely). The federal tax rate change resulted in a reduction in the gross amount of our deferred tax assets recorded as of December 30, 2017 and a corresponding reduction in our valuation allowance. As a result, no income tax expense or benefit was recognized as of the enactment date of the TCJA.

Results of Operations

Our fiscal year ends on the Saturday nearest December 31, and we report fiscal years using a 52/53-week convention. Under this convention, certain fiscal years contain 53 weeks. Each fiscal year is typically composed of four 13-week fiscal quarters, but in years with 53 weeks, the fourth quarter is a 14-week period. Our fiscal year ended December 31, 2016 included 53 weeks, and our fiscal year ended December 30, 2017 included 52 weeks.

Comparison of the Fiscal Nine Months Ended September 30, 2017 and September 29, 2018

The following table summarizes our results of operations for the fiscal nine months ended September 30, 2017 and September 29, 2018:

	Fiscal Nine Months Ended		
	September 30, 2017	September 29, 2018	Change
	(in thousands)		
Net revenue	$ 5,579	$ 9,473	$ 3,894
Cost of revenue	3,971	5,238	1,267
Gross profit	1,608	4,235	2,627
Operating expenses:			
Research, development and clinical trials	11,555	10,170	(1,385)
Selling, general and administrative	5,973	7,941	1,968
Total operating expenses	17,528	18,111	583
Loss from operations	(15,920)	(13,876)	2,044
Other income (expense):			
Interest expense	(804)	(1,647)	(843)
Change in fair value of preferred stock warrant liability	156	(423)	(579)
Other income (expense), net	421	(152)	(573)
Total other expense, net	(227)	(2,222)	(1,995)
Loss before income taxes	(16,147)	(16,098)	49
Provision for income taxes	(28)	(23)	5
Net loss	$ (16,175)	$ (16,121)	$ 54

Net Revenue, Cost of Revenue and Gross Profit

	Fiscal Nine Months Ended		
	September 30, 2017	September 29, 2018	Change
	(in thousands)		
Net revenue	$ 5,579	$ 9,473	$3,894
Cost of revenue	3,971	5,238	1,267
Gross profit	$ 1,608	$ 4,235	$2,627

Net Revenue

	Fiscal Nine Months Ended		
	September 30, 2017	September 29, 2018	Change
	(in thousands)		
Net revenue by geography:			
United States	$ 1,892	$ 4,391	$2,499
Outside the U.S.	3,687	5,082	1,395
Total net revenue	$ 5,579	$ 9,473	$3,894
Net revenue by OCS product:			
OCS Lung net revenue	$ 523	$ 3,146	$2,623
OCS Heart net revenue	4,060	4,860	800
OCS Liver net revenue	996	1,467	471
Total net revenue	$ 5,579	$ 9,473	$3,894

Net revenue increased by $3.9 million in the fiscal nine months ended September 29, 2018 compared to the fiscal nine months ended September 30, 2017 primarily as a result of an increase in the number of OCS disposable sets sold to customers in the United States and outside the U.S.

Net revenue from customers in the United States, all of which was generated by customers conducting clinical trials of our OCS products, was $4.4 million in the fiscal nine months ended September 29, 2018 and increased by $2.5 million in the fiscal nine months ended September 29, 2018 compared to the fiscal nine months ended September 30, 2017. The increase in net revenue from customers in the United States was primarily due to the sale of OCS disposable sets sold to customers for use in our OCS Lung EXPAND II Trial in the U.S., which began enrolling patients in March 2018. Sales of OCS Lung disposable sets in the U.S. increased from zero in the fiscal nine months ended September 30, 2017 to $2.8 million in the fiscal nine months ended September 29, 2018. This increase was partially offset by a $0.3 million decline in net revenue in the United States in the 2018 period primarily due to lower sales of OCS Heart disposable sets as a result of the completion of patient enrollment in our OCS Heart EXPAND Trial in March 2018. In addition, the U.S. selling price of OCS Lung disposable sets sold in the 2018 period was approximately 26% higher than the U.S. selling price of OCS Heart disposable sets sold in the 2017 period, which accounted for $0.7 million of the overall $2.5 million increase in net revenue in the United States from the 2017 period to the 2018 period. The U.S. selling prices of the OCS Heart disposable sets and OCS Liver disposable sets were unchanged from the 2017 period to the 2018 period.

Net revenue from customers outside the U.S. was $5.1 million in the fiscal nine months ended September 29, 2018 and increased by $1.4 million in the fiscal nine months ended September 29, 2018 compared to the fiscal nine months ended September 30, 2017. The increase in net revenue from customers outside the U.S. was primarily due to an increase of $1.4 million from sales of OCS Heart disposable sets from increased utilization by new and existing customers and a $0.1 million favorable impact of foreign currency rates, partially offset by a decrease of $0.2 million from sales of OCS Lung disposable sets. The selling prices of the OCS disposable sets outside the U.S. were consistent from the 2017 period to the 2018 period. In both periods, net revenue from customers outside the U.S. was derived entirely from commercial sales.

The increases in net revenue by OCS product in the fiscal nine months ended September 29, 2018 compared to the fiscal nine months ended September 30, 2017 were each primarily due to an increase in the number of OCS disposable sets sold for each organ-specific OCS product. To a lesser extent, the increase in OCS Lung net revenue was also due to the increase in the U.S. selling price of OCS Lung disposable sets described above. During these periods, there were no sales of OCS Consoles.

Cost of Revenue, Gross Profit and Gross Margin

Cost of revenue increased by $1.3 million in the fiscal nine months ended September 29, 2018 compared to the fiscal nine months ended September 30, 2017. Gross profit increased by $2.6 million in the fiscal nine months ended September 29, 2018 compared to the fiscal nine months ended September 30, 2017. Gross margin was 29% and 45% for the fiscal nine months ended September 30, 2017 and September 29, 2018, respectively. Gross profit and gross margin increased primarily as a result of a higher selling price for OCS Lung disposable sets used in our OCS Lung EXPAND II Trial during the 2018 period relative to the average selling price across OCS disposable sets in the 2017 period, a favorable foreign currency impact on sales to customers in Europe and overall higher sales, which improved efficiency in production and reduced the impact of fixed costs in our manufacturing operation.

Operating Expenses

Research, Development and Clinical Trials Expenses

	Fiscal Nine Months Ended		
	September 30, 2017	September 29, 2018	Change
	(in thousands)		
Personnel related (including stock-based compensation expense)	$ 4,467	$ 4,619	$ 152
Clinical trials costs	2,246	1,568	(678)
Consulting and third-party testing	2,049	1,456	(593)
Laboratory supplies and research materials	974	797	(177)
Facility related and other	1,819	1,730	(89)
Total research, development and clinical trials expenses	$ 11,555	$ 10,170	$(1,385)

Total research, development and clinical trials expenses decreased by $1.4 million from $11.6 million in the fiscal nine months ended September 30, 2017 to $10.2 million in the fiscal nine months ended September 29, 2018. Personnel-related costs (including stock-based compensation) increased by $0.2 million, primarily as a result of hiring additional employees in our clinical trial organization to support the initiation of our OCS Lung EXPAND II Trial, which began enrolling patients in March 2018, along with our ongoing OCS Liver PROTECT Trial and additional OCS Heart clinical trials, which we expect to initiate in early 2019. Clinical trials costs and consulting and third-party testing costs decreased by $0.7 million and $0.6 million, respectively, primarily due to reduced regulatory costs, as we received our first PMA approval from the FDA in March 2018, and due to reduced clinical trial activity in our OCS Lung EXPAND Trial, as we completed enrollment in the first quarter of 2017, and in our OCS Heart EXPAND Trial, as we completed enrollment in March 2018. Laboratory supplies and research materials costs decreased by $0.2 million as a result of fewer clinical and preclinical experiments conducted in the fiscal nine months ended September 29, 2018 compared to the fiscal nine months ended September 30, 2017.

Selling, General and Administrative Expenses

	Fiscal Nine Months Ended		
	September 30, 2017	September 29, 2018	Change
	(in thousands)		
Personnel related (including stock-based compensation expense)	$ 2,303	$ 3,358	$1,055
Professional and consultant fees	1,444	2,105	661
Tradeshows and conferences	571	793	222
Facility related and other	1,655	1,685	30
Total selling, general and administrative expenses	$ 5,973	$ 7,941	$1,968

Total selling, general and administrative expenses increased by $2.0 million from $6.0 million in the fiscal nine months ended September 30, 2017 to $7.9 million in the fiscal nine months ended September 29, 2018 primarily due to increases in personnel-related costs and professional and consultant fees as we hired additional resources and engaged consultants to support commercial sales of our OCS Lung product in the United States after receipt of our PMA approval in March 2018 and to support our preparation to operate as a public company.

Other Income (Expense)

Interest Expense

Interest expense for the fiscal nine months ended September 30, 2017 and September 29, 2018 consisted of interest on the outstanding borrowings under our loan and security agreement with Hercules and our credit agreement with OrbiMed. Our loan and security agreement with Hercules was outstanding through June 22, 2018, when we terminated and repaid in full the borrowings under that agreement and entered into a new credit agreement with OrbiMed. Interest expense increased by $0.8 million in the fiscal nine months ended September 29, 2018 compared to the fiscal nine months ended September 30, 2017 primarily as a result of a $28.3 million increase in our total outstanding borrowings in June 2018.

Change in Fair Value of Preferred Stock Warrant Liability

The change in the fair value of our preferred stock warrant liability in the fiscal nine months ended September 30, 2017 and September 29, 2018 was due primarily to the changes in the fair value of our preferred stock during those periods.

Other Income (Expense), Net

Other income (expense), net for the fiscal nine months ended September 30, 2017 and September 29, 2018 included interest income of $0.2 million in each period, resulting from interest earned on invested cash balances, and included $0.2 million of foreign currency transaction gains and less than $0.1 million of foreign currency transaction losses, respectively. Additionally, other income (expense), net for the fiscal nine months ended September 29, 2018 included a loss on extinguishment of debt of $0.3 million that we recognized in connection with the prepayment of our borrowings under our loan and security agreement with Hercules upon entering into our new credit agreement with OrbiMed.

Comparison of the Fiscal Years Ended December 31, 2016 and December 30, 2017

The following table summarizes our results of operations for the fiscal years ended December 31, 2016 and December 30, 2017:

	Fiscal Year Ended		
	December 31, 2016	December 30, 2017	Change
	(in thousands)		
Net revenue	$ 6,209	$ 7,685	$ 1,476
Cost of revenue	5,443	5,548	105
Gross profit	766	2,137	1,371
Operating expenses:			
Research, development and clinical trials	15,637	14,957	(680)
Selling, general and administrative	8,115	7,606	(509)
Total operating expenses	23,752	22,563	(1,189)
Loss from operations	(22,986)	(20,426)	2,560
Other income (expense):			
Interest expense	(979)	(1,072)	(93)
Change in fair value of preferred stock warrant liability	(105)	159	264
Other income (expense), net	5	548	543
Total other expense, net	(1,079)	(365)	714
Loss before income taxes	(24,065)	(20,791)	3,274
Provision for income taxes	—	(32)	(32)
Net loss	$ (24,065)	$ (20,823)	$ 3,242

Net Revenue, Cost of Revenue and Gross Profit

	Fiscal Year Ended		
	December 31, 2016	December 30, 2017	Change
	(in thousands)		
Net revenue	$ 6,209	$ 7,685	$1,476
Cost of revenue	5,443	5,548	105
Gross profit	$ 766	$ 2,137	$1,371

Net Revenue

	Fiscal Year Ended December 31, 2016	Fiscal Year Ended December 30, 2017	Change
	(in thousands)		
Net revenue by geography:			
United States	$ 3,468	$ 2,744	$ (724)
Outside the U.S.	2,741	4,941	2,200
Total net revenue	$ 6,209	$ 7,685	$ 1,476
Net revenue by OCS product:			
OCS Lung net revenue	$ 1,934	$ 789	$(1,145)
OCS Heart net revenue	3,598	5,761	2,163
OCS Liver net revenue	677	1,135	458
Total net revenue	$ 6,209	$ 7,685	$ 1,476

Net revenue increased by $1.5 million in the fiscal year ended December 30, 2017 compared to the fiscal year ended December 31, 2016 primarily as a result of a $2.2 million increase in sales outside of the U.S., which was partially offset by a decrease of $0.7 million in sales in the United States.

Net revenue from customers in the United States, all of which was generated by customers conducting clinical trials of our OCS products, was $2.7 million in the fiscal year ended December 30, 2017 and decreased by $0.7 million in the fiscal year ended December 30, 2017 compared to the fiscal year ended December 31, 2016. The decrease in net revenue from customers in the United States was primarily due to fewer sales of OCS Lung disposable sets as a result of the completion of patient enrollment in our OCS Lung EXPAND Trial in the fourth quarter of 2016. U.S. selling prices of our OCS disposable sets were consistent from the fiscal year ended December 31, 2016 to the fiscal year ended December 30, 2017.

Net revenue from customers outside the U.S. was $4.9 million in the fiscal year ended December 30, 2017 and increased by $2.2 million in the fiscal year ended December 30, 2017 compared to the fiscal year ended December 31, 2016. The increase in net revenue from customers outside the U.S. was due to increased sales of OCS disposable sets as existing customers increased their utilization of the OCS and as several new transplant centers began using the OCS. Foreign currency rates did not have a material impact on the net revenue increase from the fiscal year ended December 31, 2016 to the fiscal year ended December 30, 2017. Selling prices of our OCS disposable sets outside the U.S. were consistent from the fiscal year ended December 31, 2016 to the fiscal year ended December 30, 2017. In both periods, net revenue from customers outside the U.S. was derived entirely from commercial sales.

The decrease in OCS Lung net revenue and increases in OCS Heart net revenue and OCS Liver net revenue in the fiscal year ended December 30, 2017 compared to the fiscal year ended December 31, 2016 were primarily due to a decrease and increases, respectively, in the number of OCS disposable sets sold for each organ-specific OCS product. During these periods, there were no sales of OCS Consoles.

Cost of Revenue, Gross Profit and Gross Margin

Cost of revenue increased by $0.1 million in the fiscal year ended December 30, 2017 compared to the fiscal year ended December 31, 2016. Gross profit increased by $1.4 million in the fiscal year ended December 30, 2017 compared to the fiscal year ended December 31, 2016 due primarily to an increase in sales outside of the U.S. as existing customers increased their utilization of the OCS for transplants and several new transplant centers began using the OCS. Gross margin was 12% and 28% for the fiscal years ended December 31, 2016 and December 30, 2017, respectively. The increase in gross margin was primarily a result of higher volume of sales of OCS disposable sets, which reduced the impact of fixed costs in our manufacturing operation, and the impact

of the lower purchase cost of OCS Lung Solution in 2017 as compared to 2016. Selling prices of our OCS disposable sets were consistent from the fiscal year ended December 31, 2016 to the fiscal year ended December 30, 2017.

Operating Expenses

Research, Development and Clinical Trials Expenses

	Fiscal Year Ended		
	December 31, 2016	December 30, 2017	Change
	(in thousands)		
Personnel related (including stock-based compensation expense)	$ 6,995	$ 5,859	$(1,136)
Clinical trials costs	2,489	2,903	414
Consulting and third-party testing	1,703	2,114	411
Laboratory supplies and research materials	1,564	1,327	(237)
Facility related and other	2,886	2,754	(132)
Total research, development and clinical trials expenses	$ 15,637	$ 14,957	$ (680)

Total research, development and clinical trials expenses decreased by $0.7 million from $15.6 million in the fiscal year ended December 31, 2016 to $15.0 million in the fiscal year ended December 30, 2017. Personnel-related costs decreased by $1.1 million primarily as a result of headcount reductions during late 2016. Clinical trials costs and consulting and third-party testing costs each increased by $0.4 million, primarily as a result of the hiring of consultants to assist with activity related to the regulatory PMA process for our OCS Lung product.

Selling, General and Administrative Expenses

	Fiscal Year Ended		
	December 31, 2016	December 30, 2017	Change
	(in thousands)		
Personnel related (including stock-based compensation expense)	$ 3,269	$ 2,993	$ (276)
Professional and consultant fees	2,365	1,806	(559)
Tradeshows and conferences	1,194	674	(520)
Facility related and other	1,287	2,133	846
Total selling, general and administrative expenses	$ 8,115	$ 7,606	$ (509)

Total selling, general and administrative expenses decreased by $0.5 million from $8.1 million in the fiscal year ended December 31, 2016 to $7.6 million in the fiscal year ended December 30, 2017, primarily due to decreases in personnel-related costs, professional and consultant fees and tradeshow and conference expenses. These decreases were a result of headcount reductions during late 2016. These decreases were partially offset by an increase in facility-related and other expenses due to increased travel costs related to the regulatory PMA process for our OCS Lung product.

Other Income (Expense)

Interest Expense

Interest expense for the fiscal years ended December 31, 2016 and December 30, 2017 consisted primarily of interest on the outstanding borrowings under our loan and security agreement with Hercules.

Change in Fair Value of Preferred Stock Warrant Liability

The change in the fair value of our preferred stock warrant liability in the fiscal years ended December 31, 2016 and December 30, 2017 was due primarily to the changes in the fair value of our preferred stock during those periods.

Other Income (Expense), Net

Other income (expense), net for the fiscal years ended the December 31, 2016 and December 30, 2017 included interest income of $0.1 million and $0.3 million, respectively, resulting from interest earned on invested cash balances, as well as $0.1 million of foreign currency transaction losses and $0.3 million of foreign currency transactions gains, respectively.

Quarterly Results of Operations Data

The following table sets forth our quarterly statement of operations data for each of the seven most recent fiscal quarters in the period ended September 29, 2018. We have prepared the quarterly statement of operations data on the same basis as the audited consolidated financial statements included in this prospectus. In our opinion, the quarterly financial data reflects all adjustments, consisting only of normal recurring adjustments, that we consider necessary for a fair statement of this data. This information should be read together with our consolidated financial statements and related notes included elsewhere in this prospectus. Our operating results may fluctuate due to a variety of factors. Because the timing of organ transplant procedures is generally unpredictable, we have not experienced seasonality in our business from quarter to quarter and do not expect to do so in the foreseeable future. The results of historical periods are not necessarily indicative of the results to be expected for a full year or any future period.

	Fiscal Three Months Ended						
	Apr. 1, 2017	July 1, 2017	Sept. 30, 2017	Dec. 30, 2017	Mar. 31, 2018	June 30, 2018	Sept. 29, 2018
Net revenue	$ 1,480	$ 2,232	$ 1,867	$ 2,106	$ 2,519	$ 2,915	$ 4,039
Cost of revenue	1,168	1,421	1,381	1,578	1,595	1,736	1,907
Gross profit	312	811	486	528	924	1,179	2,132
Operating expenses:							
Research, development and clinical trials	3,961	4,193	3,402	3,401	3,465	3,433	3,272
Selling, general and administrative	1,829	2,330	1,813	1,634	2,243	2,899	2,799
Total operating expenses	5,790	6,523	5,215	5,035	5,708	6,332	6,071
Loss from operations	(5,478)	(5,712)	(4,729)	(4,507)	(4,784)	(5,153)	(3,939)
Other income (expense):							
Interest expense	(265)	(269)	(270)	(268)	(258)	(313)	(1,076)
Change in fair value of preferred stock warrant liability	19	123	13	4	(30)	(210)	(183)
Other income (expense), net	108	123	189	128	174	(427)	101
Total other income (expense), net	(138)	(23)	(68)	(136)	(114)	(950)	(1,158)
Loss before income taxes	(5,616)	(5,735)	(4,797)	(4,643)	(4,898)	(6,103)	(5,097)
Provision for income taxes	(10)	(9)	(9)	(4)	(7)	(8)	(8)
Net loss	$(5,626)	$(5,744)	$(4,806)	$(4,647)	$(4,905)	$(6,111)	$(5,105)

Liquidity and Capital Resources

Since our inception, we have incurred significant operating losses. To date, we have funded our operations primarily with proceeds from sales of preferred stock and borrowings under loan agreements. As of September 29, 2018, we had cash and cash equivalents of $28.9 million.

Cash Flows

The following table summarizes our sources and uses of cash for each of the fiscal periods presented:

	Fiscal Year Ended		Fiscal Nine Months Ended	
	December 31, 2016	December 30, 2017	September 30, 2017	September 29, 2018
	(in thousands)			
Cash used in operating activities	$ (24,109)	$ (23,098)	$ (17,813)	$ (19,864)
Cash provided by (used in) investing activities	(39,672)	24,859	19,006	12,441
Cash provided by financing activities	63,544	3	1	24,344
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(6)	335	339	33
Net increase (decrease) in cash, cash equivalents and restricted cash	$ (243)	$ 2,099	$ 1,533	$ 16,954

Operating Activities

During the fiscal nine months ended September 29, 2018, operating activities used $19.9 million of cash, primarily resulting from our net loss of $16.1 million and net cash used by changes in our operating assets and liabilities of $5.2 million, partially offset by net non-cash charges of $1.5 million. Net cash used by changes in our operating assets and liabilities for the fiscal nine months ended September 29, 2018 consisted primarily of a $3.0 million increase in accounts receivable and a $2.8 million increase in inventory, partially offset by a $1.1 million increase in accounts payable and accrued expenses and other current liabilities.

During the fiscal nine months ended September 30, 2017, operating activities used $17.8 million of cash, primarily resulting from our net loss of $16.2 million and net cash used by changes in our operating assets and liabilities of $2.0 million, partially offset by net non-cash charges of $0.3 million. Net cash used by changes in our operating assets and liabilities for the fiscal nine months ended September 30, 2017 consisted primarily of a $1.4 million increase in inventory and a $0.6 million decrease in accounts payable and accrued expenses and other current liabilities, partially offset by a $0.3 million decrease in accounts receivable.

During the fiscal year ended December 30, 2017, operating activities used $23.1 million of cash, primarily resulting from our net loss of $20.8 million and net cash used by changes in our operating assets and liabilities of $2.8 million, partially offset by net non-cash charges of $0.5 million. Net cash used by changes in our operating assets and liabilities for the fiscal year ended December 30, 2017 consisted primarily of a $2.5 million increase in inventory, a $0.3 million decrease in deferred rent and a $0.3 million decrease in accounts payable and accrued expenses and other current liabilities, all partially offset by a $0.5 million decrease in accounts receivable.

During the fiscal year ended December 31, 2016, operating activities used $24.1 million of cash, primarily resulting from our net loss of $24.1 million and net cash used by changes in our operating assets and liabilities of $0.9 million, partially offset by net non-cash charges of $0.8 million. Net cash used by changes in our operating assets and liabilities for the fiscal year ended December 31, 2016 consisted primarily of a $1.6 million increase in inventory, a $0.8 million increase in accounts receivable and a $0.3 million decrease in deferred rent, all partially offset by a $1.9 million increase in accounts payable and accrued expenses and other current liabilities.

Changes in accounts receivable, inventory, accounts payable, and accrued expenses and other current liabilities in each reporting period are generally due to growth in our business, including the growth in sales, expenses and employee headcount. Our deferred rent balance will continue to decrease in each reporting period during the remaining term of the leases for our leased property.

Investing Activities

During the fiscal nine months ended September 29, 2018, net cash provided by investing activities was $12.4 million, due to the maturities of marketable securities of $12.7 million, partially offset by purchases of property and equipment of $0.3 million.

During the fiscal nine months ended September 30, 2017, net cash provided by investing activities was $19.0 million, primarily due to the maturities of marketable securities of $34.6 million, partially offset by purchases of marketable securities of $15.5 million.

During the fiscal year ended December 30, 2017, net cash provided by investing activities was $24.9 million, due to the maturities of marketable securities of $44.3 million, partially offset by purchases of marketable securities of $19.2 million and purchases of property and equipment of $0.3 million.

During the fiscal year ended December 31, 2016, net cash used in investing activities was $39.7 million, due to purchases of marketable securities of $46.5 million and purchases of property and equipment of $1.5 million, partially offset by maturities of marketable securities of $8.3 million. The purchases of property and equipment during the fiscal year ended December 31, 2016 related to equipment purchases to expand our engineering and manufacturing capabilities.

Financing Activities

During the fiscal nine months ended September 29, 2018, net cash provided by financing activities was $24.3 million, consisting primarily of net proceeds from borrowings under our credit agreement with OrbiMed of $33.4 million, partially offset by the repayment of our previously outstanding borrowings under our loan and security agreement with Hercules of $9.1 million, representing principal of $8.5 million and the end-of-term interest payment of $0.6 million.

Cash provided by financing activities in the fiscal nine months ended September 30, 2017 and the fiscal year ended December 30, 2017 was less than $0.1 million.

During the fiscal year ended December 31, 2016, net cash provided by financing activities was $63.5 million, consisting primarily of proceeds from the issuance of preferred stock of $63.6 million.

Long-Term Debt

In June 2018, we entered into our Credit Agreement with OrbiMed, pursuant to which OrbiMed made certain term loans available to us. The Credit Agreement provides for aggregate maximum borrowings of up to $65.0 million, consisting of (i) $35.0 million upon entering into the Credit Agreement, which we borrowed in June 2018, and (ii) potential additional borrowings of up to $30.0 million that may become available upon our achievement of specified revenue thresholds and a regulatory milestone by determinable dates. As of September 29, 2018, we had not yet met the conditions for additional borrowings.

Borrowings under the Credit Agreement bear interest at an annual rate equal to the London Interbank Offered Rate, or LIBOR, subject to a minimum of 1.0% and a maximum of 4.0%, plus 8.5%, or the Applicable Margin, subject in the aggregate to a maximum interest rate of 11.5%. In addition, borrowings under the Credit Agreement bear paid-in-kind, or PIK interest, at an annual rate equal to the amount by which LIBOR plus the

Applicable Margin exceeds 11.5%, but not to exceed 12.5%. The PIK interest is added to the principal amount of the borrowings outstanding at the end of each quarter until the maturity date of the Credit Agreement in June 2023. Borrowings under the Credit Agreement are repayable in quarterly interest-only payments until the maturity date, at which time all principal and accrued interest is due and payable. At our option, we may prepay outstanding borrowings under the Credit Agreement, subject to a prepayment premium of 9.0% of the principal amount of any prepayment within the first three years, which percentage decreases annually until it reaches zero at the end of three years. We are also required to make a final payment in an amount equal to 3.0% of the principal amount of any prepayment or repayment, which we are accreting to interest expense over the term of the Credit Agreement using the effective interest method.

All obligations under the Credit Agreement are guaranteed by us and each of our material subsidiaries. All obligations of us and each guarantor are secured by substantially all of our and each guarantor's assets, including their intellectual property, subject to certain exceptions, including a perfected security interest in substantially all tangible and intangible assets of us and each guarantor. Under the Credit Agreement, we have agreed to certain affirmative and negative covenants to which we will remain subject until maturity. The negative covenants include maintaining a minimum liquidity amount of $3.0 million and restrictions on our activities, including limitations on dispositions, mergers or acquisitions; encumbering our intellectual property; incurring indebtedness or liens; paying dividends; making certain investments; and engaging in certain other business transactions. The obligations under the Credit Agreement are subject to acceleration upon the occurrence of specified events of default, including payment default, change in control, bankruptcy, insolvency, certain defaults under other material debt, certain events with respect to governmental approvals (if such events could cause a material adverse change in our business) and a material adverse change in our business, operations or other financial condition.

Upon the occurrence of an event of default and until such event of default is no longer continuing, the Applicable Margin will increase by 4.0% per annum. If an event of default (other than certain events of bankruptcy or insolvency) occurs and is continuing, OrbiMed may declare all or any portion of the outstanding principal amount of the borrowings plus accrued and unpaid interest to be due and payable. Upon the occurrence of certain events of bankruptcy or insolvency, all of the outstanding principal amount of the borrowings plus accrued and unpaid interest will automatically become due and payable. In addition, we may be required to prepay outstanding borrowings, subject to certain exceptions, with portions of net cash proceeds of certain asset sales and certain casualty and condemnation events. See "Description of Certain Indebtedness—Credit Agreement."

In June 2018, we repaid all amounts due under our 2015 loan and security agreement with Hercules and the loan and security agreement was terminated.

Funding Requirements

As we continue to pursue and increase commercial sales of our OCS products, we expect our costs and expenses to increase in the future, particularly as we expand our sales and clinical adoption team, scale our manufacturing operation, continue research, development and clinical trial efforts, and seek regulatory clearance for new products and product enhancements, including new indications, both in the United States and in select non-U.S. markets. In addition, upon the closing of this offering, we expect to incur additional costs associated with operating as a public company. The timing and amount of our operating and capital expenditures will depend on many factors, including:

- the amount of net revenue generated by sales of our OCS Consoles, OCS disposable sets and other products that may be approved in the United States and select non-U.S. markets;
- the costs and expenses of expanding our U.S. and non-U.S. sales and marketing infrastructure and our manufacturing operations;
- the extent to which our OCS products are adopted by the transplant community;

- the ability of our customers to obtain adequate reimbursement from third-party payors for procedures performed using the OCS products;
- the degree of success we experience in commercializing our OCS products for additional indications;
- the costs, timing and outcomes of any future clinical studies and regulatory reviews, including to seek and obtain approvals for new indications for our OCS products;
- the emergence of competing or complementary technologies;
- the number and types of future products we develop and commercialize;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims; and
- the level of our selling, general and administrative expenses.

See "Risk Factors—Risks Related to Our Financial Position and Need for Additional Capital—We may need to raise additional funding, which might not be available on favorable terms, or at all. Raising additional capital may cause dilution to our shareholders."

Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of September 29, 2018 and the effects that such obligations are expected to have on our liquidity and cash flows in future periods:

	Payments Due By Period				
	Total	Less Than 1 Year	1 to 3 Years	4 to 5 Years	More Than 5 Years
	(in thousands)				
Operating lease commitments(1)	$ 5,090	$ 1,544	$ 3,149	$ 397	$ —
Debt obligations(2)	54,311	4,145	7,698	42,468	—
Purchase commitments under manufacturing agreement(3)	1,258	1,258	—	—	—
Total	$60,659	$ 6,947	$10,847	$42,865	$ —

(1) Amounts in table reflect payments due for our leases of office and laboratory space in Andover, Massachusetts under two operating lease agreements that expire in December 2021.

(2) Amounts in table reflect the contractually required principal and interest payments payable under the Credit Agreement, under which borrowings bear interest at a variable rate. For purposes of this table, the interest due under the Credit Agreement was calculated using an assumed interest rate of 10.875% per annum, which was the interest rate in effect as of September 29, 2018. Because such interest rate is below the PIK interest threshold of 11.5%, we did not include PIK in our calculated payments.

(3) Amounts in the table reflect total payments we would be obligated to make to one of our contract manufacturers if, subsequent to September 29, 2018, we do not place any further orders for committed 2018 order quantities, the final year of the commitment. Minimum order quantities beyond 2018 will be renegotiated by both parties.

We are obligated to pay financing fees of $1.5 million to former financial advisors related to issuances of our Series B preferred stock and Series D preferred stock in periods prior to 2016. These financing fees are contingently payable in cash only upon an initial public offering or certain alternative transactions, including a sale of our company. These payments are not included in the table above as the timing of such payments is not known. See "Capitalization".

We also enter into other contracts in the normal course of business with consulting firms, material suppliers and other third parties for clinical trials and testing and manufacturing services. These contracts do not contain

minimum purchase commitments and are cancelable by us upon prior written notice. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including noncancelable obligations of our service providers, up to the date of cancellation. These payments are not included in the table above as the amount and timing of such payments are not known.

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue, costs and expenses and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to our consolidated financial statements included elsewhere in this prospectus, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our financial statements.

Revenue Recognition

We generate revenue primarily from sales of our single-use, organ-specific disposable sets (i.e., our organ-specific OCS Perfusion Sets sold together with our organ-specific OCS Solutions) used on our organ-specific OCS Consoles, each being a component of our OCS products. To a lesser extent, we also generate revenue from the sale of OCS Consoles to customers and from the implied rental of OCS Consoles loaned to customers at no charge. For each new transplant procedure, customers purchase an additional disposable set for use on the customer's existing organ-specific OCS Console.

We recognize revenue from sales to customers when all of the following criteria are met: persuasive evidence of an arrangement exists, delivery has occurred (based on contractual shipping terms), the sales price is fixed or determinable, and collectability is reasonably assured. Revenue is recognized upon delivery to the customer or upon the later receipt of customer acceptance, if such acceptance is required. Because all elements of a customer order are delivered and recognized as revenue at the same time and because revenue allocated to elements other than OCS disposable sets, such as implied rental income and service revenue, is insignificant, all elements of revenue from customer arrangements are classified as a single category of revenue in our consolidated statement of operations.

Our products have both software and non-software (e.g., hardware) components that function together to deliver the products' essential functionality. In addition, the hardware sold cannot be used apart from the embedded software. As a result, all of our product offerings are excluded from the scope of software revenue recognition requirements and instead fall within the scope of Accounting Standards Codification, or ASC, Topic 605, *Revenue Recognition*.

Substantially all of our customer arrangements are multiple-element arrangements that contain deliverables consisting of OCS Perfusion Sets and OCS Solutions. In some of those multiple-element arrangements, the deliverables also include an OCS Console, whether sold or loaned to the customer. We evaluate each element within a multiple-element arrangement to determine whether it represents a separate unit of accounting. An element constitutes a separate unit of accounting when the delivered item has standalone value to the customer and delivery of any undelivered element is probable and within our control.

When a customer order includes an OCS Console, whether sold or loaned, we have determined that customer training and the equipment set-up of the OCS Console, each performed by us, lack standalone value to the customer because they are not sold on a standalone basis and can only be performed by us in conjunction with a sale or loan of our OCS Console. As a result, we have concluded that training, OCS Console equipment set-up and the OCS Console itself represent a single unit of accounting. Consequently, we do not recognize any revenue from any element of a customer order that includes an OCS Console, whether sold or loaned, until the OCS Console has been delivered and the training and equipment set-up have been completed by us. Further, we deem that "delivery" of an OCS Console occurs only after the console has been delivered and the training and equipment set-up have been completed by us.

Some of our revenue has been generated from products sold in conjunction with the clinical trials conducted for our OCS products, under arrangements referred to as customer clinical trial agreements. Under most of these customer clinical trial agreements, we place an organ-specific OCS Console at the customer site for its use free of charge for the duration of the clinical trial, and the customer separately purchases from us the OCS disposable sets used in each transplant procedure during the clinical trial. When we loan the OCS Console to the customer, we retain title to the console at all times and do not require minimum purchase commitments from the customer related to any OCS products. In such cases, we invoice the customer for OCS disposable sets based on customer orders received for each new transplant procedure and the prices set forth in the customer agreement. Over time, we typically recover the cost of the loaned OCS Console through the customer's continued purchasing and use of additional disposable sets. For these reasons, we have determined that part of the arrangement consideration for the disposable set is an implied rental payment for use of the OCS Console.

When our customer arrangements are multiple-element arrangements that contain a loan of an OCS Console for the customer's use at its customer site as well as OCS disposable sets that are delivered simultaneously, we allocate the arrangement consideration between the lease deliverables (i.e., the OCS Console) and non-lease deliverables (i.e., the disposable sets) based on the relative selling price of each deliverable, determined using the selling price hierarchy. To date, the amounts allocated to lease deliverables have been insignificant. The selling price hierarchy includes (1) vendor-specific objective evidence, or VSOE, if available, (2) third-party evidence, or TPE, if VSOE is not available, or (3) best estimate of selling price, or BESP, if neither VSOE or TPE is available. We have not been able to establish a selling price for the lease deliverables (i.e., the OCS Console) using VSOE or TPE. We determine BESP by considering our overall pricing objectives and market conditions. Significant pricing practices taken into consideration include our discounting practices, our price lists, our go-to-market strategy, historical sales and contract prices. The determination of BESP is made in consultation with, and is approved by, our management.

In any multiple-element arrangement, we limit the amount of the arrangement fee allocated to deliverables to the amount that is not contingent on the future delivery of products or future performance obligations and the amount that is not subject to customer-specific return or refund privileges. Because we do not require minimum purchase commitments in any of our customer arrangements, the arrangement fee generated by expected future sales of OCS disposable sets is considered contingent for purposes of the allocation of the arrangement fee in each customer arrangement.

Other Revenue Recognition Policies

Under all of our customer arrangements that include a customer clinical trial agreement, we receive payments from sales to the customer of our OCS products and also make payments to that customer for reimbursements of clinical trial materials and for specified clinical documentation related to the customer's use of our OCS products. If the clinical trial includes a patient arm that uses existing standard-of-care protocols for organ transplants (and does not use our OCS products), then we make additional payments to that customer to obtain clinical documentation related to existing standard-of-care protocols (i.e., unrelated to our OCS products).

In these cases, we have determined that the payments made to the customer for clinical trial materials and its costs incurred to execute specific clinical trial protocols related to our OCS products do not provide us with a

separately identifiable benefit, and therefore, such payments are recorded as a reduction of revenue from the customer in our consolidated statements of operations. Reductions of revenue related to such payments made to customers for reimbursements are recognized when we recognize the revenue for the sale of our OCS disposable sets. For the fiscal years ended December 31, 2016 and December 30, 2017 and the fiscal nine months ended September 30, 2017 and September 29, 2018, we recorded as a reduction of revenue $0.9 million, $0.7 million, $0.6 million and $1.3 million, respectively, of reimbursable clinical trial costs.

In these same cases, we have also determined that payments made to the customer to obtain clinical documentation related to existing standard-of-care protocols (i.e., unrelated to our OCS products) do meet the criteria to be classified as a cost because we receive an identifiable benefit separate from the customer's purchase of our OCS products and the consideration paid represents the fair value of the benefit received by us. As a result, payments made by us to customers for standard-of-care protocols are recorded as research, development and clinical trials expenses. For the fiscal years ended December 31, 2016 and December 30, 2017 and the fiscal nine months ended September 30, 2017 and September 29, 2018, we recorded as research, development and clinical trials expenses $0.3 million, $0.2 million, $0.1 million and $0.3 million, respectively, related to payments made to customers at clinical trial sites for documentation related to existing standard-of-care protocols.

Billings to customers for shipping costs and reimbursement of out-of-pocket expenses, including travel, lodging and meals, are recorded as revenue, and the associated costs incurred by us for those items are recorded as cost of revenue.

We exclude any taxes assessed by a governmental authority that are directly imposed on a revenue-producing transaction (e.g., sales, use and value added taxes) from our revenue and costs.

Distributors

We market and sell our products primarily through our direct sales force, which sells our products to end customers globally. A small portion of our revenue is generated by sales to a limited number of distributors in Europe and Asia-Pacific. When we transact with a distributor, our contractual arrangement is with the distributor and not with the end customer. Whether we transact business with and receive the order from a distributor or directly from an end customer, our revenue recognition policy and resulting pattern of revenue recognition for the order are the same.

In our business with distributors, we enter into a distributor agreement under which the distributor places orders to us for our products in connection with the distributor's own sales to identified end customers, and we confirm the identification of the end customer prior to accepting each order. Our distributors do not stock OCS Consoles purchased from us and stock only minimal quantities of OCS disposable sets. Under these contractual arrangements, we invoice the distributor for the arrangement fee (which reflects a distributor discount relative to typical end customer pricing) and payment to us from the distributor is not contingent upon the distributor's collection from the end customer. We record revenue based on the amount of the discounted arrangement fee.

When a sale to a distributor includes an OCS Console, we perform the training and OCS Console equipment set-up for the end customer. We recognize no revenue from a distributor order that includes an OCS Console until the OCS Console has been delivered and the training and equipment set-up have been completed by us.

New Revenue Recognition Standard

Effective December 30, 2018, we will be required to adopt ASC Topic 606, *Revenue from Contracts with Customers*, or ASC 606. We are currently evaluating the method of adoption and the potential impact that the adoption of ASC 606 will have on our consolidated financial statements. For additional information, see "—Emerging Growth Company Status" and Note 2 to our consolidated financial statements included elsewhere in this prospectus.

Stock-Based Compensation

We measure stock-based option awards granted to employees and directors based on their fair value on the date of the grant using the Black-Scholes option-pricing model. Compensation expense for those awards is recognized over the requisite service period, which is generally the vesting period of the respective award. Generally, we issue awards with only service-based vesting conditions and record the expense for these awards using the straight-line method.

For stock-based option awards granted to non-employee consultants, we recognize compensation expense over the period during which services are rendered by such consultants until completed. At the end of each financial reporting period prior to the completion of the service, the fair value of these awards is remeasured using the then-current fair value of our common stock and updated assumption inputs in the Black-Scholes option-pricing model.

The Black-Scholes option-pricing model uses as inputs the fair value of our common stock and assumptions we make for the volatility of our common stock, the expected term of our common stock options, the risk-free interest rate for a period that approximates the expected term of our common stock options, and our expected dividend yield.

Determination of Fair Value of Common Stock

As there has been no public market for our common stock to date, the estimated fair value of our common stock has been determined by our board of directors as of the date of each option grant, with input from management, considering our most recently available third-party valuations of common stock, and our board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant. These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. Our common stock valuations were prepared using a Monte Carlo simulation method, which used either a market or income approach to estimate our enterprise value. A Monte Carlo simulation method is used to calculate the value of an enterprise (or other asset) with multiple sources of uncertainty or with complicated features and to allocate the total equity value among the various holders of a company's securities upon the simulated exit using a waterfall. Under this method, the common stock has value only if the funds available for distribution to stockholders exceeded the value of the preferred stock liquidation preferences at the time of the liquidity event, such as a strategic sale or a merger. A discount for lack of marketability of the common stock is then applied to arrive at an indication of value for the common stock. These third-party valuations were performed at various dates, which resulted in valuations of our common stock of $0.63 per share as of May 12, 2016, $0.92 per share as of April 5, 2018 and $2.47 per share as of October 9, 2018. In addition to considering the results of these third-party valuations, our board of directors considered various objective and subjective factors to determine the fair value of our common stock as of each grant date, including:

- the prices at which we sold shares of preferred stock and the superior rights and preferences of the preferred stock relative to our common stock at the time of each grant;
- the progress of our research and development, including the status and results of clinical trials to develop clinical evidence of our products' safety and effectiveness and progress of our development of our OCS products;
- our stage of development and commercialization and our business strategy;
- external market conditions affecting the medical device industry and trends within the medical device industry;
- our financial position, including cash on hand, and our historical and forecasted performance and operating results;

- the lack of an active public market for our common stock and our preferred stock;
- the likelihood of achieving a liquidity event, such as an initial public offering, or IPO, or sale of our company in light of prevailing market conditions; and
- the analysis of IPOs and the market performance of similar companies in the medical device industry.

The assumptions underlying these valuations represented management's best estimate, which involved inherent uncertainties and the application of management's judgment. As a result, if we had used significantly different assumptions or estimates, the fair value of our common stock and our stock-based compensation expense could have been materially different.

Once a public trading market for our common stock has been established in connection with the closing of this offering, it will no longer be necessary for our board of directors to estimate the fair value of our common stock in connection with our accounting for granted stock options and other such awards we may grant, as the fair value of our common stock will be determined based on the quoted market price of our common stock.

Options Granted

The following table summarizes by grant date the number of shares subject to options granted between January 1, 2017 and October 27, 2018, the per share exercise price of the options, the fair value of common stock on each grant date, and the per share estimated fair value of the options:

Grant Date	Number of Shares Subject to Options Granted	Per Share Exercise Price of Options	Fair Value of Common Stock per Share on Grant Date	Per Share Estimated Fair Value of Options
March 30, 2017	145,000	$ 0.63	$ 0.63	$ 0.29
June 22, 2017	1,282,959	$ 0.63	$ 0.51(1)	$ 0.19
April 5, 2018	245,000	$ 0.92	$ 0.92	$ 0.47
July 18, 2018	65,000	$ 0.92	$ 0.92	$ 0.47
October 9, 2018	319,000	$ 2.47	$ 2.47	$ 1.28

(1) At the time of the option grant on June 22, 2017, our board of directors determined that the fair value of our common stock of $0.63 per share calculated in the third-party valuation as of May 12, 2016 described above reasonably reflected the per share fair value of our common stock as of the grant date. However, as described below, the fair value of common stock at the date of this grant was adjusted in connection with a retrospective fair value assessment for accounting purposes.

In preparing for the issuance of our financial statements for the fiscal year ended December 30, 2017, in September 2018, we performed a retrospective fair value assessment and concluded that the fair value of our common stock underlying stock options that we granted on June 22, 2017 was $0.51 per share for accounting purposes. We applied the fair value of our common stock from our retrospective fair value assessment to determine the fair value of these awards and calculate stock-based compensation expense for accounting purposes. This reassessed value was based, in part, upon a third-party valuation of our common stock prepared as of the June 22, 2017 grant date on a retrospective basis. The third-party valuation was prepared using a Monte Carlo simulation method and used an income approach to determine our enterprise value.

Valuation of Warrants to Purchase Preferred Stock

We classify warrants to purchase shares of our Series B, Series D and Series F preferred stock as liabilities on our consolidated balance sheets as these warrants are free-standing financial instruments that may require us to transfer assets upon exercise. The warrant liability associated with each of these warrants was initially recorded at fair value on the issuance date of each warrant and is subsequently remeasured to fair value at each

reporting date. Changes in fair value of the warrant liability are recognized as a component of other income (expense) in our consolidated statements of operations. We will continue to recognize changes in fair value of each warrant comprising the warrant liability until each respective warrant is exercised, expires or qualifies for equity classification.

We utilize the Black-Scholes option-pricing model, which incorporates assumptions and estimates to value the preferred stock warrants. We assess these assumptions and estimates on a quarterly basis as additional information impacting the assumptions is obtained. Estimates and assumptions impacting the fair value measurement include the fair value per share of the underlying Series B, Series D and Series F preferred stock, the remaining contractual term of the warrants, risk-free interest rate, expected dividend yield and expected volatility of the price of the underlying preferred stock. The most significant assumption in the Black-Scholes option-pricing model impacting the fair value of the preferred stock warrants is the fair value of our preferred stock as of each remeasurement date. We determine the fair value per share of the underlying preferred stock by taking into consideration our most recent sales of our preferred stock, results obtained from third-party valuations and additional factors that we deem relevant. As of December 31, 2016, the fair value our Series B, Series D and Series F preferred stock was $0.98 per share, $3.76 per share and $4.99 per share, respectively. As of December 30, 2017, the fair value of our Series B, Series D and Series F preferred stock was $0.75 per share, $2.99 per share and $4.83 per share, respectively. As of September 29, 2018, the fair value of our Series D and Series F preferred stock was $5.50 per share and $5.32 per share, respectively. We have historically been a private company and lack company-specific historical and implied volatility information of our stock. Therefore, we estimate expected stock volatility based on the historical volatility of publicly traded peer companies for a term equal to the remaining contractual term of the warrants. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the warrants. We have estimated a 0% dividend yield based on the expected dividend yield and the fact that we have never paid or declared dividends.

In connection with the Corporate Reorganization, the warrants to purchase preferred stock will be converted into warrants to purchase common stock, and the fair value of the warrant liability at that time will be reclassified to common stock.

Valuation of Inventory

We value inventory at the lower of cost or net realizable value, with cost computed using the first-in, first-out method. We regularly review inventory quantities on-hand for excess and obsolete inventory and, when circumstances indicate, record charges to write down inventories to their estimated net realizable value, after evaluating historical sales, future demand, market conditions and expected product life cycles. Such charges are classified as cost of revenue in our consolidated statements of operations. Any write-down of inventory to net realizable value creates a new cost basis.

At the end of each reporting period, we assess whether losses should be accrued on long-term manufacturing purchase commitments in accordance with ASC 330, *Inventory*, which requires that losses that are expected to arise from firm, noncancelable and unhedged commitments for the future purchase of inventory, measured in the same way as inventory losses, should be recognized in the current period in the statement of operations unless they are deemed recoverable through firm sales contacts or when there are other circumstances that reasonably assure continuing sales without price decline. As of the end of each reporting period presented in our consolidated financial statements included elsewhere in this prospectus, we did not identify any potential losses arising from remaining future purchase commitments as compared to estimated future customer sales through the remainder of the term of the manufacturing purchase commitment and, as a result, did not recognize in a current period any loss provision for future-period remaining purchase commitments.

Backlog

We define backlog as contractually committed orders for our products for which the associated revenue has not been recognized and the customer has not been invoiced. Amounts that have been invoiced but not yet recognized as revenue are reported as deferred revenue on our consolidated balance sheets and are not included in our calculation of backlog. As of September 30, 2017, December 30, 2017 and September 29, 2018, we had backlog of $0.4 million, $0.6 million and $1.2 million, respectively. The increase in backlog was primarily due to increased sales of our OCS disposable sets and timing of orders. Of the amount of backlog as of September 29, 2018, we expect that substantially all of it will be invoiced to customers within the following 12 months. However, because our customers may cancel, change or reschedule orders without penalty at any time prior to shipment, we have no assurance that we will be able to convert our backlog into shipped orders.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position, results of operations or cash flows is disclosed in Note 2 to our consolidated financial statements included elsewhere in this prospectus.

Quantitative and Qualitative Disclosures about Market Risks

We are exposed to changes in interest rates and foreign currency exchange rates because we finance certain operations through variable rate debt instruments and denominate our transactions in a variety of foreign currencies. Changes in these rates may have an impact on future cash flow and earnings. We manage these risks through normal operating and financing activities.

Foreign Currency Exchange Risk

Our foreign currency transaction exposure results primarily from intercompany transactions and transactions with customers or vendors denominated in currencies other than the functional currency of the legal entity in which the transaction is recorded by us. Assets and liabilities arising from such transactions are translated into the legal entity's functional currency using the period-end exchange rates. Foreign currency transaction gains (losses) are included in the consolidated statements of operations as a component of other income (expense). We recognized foreign currency transaction losses of less than $0.1 million during the fiscal nine months ended September 29, 2018.

Foreign currency translation exposure results from the translation of the financial statements of our subsidiaries whose functional currency is not the U.S. dollar into U.S. dollars for consolidated reporting purposes. Assets and liabilities of these subsidiaries are translated into U.S. dollars using the period-end exchange rates, and income and expense items are translated into U.S. dollars using average exchange rates in effect during each period. The effects of these foreign currency translation adjustments are included in accumulated other comprehensive loss, a separate component of stockholders' equity (deficit) on our consolidated balance sheets. We recorded a foreign currency translation gain of less than $0.1 million during the fiscal nine months ended September 29, 2018.

For the fiscal nine months ended September 29, 2018, 43% of our net revenue and 7% of our operating costs and expenses were generated by subsidiaries whose functional currency is not the U.S. dollar and therefore are subject to foreign currency exposure.

Currently, our largest foreign currency exposure is that with respect to the euro. We believe that a 10% change in the exchange rate between the U.S. dollar and euro would not materially impact our operating results or financial position. We have experienced and we will continue to experience fluctuations in our net loss as a result of revaluing our assets and liabilities that are not denominated in the functional currency of the entity that recorded the asset or liability. At this time, we do not hedge our foreign currency risk.

Interest Rate Sensitivity

As of December 30, 2017, we had cash, cash equivalents and marketable securities of $24.7 million, which consisted of cash, money market funds, U.S. Treasury notes and U.S. government agency bonds. As of September 29, 2018, we had cash and cash equivalents of $28.9 million, which consisted of cash and money market funds. Interest income is sensitive to changes in the general level of interest rates; however, due to the nature of these investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our investment portfolio.

As of December 30, 2017, we had $8.5 million of borrowings outstanding under our 2015 loan and security agreement with Hercules, of which we repaid $1.8 million during the fiscal six months ended June 30, 2018 according to the repayment terms of the loan agreement. In June 2018, we repaid the remaining outstanding amount and terminated this agreement. In June 2018, we entered into our Credit Agreement with OrbiMed. Borrowings under the Credit Agreement bear interest at a variable rate per annum equal to LIBOR plus 8.5%. As of September 29, 2018, borrowings outstanding under the Credit Agreement totaled $35.0 million and the interest rate applicable to such borrowings was 10.875%. An immediate 10% change in LIBOR would not have a material impact on our debt-related obligations, financial position or results of operations.

Inflation Risk

We do not believe that inflation has had a material effect on our business, financial condition or results of operations. If our costs were to become subject to significant inflationary pressures, we may not be able to fully offset such higher costs through price increases. Our inability or failure to do so could harm our business, financial condition or results of operations.

Emerging Growth Company Status

The Jumpstart Our Business Startups Act of 2012 permits an “emerging growth company” such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected not to “opt out” of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that we either (i) irrevocably elect to “opt out” of such extended transition period or (ii) no longer qualify as an emerging growth company.

BUSINESS

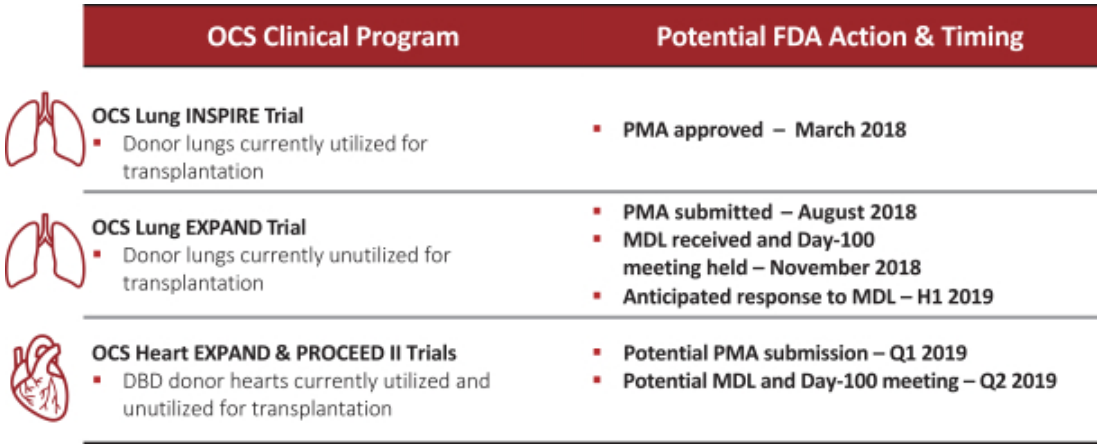
Overview

We are a commercial-stage medical technology company transforming organ transplant therapy for end-stage organ failure patients across multiple disease states. We developed the OCS to replace a decades-old standard of care that we believe is significantly limiting access to life-saving transplant therapy for hundreds of thousands of patients worldwide. Our innovative OCS technology replicates many aspects of the organ's natural living and functioning environment outside of the human body. As such, the OCS represents a paradigm shift that transforms organ preservation for transplantation from a static state to a dynamic environment that enables new capabilities, including organ optimization and assessment. We believe our substantial body of clinical evidence has demonstrated the potential for the OCS to significantly increase the number of organ transplants and improve post-transplant outcomes.

Incidence of end-stage organ failure has been rapidly rising worldwide due to demographic trends that contribute to chronic diseases. Organ transplantation is the treatment of choice for addressing end-stage organ failure due to its positive clinical outcomes and favorable health economics. However, transplant volumes have been significantly restricted by the limitations of cold storage, the standard of care for organ transplantation. Cold storage is a rudimentary approach to organ preservation in which a donor organ is flushed with cold pharmaceutical solutions, placed in a plastic bag on top of ice and transported in a cooler. Cold storage subjects organs to significant injury due to a lack of oxygenated blood supply, or ischemia, does not allow physicians to assess organ viability and lacks the ability to optimize an organ's condition once it has been retrieved from the donor. Time-dependent ischemic injury has been shown to result in short- and long-term post-transplant clinical complications and, together with the inability to assess or optimize organs, contributes to the severe underutilization of donor organs. While there are approximately 67,000 potential donors annually in the United States, Canada, the European Union and Australia, which we refer to as our key geographies, the majority of lungs and hearts donated after brain death, or DBD, go unutilized, and almost no available lungs and hearts donated after circulatory death, or DCD, are utilized.

We developed the OCS to comprehensively address the major limitations of cold storage. The OCS is a portable organ perfusion, optimization and monitoring system that utilizes our proprietary and customized technology to replicate near-physiologic conditions for donor organs outside of the human body. We designed the OCS technology platform to perfuse donor organs with warm, oxygenated, nutrient-enriched blood, while maintaining the organs in a living, functioning state; the lung is breathing, the heart is beating and the liver is producing bile. Because the OCS significantly reduces injurious ischemic time on donor organs as compared to cold storage and enables the optimization and assessment of donor organs, it has demonstrated improved clinical outcomes relative to cold storage and offers the potential to significantly improve donor organ utilization.

We designed the OCS to be a platform that allows us to leverage core technologies across products for multiple organs. To date, we have developed three OCS products, one for each of lung, heart and liver transplantations, making the OCS the only multi-organ technology platform. Our OCS products have been used for over 1,100 human organ transplants. We have commercialized the OCS Lung and OCS Heart outside of the United States and received our first PMA approval from the FDA in March 2018 for the use of the OCS Lung for donor lungs currently utilized for transplantation. We expect FDA action on additional applications for PMAs we submitted or that we expect to submit in connection with our other OCS products over the next 18 months. We received a major deficiency letter, or MDL, from the FDA in November 2018 for our PMA application based on the results of our OCS Lung EXPAND Trial for the use of the OCS Lung for donor lungs currently unutilized for transplantation. We intend to respond to the MDL during the first half of 2019 by providing the requested supplemental data, such as clarification for subgroups, longer time frames and other analyses as described further herein.



We are focused on establishing the OCS as the standard of care for organ transplantation. Because we believe cold storage is the primary factor limiting donor organ utilization today, we estimate our opportunity based on the existing donor pools and the potential for significantly expanded utilization with the OCS. We estimate the potential pool of DBD and DCD donors in our key geographies to be approximately 67,000 annually, with each donor having the capacity to donate more than one organ, including lung, heart and liver. Based on the utilization rates in our clinical trials and our commercial experience outside the United States, we estimate the potential annual addressable commercial opportunity for the OCS to be approximately $8 billion for lung, heart and liver transplantation combined. Our clinical trials have demonstrated that the OCS may result in improved post-transplant outcomes as compared to cold storage, and we believe this will enable us to capture a significant portion of the expanded transplant opportunity.

The vast majority of transplant procedures are performed at a relatively small number of hospitals that have specialized organ transplant centers. We estimate that approximately 50 to 55 transplant centers in the United States perform over 70% of the lung, heart and liver transplant volume. The lead transplant surgeons at each of these centers are the primary decision-makers on most aspects of the transplant programs. These surgeons rely primarily on clinical evidence to drive changes in their programs. During our clinical trials, we established relationships with over 55 leading transplant programs in our key geographies and have generated a substantial body of clinical evidence. Our commercial strategy is focused on leveraging these relationships to drive deeper adoption of the OCS at the leading, large-volume academic transplant institutions. As of October 27, 2018, our sales and clinical adoption team consisted of 24 sales and clinical professionals.

We believe the OCS will drive significant benefits to all stakeholders in the field of organ transplantation. For patients, we believe the OCS provides more patients with access to life-saving transplants and allows for quicker recovery following transplantation. For hospitals, we believe the OCS provides a means to increase transplant volume, treat more patients, enhance provider status and improve transplant program economics. Finally, we believe the OCS provides payors with a more cost-effective treatment for end-stage organ failure and reduces exposure to significant post-transplant complication costs and extended hospital stays.

Our OCS products are reimbursed in the United States through existing, standard commercial transplant billing mechanisms. The Medicare program and private payors have been providing reimbursement for the OCS Lung, OCS Heart and OCS Liver during the U.S. pivotal trials and have been providing reimbursement for the OCS Lung following FDA approval in March 2018. We believe these established channels will continue to facilitate commercial reimbursement for the OCS Lung and, if they are approved by the FDA, for the OCS Heart

and OCS Liver. We are in the process of seeking long-term reimbursement for our products outside of the United States.

Our corporate headquarters, manufacturing and clinical training facilities are located in Andover, Massachusetts. We have additional distribution and commercial operations in Europe and Asia-Pacific. As of October 27, 2018, we employed 83 people globally. We generated $7.7 million of net revenue during the fiscal year ended December 30, 2017 and $9.5 million of net revenue during the fiscal nine months ended September 29, 2018, of which $4.0 million of net revenue was generated during the fiscal three months ended September 29, 2018, representing a 116% increase as compared to the fiscal three months ended September 30, 2017. Our business model is characterized by a high level of recurring revenue, which is derived primarily from sales of our single-use, organ-specific disposable sets that are required for each transplant using the OCS. We expect that greater than 90% of our revenue will be related to sales of our single-use OCS disposable sets.

Commercial Opportunity

Demand for Organ Transplants

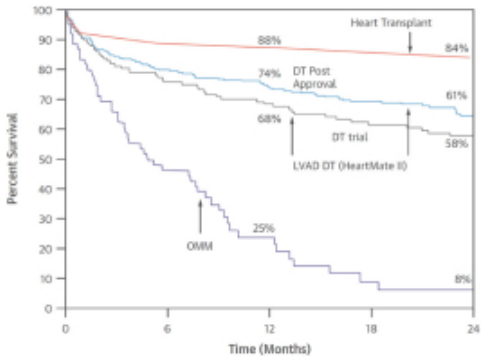
Incidence of end-stage organ failure has been rapidly rising worldwide due to demographic trends that contribute to chronic disease, including an aging population and obesity. Key disease states resulting in organ failure include COPD, chronic heart failure, diabetes, chronic liver disease and end-stage renal disease, or ESRD. COPD, which is primarily caused by smoking and can result in lung failure, has been diagnosed in over 12 million Americans and is responsible for 120,000 deaths in the United States annually. Approximately 6 million Americans live with chronic heart failure, with approximately 650,000 new patients diagnosed with heart failure each year. Of these patients, an estimated 250,000 could benefit from heart transplantation annually. Approximately 2.8 million patients globally are diagnosed with liver cirrhosis, a leading cause of liver failure. In addition, approximately 468,000 Americans are on chronic dialysis as a result of kidney failure associated with ESRD.

Organ Transplantation Represents the Treatment of Choice for End-Stage Organ Failure

Life-sustaining therapies for patients with end-stage organ failure are costly to the healthcare system. According to data from the 2017 Milliman U.S. Organ and Tissue Transplant research report, in the United States the average billed charges in the 30 days prior to transplant are approximately $39,000 per double-lung transplant patient, approximately $43,000 per heart transplant patient and approximately $41,000 per liver transplant patient.

We believe organ transplantation is the most effective treatment for end-stage organ failure in terms of both clinical outcomes and health economics. For example, the therapeutic options for end-stage heart failure include optimum medical management with pharmaceutical treatments, or OMM, mechanical support with a left ventricular assist device, or LVAD, and heart transplantation. As indicated in the figure below, heart transplantation is associated with materially longer survival rates as compared to OMM and LVADs, which are either used as a bridge to transplant or as destination therapy, an alternative to transplant.

Survival Curves of Stage IV Heart Failure Following Different Treatment Modalities
Mancini, et al. LVADs vs. Transplants, JACC 2015



Survival for HeartMate II in the post-approval DT study compared with the initial DT trial, OMM in the REMATCH (Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure) trial (19), and post-transplant survival. Modified with permission from Jorde et al. DT= destination therapy; HF= heart failure.

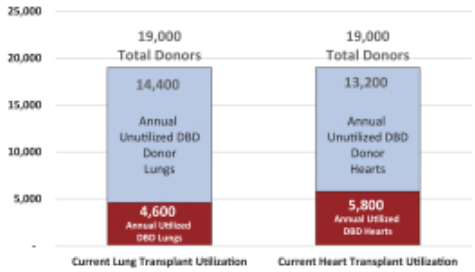
These improved survival rates, in turn, result in favorable economics on the basis of quality-adjusted life years. According to 2004 studies, the cost of adding one quality-adjusted life year is approximately $40,000 for a heart transplant as compared to approximately $800,000 for an LVAD or approximately $110,000 for OMM. Despite the large and growing incidence of organ failure worldwide, and the significant clinical and economic benefits of organ transplantation, the number of transplants severely lags demand due to the limitations of traditional methods of organ preservation prior to transplantation.

Supply of Donor Organs for Transplantation

The supply of donor organs for transplantation comes from two primary sources:

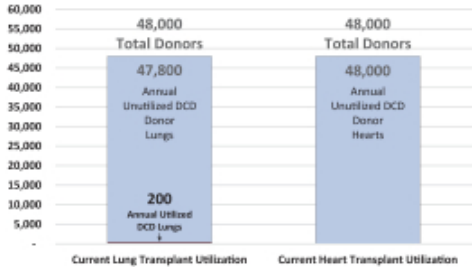
- ***Donation After Brain Death—DBD Donors***: DBD donors suffered irreversible brain damage. Because hearts continue to beat naturally for a few days in these donors, the organs continue to be perfused with oxygenated blood until retrieval, allowing transplant clinicians the opportunity to assess organ viability. We estimate that the pool of DBD donors is approximately 19,000 DBD donors annually in our key geographies, with approximately 8,400 DBD donors annually in the United States. While DBD donors represent the vast majority of donor organs transplanted, only approximately 23% of donated lungs and 32% of donated hearts were utilized in the United States in 2016, which we believe is primarily due to the limitations of current organ preservation methods.
- ***Donation After Circulatory Death—DCD Donors***: DCD donors suffered cardiac and circulatory arrest. Because hearts cease to beat in these donors, the organs do not receive oxygenated blood and transplant clinicians are unable to assess organ viability. We estimate that the potential DCD donor pool is approximately 48,000 donors annually in our key geographies, with over 22,000 DCD donors annually in the United States. Despite the large size of this donor pool, we estimate that DCD donor organs are used in fewer than 5% of lung transplants and are not used for heart transplants because current methods for organ preservation are unable to overcome the challenges presented by the lack of perfusion.

Annual Lung and Heart DBD Donor Utilization
United States, Canada, European Union, Australia



Sources: Organ Procurement Transplantation Network; Global Observatory on Donation and Transplantation

Estimated Annual Lung and Heart DCD Donor Utilization
United States, Canada, European Union, Australia



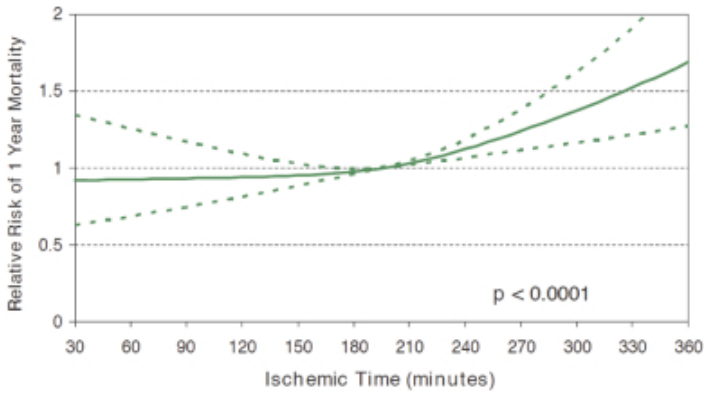
Source: Institute of Medicine of the National Academy of Science (2006)

Limitations of Current Organ Preservation Methods

In recent years, significant innovations have been implemented in most aspects of organ transplantation surgery. However, organ preservation remains primarily limited to cold storage. Cold storage involves flushing the organs with cold pharmaceutical solutions designed to reduce organ temperature and arrest organ function. The donor organ is then placed in a sterile plastic bag and stored on ice in a cooler. This process adversely impacts clinical outcomes and leads to underutilization of viable donor organs due to the following inherent challenges:

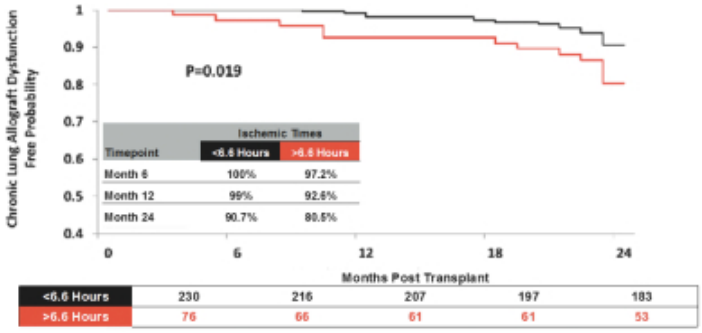
- ***Time-dependent ischemic injury:*** Cold storage subjects donor organs to significant injury due to a lack of oxygenated blood supply, or ischemia. Ischemia has been reported to be an independent predictor of mortality after heart transplantation and development of short-term severe primary graft dysfunction, or PGD, which is associated with long-term complications in lung transplantation. A long-term consequence of PGD3, the most severe form of PGD, is chronic lung allograft dysfunction. Published data from the thoracic transplant registry of the International Society for Heart and Lung Transplantation shows that the risk for post-transplant patient mortality increases dramatically after approximately 190 minutes of injurious ischemic time in heart transplantation. This data highlights that the longer an organ spends on ice, the higher the risk of poor clinical outcomes, including mortality. In addition to resulting in poor transplant outcomes, time-dependent ischemic injury limits the acceptable time that transplant centers permit between organ retrieval and transplantation to four to six hours, resulting in restrictions on geographical distance between donors and transplant recipients.

Ischemic Times Correlates Positively with Increased Risk for Patient Mortality After Heart Transplantation



Dotted lines represent upper and lower confidence bound for the data plotted.

Correlation between Ischemic Injury and Development of Long-Term Complications after Lung Transplantation— Results of the OCS Lung INSPIRE Trial



A p-value is a statistical calculation that relates to the probability that a difference between groups happened by chance. Typically, a p-value less than 0.05 represents statistical significance.

- ***Lack of diagnostic assessment of organ viability or function:*** Cold storage does not support the assessment of organ function or viability because the organs are not functioning or metabolically active during cold storage. This lack of diagnostic assessment largely limits the donor pool to DBD donors, whose organs can be assessed for viability prior to retrieval because their hearts continue to beat. The lack of diagnostic assessment of organ viability during cold storage is the primary reason that DCD organs are rarely used for lung transplants and never used for heart transplants.
- ***Lack of therapeutic or optimization capabilities:*** Clinical studies have demonstrated the clinical benefits of replenishing donor organs with glucose, oxygen, hormones and electrolytes that are significantly altered or depleted during the donation process. Cold storage, however, does not allow for therapeutic intervention to optimize the condition of donor organs, which results in suboptimal post-transplant outcomes. In addition, transplant programs are less likely to accept organs that may appear compromised if they are unable to treat or optimize the organ, which prevents utilization of the vast majority of organs from DBD and DCD donors.

We believe the limitations of cold storage are directly responsible for the severe shortage in donor organ supply, which results in nearly all lungs and hearts from DCD donors, and the majority of lungs and hearts from DBD donors, going unutilized each year. In 2016, approximately 77% of donated lungs and approximately 68% of donated hearts went unutilized in the United States. In addition, we believe the limitations of cold storage are the primary driver of the high rate of severe post-transplant complications that negatively impact both patients' clinical outcomes and transplant economics for payors and providers.

We developed the OCS technology platform to comprehensively address the major limitations of cold storage. The OCS represents a paradigm shift that transforms organ preservation with a dynamic technology that replicates many aspects of an organ's natural state outside of the human body and enables new capabilities of organ optimization and assessment. Because the OCS reduces injurious ischemic time significantly and enables the optimization and assessment of donor organs, it offers the potential to significantly improve organ utilization relative to cold storage and could lead to improved clinical outcomes.

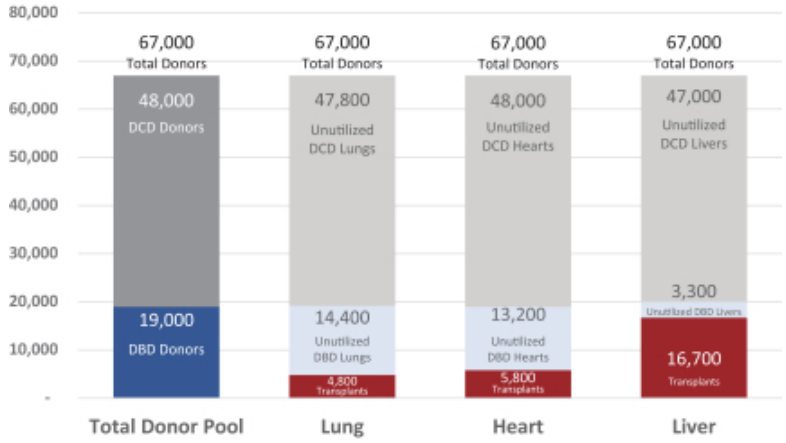
Our Commercial Opportunity

We believe organ transplantation is severely supply constrained by the limitations of cold storage. While there is a national transplant waiting list that represents a snapshot of demand, we believe this waiting list significantly underrepresents the true clinical demand for organ transplants. Because the supply of donor organs has historically been constrained, the waiting list is fairly static, with annual additions to the waiting list typically matching closely the number of transplants performed or patients otherwise removed from the list. We believe that with increased utilization of donor organs for transplant, the waiting list will grow to match any increase in global supply.

We estimate our commercial opportunity based on the existing donor pools and the potential for significantly improved utilization resulting from the use of our OCS technology. We estimate that the potential pool of donors in our key geographies includes approximately 67,000 DBD and DCD donors annually. Because the OCS reduces injurious ischemic time significantly, allows for therapeutic optimization of the organ's condition and enables diagnostic assessment, we believe the OCS could allow surgeons to utilize the vast majority of the donor pool that is currently unutilized due to the limitations of cold storage.

Estimated Transplant Pool Underutilization

United States, Canada, European Union, Australia



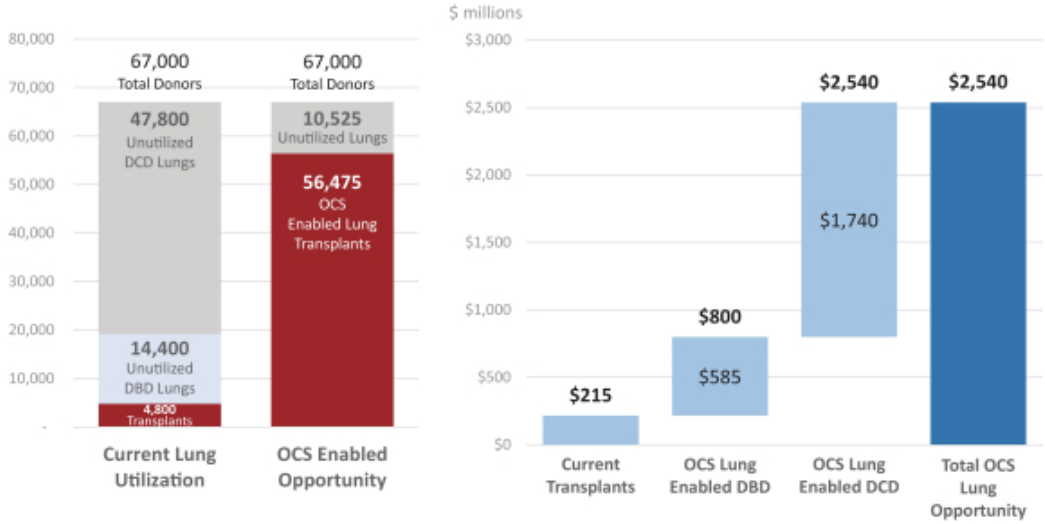
Sources: Organ Procurement and Transplantation Network; Global Observatory on Donation and Transplantation; Institute of Medicine of the National Academy of Science (2006)

We are focused on establishing the OCS as the standard of care for organ transplantation. Our clinical trial results have demonstrated that the OCS may result in improved post-transplant outcomes as compared to cold storage. In addition, our clinical trial results and commercial experience outside the United States have demonstrated a significant improvement in donor organ utilization to approximately 87% of DBD and DCD donor lungs, approximately 81% of DBD donor hearts and approximately 80% of DCD donor hearts, with improved post-transplant outcomes compared to cold storage. As a result, we believe that the OCS will also expand the existing pool of utilizable donor organs to include a significant share of the 67,000 potential annual donors and increase the overall number of transplants performed each year. We believe the OCS could be adopted for use in a significant share of transplants; however, certain factors may limit the actual utilization of the OCS, including the need to continue to educate surgeons, transplant centers and private payors of the merits of the OCS as compared with cold storage, the requisite training of surgeons prior to their use of the OCS and the overall capacity of transplant centers to perform organ transplants due to factors such as the availability of surgeons. See "Risk Factors—We depend heavily on the success of the OCS and achieving market acceptance. If we are unable to successfully commercialize the OCS, our business may fail" and "—We must continue to educate surgeons, transplant centers and private payors and demonstrate the merits of the OCS compared with cold storage or new competing technologies. Surgeons, transplant centers and private payors may require additional clinical data prior to adopting or maintaining coverage of the OCS."

Lung Opportunity

Today, there are only 4,800 donor lungs utilized annually for transplantation in our key geographies, resulting in approximately 62,200 organs, comprised of 14,400 from potential DBD donors and 47,800 from potential DCD donors, going unutilized each year due to the limitations of cold storage. Our OCS Lung EXPAND Trial demonstrated that the use of the OCS Lung in the types of organs that currently are not transplanted resulted in a blended DBD and DCD utilization rate of approximately 87%, based on 90% DBD utilization and 81% DCD utilization. Applying this 90% utilization rate to DBD donor lungs and 81% utilization rate to DCD donor lungs implies a total potential addressable opportunity of approximately $2.5 billion annually, of which approximately $215 million represents currently transplantable lungs, approximately $585 million represents improved utilization of DBD donors and the remaining approximately $1.7 billion represents utilization of DCD donors.

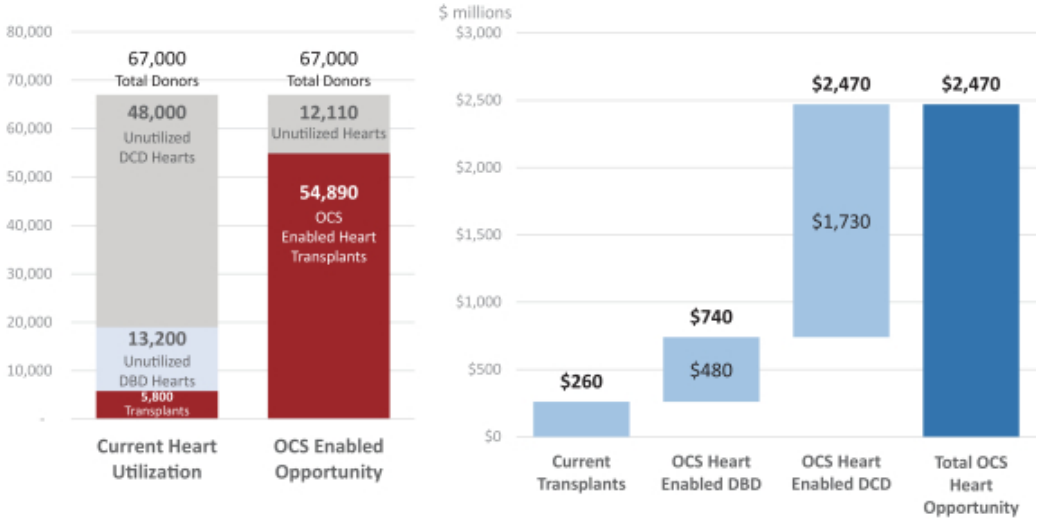
Estimated Addressable Lung Opportunity
United States, Canada, European Union, Australia



Heart Opportunity

Today, there are only 5,800 donor hearts utilized annually for transplantation in our key geographies, resulting in approximately 61,200 organs, comprised of 13,200 from potential DBD donors and 48,000 from potential DCD donors, going unutilized each year due to the limitations of cold storage. Results from our OCS Heart EXPAND Trial demonstrated that the use of the OCS Heart in the types of organs that are currently unutilized resulted in a DBD utilization rate of approximately 81%. In addition, the results of the OCS Heart DCD commercial activities in Europe and Australia have resulted in a utilization rate of approximately 80% of DCD donor hearts. Applying this 81% utilization rate to DBD donor hearts and 80% utilization rate to DCD donor hearts implies a total addressable opportunity of approximately $2.5 billion annually, of which approximately $260 million represents currently transplantable hearts, approximately $480 million represents improved utilization of DBD donors and the remaining approximately $1.7 billion represents utilization of DCD donors.

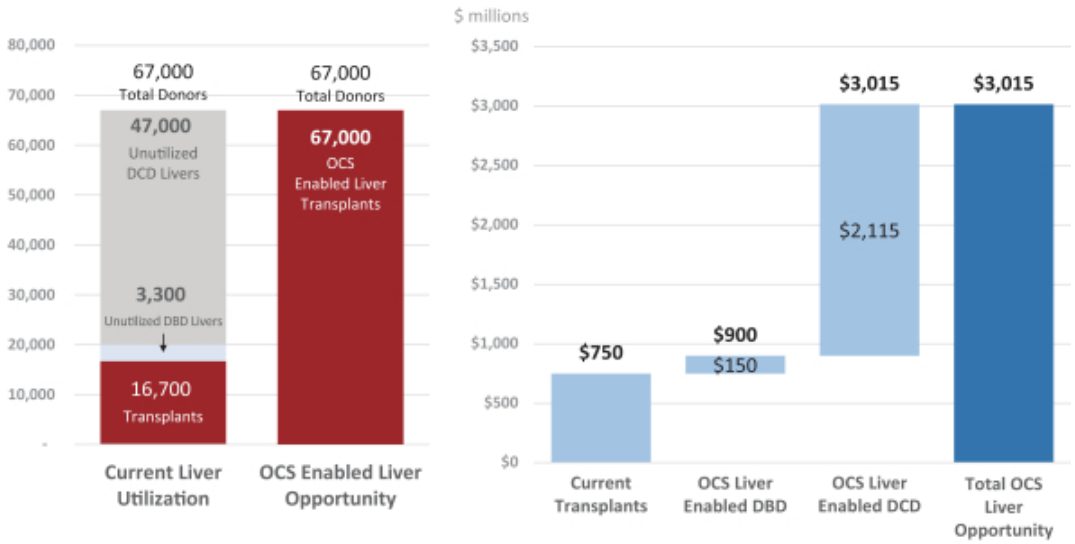
Estimated Addressable Heart Opportunity
United States, Canada, European Union, Australia



Liver Opportunity

Today, only 16,700 donor livers are utilized annually for transplantation in our key geographies, resulting in approximately 50,300 organs, comprised of 3,300 from potential DBD donors and 47,000 from potential DCD donors, going unutilized each year due to the limitations of cold storage. To support an FDA PMA for the OCS Liver, we are currently conducting a pivotal trial to preserve and assess donor livers from both DBD and DCD donors. Final results from the OCS Liver European REVIVE Trial demonstrated that the OCS Liver resulted in approximately 100% utilization of DBD and DCD donor livers. Applying this 100% utilization rate implies a total potential addressable opportunity of approximately $3.0 billion annually, of which approximately $750 million represents currently transplantable livers, approximately $150 million represents improved utilization of DBD donors and the remaining approximately $2.1 billion represents utilization of DCD donors.

Estimated Addressable Liver Opportunity
United States, Canada, European Union, Australia



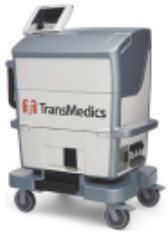
Our Technology and Solution

We developed the OCS to comprehensively address the major limitations of cold storage. The OCS is a portable organ perfusion, optimization and monitoring system that utilizes our proprietary and customized technology to replicate near-physiologic conditions for donor organs outside of the human body. The OCS was designed to perfuse donor organs with warm, oxygenated and nutrient-enriched blood, while maintaining the organs in a living, functioning state; the lung is breathing, the heart is beating and the liver is producing bile. As such, the OCS represents a paradigm shift that transforms organ preservation for transplantation from a static state to a dynamic environment that enables new capabilities, including organ optimization and assessment.

The OCS Technology Platform

We developed the OCS, the first and only multi-organ platform, to leverage proprietary core technologies across multiple organs. For each OCS product, we supplement the platform with organ-specific, customized and proprietary technologies. To date, we have developed three OCS products, one for each of lung, heart and liver transplantation. OCS products for additional organs, including kidneys, are under development.

Each OCS product consists of three primary components customized for each organ:



- **OCS Console:** The OCS Console is a highly portable electromechanical medical device that houses and controls the function of the OCS and is designed to fit in the current workflow for organ transplantation.

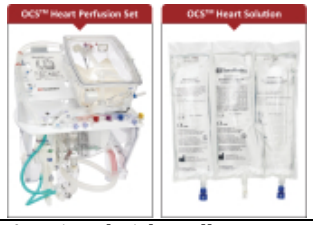
- **OCS Perfusion Set:** The OCS Perfusion Set is a sterile, biocompatible single-use disposable set that stores the organ and circulates blood. The OCS Perfusion Set includes all accessories needed to place the organ on the system.

- **OCS Solutions:** The OCS Solutions are a set of nutrient-enriched solutions used with blood to replenish depleted nutrients and hormones needed to optimize the organ's condition outside of the human body.

The OCS technology platform is equipped with the following core technologies that we designed to comprehensively address the limitations of cold storage and improve transplant outcomes:

- **proprietary pulsatile blood pump** to simulate beating heart perfusion in organs outside of the human body;
- **proprietary software-controlled titanium blood warmer** to maintain blood at body temperature while maximizing portability;
- **gas exchanger** to maintain organ oxygenation outside of the human body;
- **customized hemodynamics sensors** to monitor and assess organ function outside of the human body;
- **proprietary software-controlled, miniaturized, electromechanical system with universal power supply and hot-swappable batteries** to maximize portability and travel distance for organ retrieval;
- **proprietary wireless monitor and control software** to provide an intuitive user interface for monitoring critical organ function; and
- **customized carbon fiber OCS console structure** to reduce the overall weight of the system and maximize portability.

For each organ product, the OCS core technologies are supplemented with additional customized and proprietary organ-specific features to meet each organ's requirements. The following table summarizes the key features of our current commercial products.

	OCS Lung	OCS Heart	OCS Liver
Console			
Perfusion set / Solution			
Regulatory status	• FDA—PMA approved for donor lungs currently utilized for transplantation. PMA application submitted to the FDA in August 2018 for donor lungs currently unutilized for transplantation, MDL received and Day-100 meeting held in November 2018 with anticipated response to MDL in H1 2019 • CE Marked for console, perfusion set and solutions	• FDA—Pivotal trial enrollment completed for currently utilized and unutilized DBD donor hearts and potential PMA submission in Q1 2019 • CE Marked for console, perfusion set and solutions	• FDA—Pivotal trial ongoing for current and unutilized DBD and DCD donor livers • CE Marked for console and perfusion set and under review for bile salts
Key features	• **Proprietary and customized ventilation circuit and method** allows the lung to breathe outside of the human body, while maximizing portability • **Customized cannulation** enables the lung to be maintained and assessed using standard clinical diagnostics • **Proprietary nutrient-rich, lung-specific solution** improves lung condition from negative effects of brain death	• **Proprietary organ chamber** maintains critical valve heart function with embedded EKG sensors to monitor heart viability during preservation • **Proprietary automated drug delivery system** optimizes condition of the heart perfusion during preservation • **Proprietary nutrient- and hormone-rich physiologic solutions** replenish and optimize the heart with depleted nutrients	• **Proprietary perfusion circuit** enables physiologic dual blood supply of the liver using a single pump and a **bile collection system** assesses liver function during organ preservation • **Proprietary automated drug delivery** optimizes condition of the liver perfusion during preservation • **Customized OCS bile salt solution** stimulates the liver to continue to produce bile

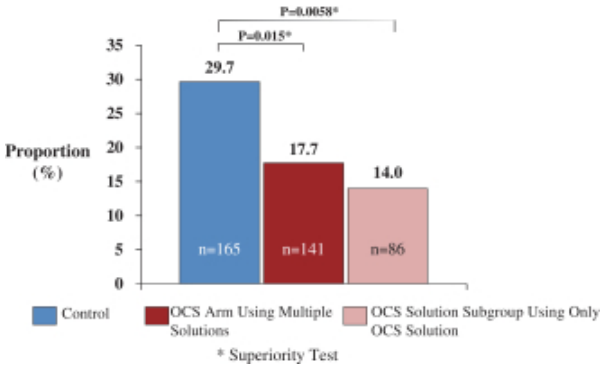
Key Advantages of the OCS Platform

We believe the OCS platform provides significant benefits relative to cold storage.

Improved Clinical Outcomes

Use of the OCS has demonstrated a substantial reduction in injurious ischemic time in all of our clinical trials. The results of our OCS Lung INSPIRE Trial, which compared the use of the OCS Lung to cold storage, demonstrated a statistically significant reduction of approximately two hours in the amount of time the organ went without oxygenation, or ischemic time. These results were achieved while allowing for an average of 1.5 incremental hours between donor and recipient. This decrease in injurious ischemic time resulted in an approximately 50% reduction relative to cold storage in the most common and severe form of lung transplant complication called primary graft dysfunction grade 3, or PGD3. PGD3 is a dangerous and costly complication as patients with it typically experience longer time on mechanical ventilation and in the intensive care unit, as well as potential long-term negative consequences. We believe these results are consistent with those of our other clinical trials and will support adoption of the OCS.

Use of OCS Lung Significantly Reduced Incidence of PGD3
In Lung Transplant Recipients—INSPIRE Trial Results

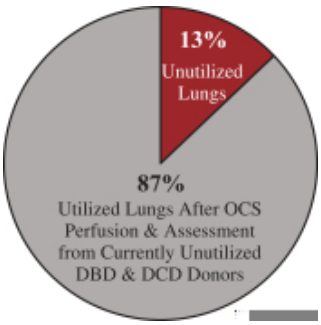


Increased Donor Organ Utilization

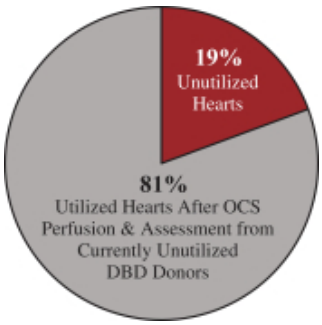
In our OCS Lung EXPAND Trial, we evaluated the use of the OCS Lung for donor organs from both DBD and DCD donors that would not otherwise have been utilized, and in the OCS Heart EXPAND Trial, we evaluated the use of the OCS Heart for donor organs from DBD donors that would not otherwise have been utilized. The lungs and hearts that were transplanted in these studies were rejected an average of 35 and 66 times, respectively, by other institutions using cold storage due to a variety of clinical and logistical reasons that may have included donor organ quality, donor age, expected injurious ischemic time or travel distance, or type of donor. In these trials, the use of the OCS resulted in an 87% utilization rate of DBD and DCD donor lungs and an 81% utilization rate of DBD donor hearts that otherwise would have been unutilized. The results of these trials

support our belief that the OCS can significantly expand the number of organs that can be transplanted and better serve the large population of patients who need an organ transplant to survive.

OCS Lung EXPAND Trial Utilization Results



OCS Heart EXPAND Trial Utilization Results



Benefits of the OCS Platform for Key Stakeholders

We believe the OCS platform provides significant benefits to key constituents across the transplant continuum.

Value to Patients

We believe the OCS increases patients' access to what we believe is the best treatment option for end-stage organ failure, which results in improved quality of life and longer life expectancy. In addition, we believe improved clinical outcomes from use of the OCS will allow patients to recover more quickly following a transplant.

Value to Providers

We believe the OCS allows providers to improve clinical outcomes and increase the number of patients who receive organ transplants. Improvements in clinical outcomes could enable providers to meet the CMS post-transplant survival metrics required for reimbursement coverage and improve the overall financial profile of their transplant programs. In addition, we believe the increase in transplant volumes enabled by the OCS will help providers achieve "Center of Excellence" designations with payors and thus drive significant revenue growth for their transplant programs.

Value to Payors

We believe organ transplantation is a cost-effective treatment for end-stage organ failure as it provides the longest life expectancy, and better quality of life, compared to other treatments like mechanical support or medical therapy. We believe the OCS will enable payors to benefit from these favorable health economics and limit their exposure to the high cost of severe post-transplantation complications and extended hospital stays.

Our Strategy

We are committed to transforming organ transplantation with our OCS platform by increasing the utilization of donor organs and improving clinical outcomes. We are targeting a large and highly concentrated opportunity that, we believe, currently lacks an effective solution for organ preservation, optimization and assessment. Our goal is to establish the OCS as the standard of care for organ transplantation and increase the number of organ transplants performed.

The key elements of our strategy are:

- **Target and drive deeper adoption of the OCS at leading transplant institutions.** We are focused on driving adoption at leading, high volume transplant programs where we have established strong relationships during our clinical trials. We plan to leverage these centers' familiarity with the value of the OCS to increase the number of transplants they perform and increase our penetration of their case volumes. Moreover, the substantial overlap among organ transplant programs should enable us to deploy multiple OCS products at the same institutions. For example, there are several centers that use both the OCS Lung and OCS Heart and centers that use all three of the OCS Lung, OCS Heart and OCS Liver. We also plan to expand our reach to additional high volume transplant programs.
- **Continue to build clinical evidence to substantiate the benefits of the OCS and expand clinical transplant indications.** Surgeons affiliated with leading academic transplant centers rely primarily on clinical evidence to drive changes in their practice. We have developed a substantial body of clinical evidence to support our PMA applications, potential PMA applications and other regulatory approvals for the use of the OCS technology in the field of organ transplantation. We plan to expand this body of clinical evidence in the post-market setting. For example, our ongoing post-market Thoracic Organ Perfusion Registry will continue to collect all OCS Lung transplant patient outcomes. We believe this registry could become the global clinical reference on post-transplant outcomes in the new era of organ transplantation using the OCS.
- **Expand the existing pool of utilizable donor organs by securing additional FDA PMA Supplements and new PMAs for expanded indications.** We secured our first PMA approval for the OCS Lung in March 2018. We have several additional applications for PMAs in the pipeline, including for our expanded lung indications and for our heart products, and we also plan to seek PMA approval for our liver products. If we are successful in obtaining such FDA approvals, we believe we will significantly expand the available donor organ pool.
- **Leverage the established commercial reimbursement process and billing mechanisms to accelerate U.S. commercial traction.** Medicare and private payors provided reimbursement for the OCS Lung, OCS Heart and OCS Liver during our U.S. pivotal trials using existing commercial billing and reimbursement processes for organ transplant procedures and have provided reimbursement for the OCS Lung following FDA approval in March 2018. We believe these established methods will continue to facilitate commercial reimbursement for the OCS Lung and, if they are approved by the FDA, for the OCS Heart and OCS Liver. We are in the process of seeking long-term reimbursement for our OCS products in several other countries.
- **Develop the next generation OCS technology platform to improve user experience and expand OCS products.** We intend to invest in developing the next generation multi-organ platform to improve the user experience. We also intend to develop and seek approval for additional OCS products for other organs, including kidneys.

Commercialization Strategy & Business Model

We have developed a customized commercial strategy to address the characteristics of the organ transplant field and position us for future growth.

Organ Transplant Opportunity Characteristics

The vast majority of transplant procedures are performed at a relatively small number of hospitals that have specialized organ transplant centers. For example, we estimate that approximately 50 to 55 transplant centers in the United States perform over 70% of the lung, heart and liver transplant volume. Furthermore, there is a high degree of overlap within each center. For example, the top 30 U.S. lung transplant centers, which were responsible for 77% of the total adult lung transplant volume in 2017, also performed a significant portion of heart and liver transplants.

The field of organ transplantation is driven by leading clinical academic institutions. The lead transplant surgeon at each of these institutions is often the primary decision-maker on most aspects of the transplant program, including preservation technology, threshold for accepting donor organs and travel distance for accepting organs. Unlike other specialties for which hospital administrators are more likely to exercise control over purchasing decisions, lead transplant surgeons are typically the primary purchasing decision-makers for new transplant technologies. To effect these changes in their programs, lead transplant surgeons rely primarily on clinical evidence and are focused on the following major factors:

- **Improving post-transplant clinical outcomes** in order to:
  - enhance patients' quality of life,
  - meet CMS post-transplant survival metrics required for reimbursement coverage, and
  - support the financial health of programs; and
- **Increasing the volume of organ transplantation** in order to:
  - facilitate more patients receiving an organ transplant,
  - achieve "Center of Excellence" designation with payors, and
  - drive revenue growth.

Our Commercial Strategy

In light of these dynamics, we designed our commercialization strategy to drive adoption of the OCS at the leading, large-volume academic transplant institutions that were involved with the OCS trials as well as to expand our presence to new centers. We believe our substantial body of clinical evidence has demonstrated the potential benefits of the OCS and we are also focused on continuing to increase our clinical evidence in the post-market setting to maintain a high level of engagement with transplant program directors and enable further penetration of the OCS at transplant programs.

We believe the concentrated nature of organ transplant activity in the United States and the reputation we established during our clinical trials will enable us to rely on a focused commercial team. As of October 27, 2018, our sales and clinical adoption team consisted of 24 sales and clinical professionals. The sales and clinical adoption team sells our OCS products and provides clinical education for their use in leading academic transplant centers in our key geographies during our clinical trials and commercially where our OCS products are approved. In addition, our team targets new leading transplant centers to expand our user base. We believe the team has established deep knowledge and credibility with our clinical users and customers. We believe the close relationship between transplant surgeons and our team provides us with unparalleled customer access that should enable us to further penetrate these transplant centers.

Business Model

Our business model is characterized by a high level of recurring revenue, which is derived primarily from sales of our single-use OCS Perfusion Sets and OCS Solutions, which we refer to collectively as a disposable set, that are required for each transplant using the OCS. Each OCS product is comprised of three components: the OCS Console, the OCS Perfusion Set and the OCS Solutions.

The OCS Console is either purchased by or loaned to a transplant program depending on individual center arrangements. Given the independent buying power of each transplant program within an institution, as well as the unique organ-specific characteristics of each OCS product, a multi-organ transplant center will require at least one OCS Console for each organ transplant program within the same center. For example, there are several centers that use both the OCS Lung and OCS Heart and centers that use all three of the OCS Lung, OCS Heart and OCS Liver.

Our recurring revenue stream is derived primarily from sales of our single-use OCS disposable sets. In light of the unscheduled nature of transplant procedures, our users replenish OCS disposable sets to maintain a minimum stock of three to five units per OCS product, on average. We expect that greater than 90% of our revenue will be related to sales of our single-use OCS disposable sets.

We generate a significant amount of our net revenue from a limited number of customers. For the fiscal year ended December 30, 2017 and the fiscal nine months ended September 29, 2018, Harefield Hospital accounted for 16% and 11%, respectively, of our net revenue. We expect that sales to relatively few customers will continue to account for a significant percentage of our net revenue in future periods. See "Risk Factors—We depend on a limited number of customers for a significant portion of our net revenue and the loss of, or a significant shortfall in demand from, these customers could have a material adverse effect on our financial condition and results of operations."

Reimbursement

Due to the significant economic benefits of organ transplantation, Medicare's reimbursement for organ transplant procedures is well-established and involves two payment mechanisms. The first is the inpatient hospital prospective payment system, which reimburses the transplant hospital for operating costs incurred during the inpatient stay in which the transplant procedure is performed. The payment for this stay is determined by the MS-DRG into which the case is assigned. The second mechanism involves a separate payment, in addition to the MS-DRG-based payment, for organ acquisition costs, which include organ preservation and transportation costs. Medicare reimburses hospitals for allowable organ acquisition costs on a reasonable cost basis. The OCS is reimbursed under this second mechanism.

For Medicaid transplant recipients, reimbursement to a transplant hospital for the incurred cost of the OCS is determined based on the applicable state Medicaid program. Some states establish a global payment for the transplant and organ acquisition costs, and some states have separate payments for the inpatient stay based on the MS-DRG system and for organ acquisition costs. Private insurers typically have agreements as to how they reimburse for the transplant costs and the organ acquisition costs, which may be through a global payment for both, or a payment for the transplant and a separate mechanism for paying for organ acquisition costs. Nearly half of U.S. lung, heart and liver transplants are covered under the Medicare and Medicaid programs, with the remainder being reimbursed through private payors.

Data from the 2017 Milliman U.S. Organ and Tissue Transplant research report estimates the average billed charges per organ transplant, including costs billed to organ acquisition costs. The report estimates that in the United States the overall billed charges for a double-lung transplant are approximately $1.2 million, of which only approximately $130,000 is associated with organ acquisition; overall billed charges for a heart transplant are approximately $1.4 million, of which only approximately $100,000 is associated with organ acquisition; and overall billed charges for a liver transplant are approximately $800,000, of which only approximately $95,000 is associated with organ acquisition.

Medicare and private payors provided reimbursement for the OCS Lung, OCS Heart and OCS Liver during the U.S. pivotal trials and have provided reimbursement for the OCS Lung following FDA approval in March 2018. This has established multiple years of billing precedent. We believe these established methods will continue to facilitate commercial reimbursement for the OCS Lung and, if they are approved by the FDA, for the OCS Heart and OCS Liver. Reimbursement outside of the United States follows a similar overall structure; however, reimbursement decisions are required in each individual country and may require national health systems to review and approve OCS reimbursement for each organ-specific product. Currently, national healthcare systems do not reimburse transplant centers for the use of the OCS and reimbursement in international markets may require us to undertake additional clinical studies. However, international hospitals using the OCS currently pay for the OCS from their hospital budget or charitable funds. We are in the process of seeking long-term reimbursement for our OCS products in several jurisdictions.

Clinical Evidence

The lead transplant surgeons at transplant centers are clinically focused and rely primarily on clinical evidence to drive changes in their practice of organ transplantation. We have developed a substantial body of global clinical evidence to support our PMA applications, potential PMA applications and other regulatory approvals for the OCS for lung, heart and liver transplantation. Many of these clinical trials and studies have been published in peer-reviewed clinical journals and several additional studies are ongoing. Our clinical trials have evaluated the use of the OCS for transplantation of organs that meet the current criteria for organ transplantation, as well as organs that would otherwise go unutilized from DBD and DCD donors. We believe the results of our clinical trials across lung, heart and liver transplantation may support the potential of the OCS in improving clinical outcomes and increasing utilization of available donor organs.

OCS Lung Clinical Trials

Below is a summary of our key clinical trials evaluating the OCS Lung.

	OCS Lung INSPIRE Trial For Current Lung Transplants	**OCS Lung EXPAND Trial For Currently Unutilized DBD and DCD Donor Lungs**
FDA Status	• PMA approved in March 2018	• PMA is under review by FDA
Objectives	• International pivotal trial for FDA approval and market access for current lung transplant market • Compare OCS Lung clinical outcomes to cold storage	• International pivotal trial for FDA approval and market access for currently unutilized DBD and DCD donors • Single arm trial to assess the ability of the OCS to improve donor lung utilization from currently unutilized DBD and DCD donors
Number of Patients	• 320 patients in pre-specified cohort and 29 additional patients as administrative extension	• 79 patients
Length of Follow-up	• 24 months post-transplantation	• 12 months post-transplantation
Number of Centers	• 21 international centers	• 8 international centers
Summary Outcomes	• Met primary effectiveness and safety endpoints • Demonstrated significant reduction of most severe and common form of post-lung transplant complication, PGD3, compared to cold storage controls • Demonstrated significant reduction of injurious ischemic time on donor lungs compared to cold storage controls	• Did not meet the primary effectiveness endpoint • Demonstrated significant increase in donor lung utilization from currently unutilized DBD and DCD donors to 87% utilization • Demonstrated good patient survival at one year post-transplantation, comparable to current standard lung transplant outcomes • Demonstrated substantial reduction of PGD3 in unutilized DBD and DCD donors, when compared to other published results of similar trials
Publication Status	• Warnecke et al., Lancet Respiratory Medicine, April 2018	• Anticipated publication in the first half of 2019

Summary Overview of OCS Lung INSPIRE Trial & Results

We sponsored the OCS Lung INSPIRE Trial, a randomized, controlled, multi-center study, at 21 leading global academic lung transplant centers. The objective of the OCS Lung INSPIRE Trial was to compare the safety and effectiveness of the OCS Lung to cold storage preservation for lung transplants. The trial inclusion criteria focused on current standard lung transplant donor lung criteria. The trial enrolled 349 patients in total, of which 320 lung transplant recipients were randomized between OCS Lung perfusion and cold storage control. Twenty-nine additional patients were added as an administrative extension.

The OCS Lung INSPIRE Trial protocol allowed donor lungs to be perfused on the OCS Lung device with either OCS Lung Solution or a commercial low potassium dextran, or LPD, solution, both supplemented with packed red blood cells. In addition to comparing the outcomes of all transplants performed with the OCS, our results included a subgroup analysis of the transplants that also used the OCS Solutions. We believe this subgroup is the most clinically relevant given it is the product approved by the FDA for exclusive use in the OCS Lung.

PGD is a form of acute lung injury that is a common and serious complication after lung transplantation. The most severe form of PGD, PGD3, has been shown to be positively correlated with poor short- and long-term transplant outcomes. Generally, in lung transplant procedures, PGD3 is assessed at four distinct timepoints: within a few hours of the transplantation, and at 24 hours, 48 hours and 72 hours following the transplantation. In the OCS Lung INSPIRE Trial, we assessed the incidence of PGD at the same four timepoints during the initial 72 hours following the transplantation.

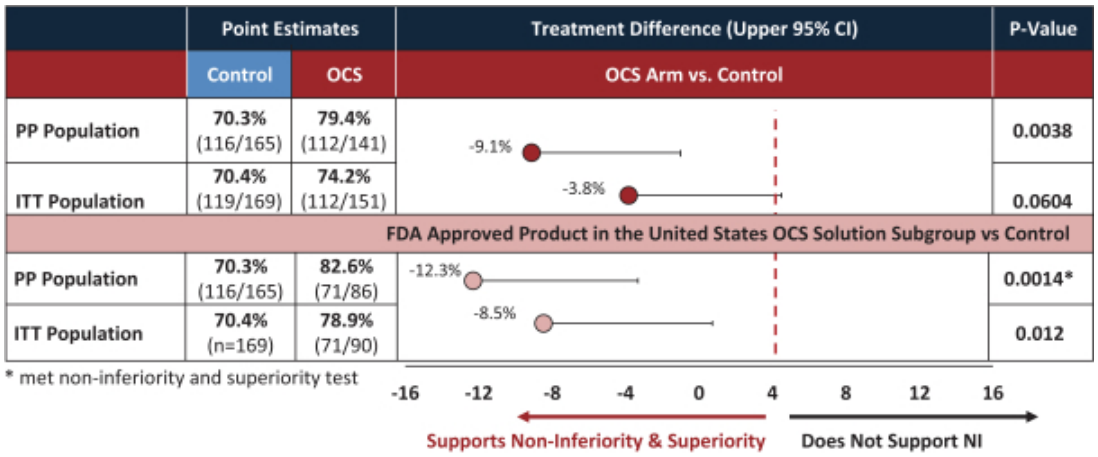
The OCS Lung INSPIRE Trial's initial primary effectiveness endpoint was a composite of patient survival at day 30 post-lung transplant and freedom from PGD3 measured at only a single timepoint of 72 hours post-transplantation. After the initiation of the trial, and based on a successful appeal to the Director of the FDA's Office of Device Evaluation at the time, we amended the primary effectiveness endpoint to be a composite of patient survival at day 30 post-lung transplant and freedom from PGD3 within all assessment timepoints in the initial 72-hour period post-transplantation. The intention of this amendment was to comprehensively assess the impact of the OCS Lung on PGD3 development. We achieved statistical non-inferiority in three of four analysis populations based on the amended primary effectiveness endpoint but did not achieve statistical non-inferiority relative to the control arm for the initial primary effectiveness endpoint. While we provided the results of both the initial and amended primary effectiveness endpoints to the FDA, the amended primary effectiveness endpoint ultimately served as the basis for the OCS Lung approval by the FDA.

We analyzed these results on a "per protocol," or PP, basis and an "intent to treat," or ITT, basis. PP included all randomized patients that were transplanted without any major protocol deviations and for whom the eligible donor lung received the complete preservation procedure as per the randomization assignment. ITT consisted of all randomized patients for whom a matching donor lung had been retrieved and was determined to be eligible before any attempt had been made to preserve the lung with either OCS or cold storage. The ITT results were confounded by the fact that the ITT population included two randomized OCS patients who were transplanted using cold storage as well as patients who were transplanted with lungs that did not meet the eligibility criteria. While the typical non-inferiority threshold for medical device pivotal trials allows for a differential of 7.5% – 15.0% between treatment and control, for this trial the FDA also imposed a narrow 4.0% non-inferiority margin for comparing the OCS results to the control arm.

Based on observed results, the OCS arm was numerically better than the control arm for all analyses of the primary endpoint. Relative to the amended primary effectiveness endpoint, the OCS achieved statistical non-inferiority in all analysis populations, except the ITT population. We believe that the imposition of a narrow 4.0% non-inferiority margin is the only reason the ITT population did not meet the statistical non-inferiority test despite performing 3.8% better than the control group.

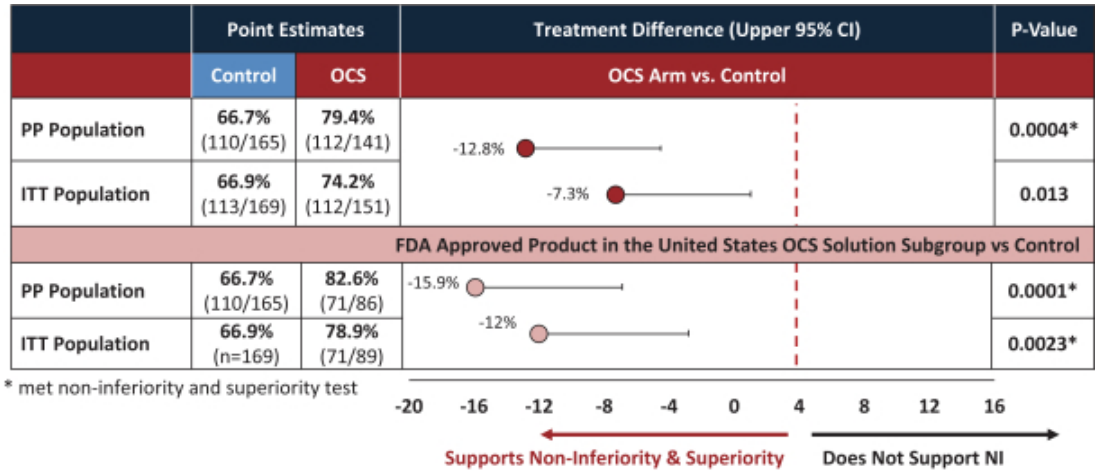
In addition, when assessing the results from the actual product to be marketed, the OCS Solution subgroup, the OCS met the non-inferiority test in all analyses and was statistically superior to the control arm in the PP

population. The figure below is a forest plot summarizing the results of the amended primary effectiveness endpoint.



Primary Effectiveness Composite Endpoint: patient survival at day 30 and freedom from PGD3 within the initial 72 hours after lung transplantation. This forest plot shows the point estimates (observed results) of the treatment arms and the percentage difference between the two treatment arms for the different study populations and subgroups. Upper 95% confidence interval is reported as we used a one-sided test for non-inferiority.

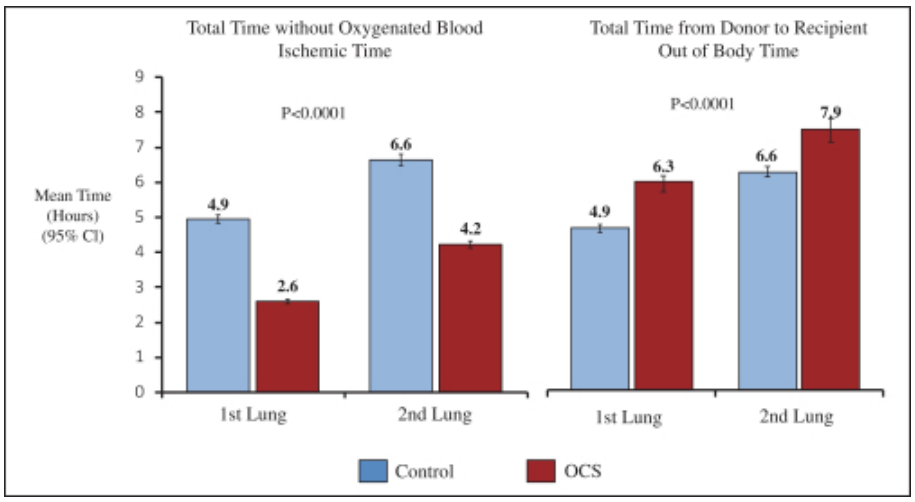
We also performed an adjunctive effectiveness composite analysis to evaluate patient survival at day 30 and throughout the initial transplant hospital admission, which comprehensively assessed surgical survival following transplantation and freedom from PGD3. In the adjunct analysis, the OCS arm not only met the non-inferiority test in all analysis populations, but was statistically superior to the control arm in three out of four analyses.



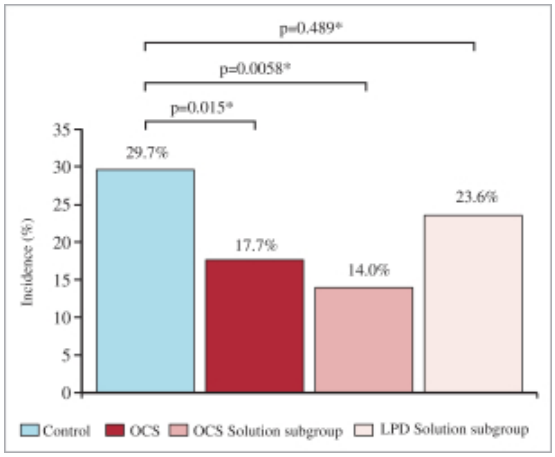
Adjunct Effectiveness Composite Analyses: patient survival at day 30 and throughout the initial transplant hospital admission and freedom from PGD3 within the initial 72 hours after lung transplantation. This forest plot shows the point estimates (observed results) of the treatment arms and the percentage difference between the two treatment arms for the different study populations and subgroups. Upper 95% confidence interval is reported as we used a one-sided test for non-inferiority.

Summary results of the OCS Lung INSPIRE Trial include:

- ***Significant Reduction of Injurious Ischemic Time on Donor Lungs***: OCS Lung significantly reduced the injurious ischemic time on donor lungs, while permitting the organ to remain out of the body for a significantly longer time compared to cold storage. These clinically significant results marked the first time in organ transplant history that a preservation technology demonstrated the ability to reduce the injurious ischemic time on the donated lung, regardless of the travel distance.



- ***Significant Reduction of PGD3 Post-Lung Transplantation:*** The OCS Lung also significantly reduced PGD3, the most severe and common clinical complication resulting from lung transplantation. PGD3 has been associated with poor short- and long-term outcomes following lung transplantation. We believe the OCS is the only technology or therapy that has demonstrated a significant reduction in this common and severe short-term complication in lung transplantation.



Incidence of PGD3 in the per-protocol analysis
OCS=Organ Care System; LPD=low potassium dextran; *Superiority test

Summary Overview of OCS Lung EXPAND Trial & Results

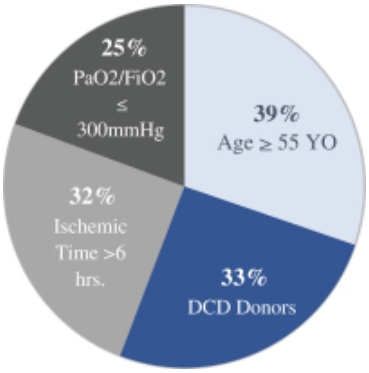
We sponsored the OCS Lung EXPAND Trial, a single arm, multi-center U.S. FDA pivotal trial in eight leading global academic lung transplant centers. The objective of the OCS Lung EXPAND Trial was to demonstrate the ability of the OCS Lung to improve donor lung utilization from currently unutilized DBD and DCD donors and to demonstrate reasonable assurance of effectiveness and safety required for U.S. FDA approval for this indication. The trial inclusion criteria focused on currently unutilized DBD and DCD donor lungs and enrolled 79 lung transplant recipients with donor lungs that would otherwise have been unutilized. In fact, data obtained from the U.S. United Network for Organ Sharing, or UNOS, demonstrated that the U.S. donor lungs used for the OCS Lung EXPAND Trial had been declined for transplantation on average 35 times by other transplant centers before reaching a center participating in the OCS Lung EXPAND Trial due to a variety of clinical and logistical reasons, including donor organ quality, donor age, expected injurious ischemic time or travel distance, or type of donor.

The primary effectiveness endpoint in the OCS Lung EXPAND Trial was a composite of patient survival at day 30 post-transplantation and freedom from PGD3 within the initial 72-hour period post-transplantation. The results of the OCS Lung EXPAND Trial did not meet the pre-specified performance goal that 65% of transplants meet the composite endpoint. The key clinical driver for missing the primary endpoint was the 44.3% rate of PGD3 within the initial 72-hour period post-transplantation due to the challenging nature of the donor lung criteria included in the OCS Lung EXPAND Trial. However, patient survival at day 30 post-transplantation was 98.7%. The primary endpoint of the OCS Lung EXPAND trial was established prior to the initiation of the study and was based on the only published data available for PGD3 within the initial 72-hour period post-transplantation, which reflected data from currently utilized donor lungs. Several recently-published studies have demonstrated higher rates of PGD3 within the initial 72-hour period post-transplantation when using donor lungs from currently unutilized DBD and DCD donors. We performed a comparative benchmark analysis against these studies with the results of the OCS Lung EXPAND Trial. Although the analysis was not a head-to-head comparison and thus is not definitive evidence of efficacy, the OCS Lung resulted in significantly lower rates of PGD3 within the initial 72-hour period post-transplantation as compared to similar donor cohorts.

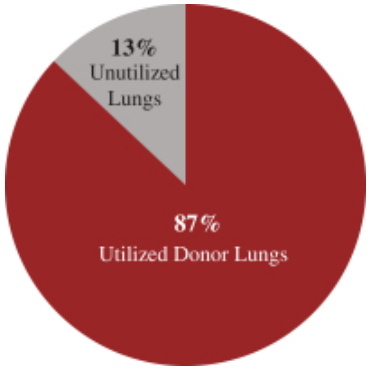
Summary results of the OCS Lung EXPAND Trial include:

- ***Observed 87% Utilization Rate for Lung Transplantation Using OCS Lung:*** The OCS Lung EXPAND Trial included several clinical criteria that would typically result in the rejection of lungs from DBD donors, including donor age above 55 years old, lung oxygenation function assessed by fraction oxygenation index, or PaO2/FiO2, below 300 mmHg and injurious ischemic time greater than six hours. In addition, the trial included DCD donor organs that are seldom utilized for transplantation today. Use of the OCS Lung resulted in successful utilization of 87% of these donor lungs that had been rejected for transplantation by other transplant centers using cold storage. The figure below demonstrates the donor lung criteria and observed rates of successful transplantation in the OCS Lung EXPAND Trial.

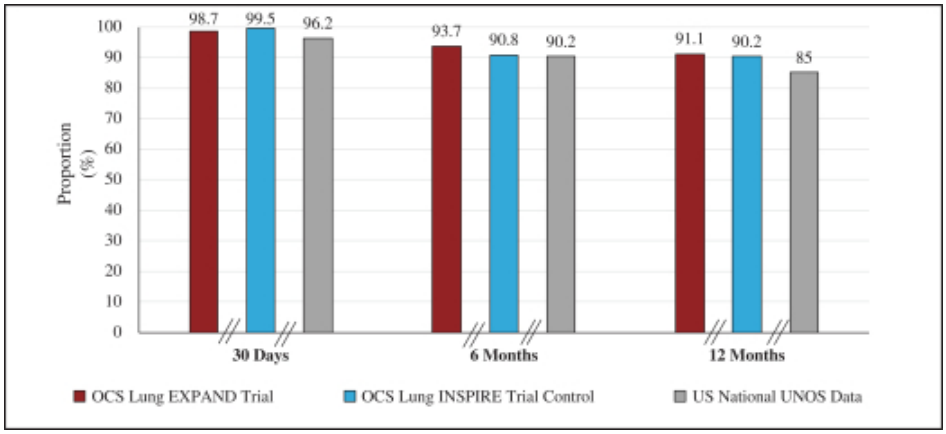
OCS Lung EXPAND Trial Donors Inclusion Criteria



OCS Lung EXPAND Trial Utilization Result



- ***The OCS Lung Resulted in Good Short- and Long-Term Patient Survival at One Year Post-Lung Transplantation:*** As indicated in the figure below, the 30-day, 6-month and one-year survival of patients in the OCS Lung EXPAND Trial was good and compared favorably to the survival rates of patients receiving donor lungs in our OCS Lung INSPIRE Trial as well as to U.S. national averages post-transplantation.



Summary Overview of OCS Lung EXPAND II Trial

We are also currently enrolling patients in our OCS Lung EXPAND II Trial, which is intended to provide continued clinical access to the OCS Lung for use in unutilized DBD and DCD donor lungs, similar to our OCS Lung EXPAND Trial, while the PMA for our OCS Lung EXPAND Trial is under review by the FDA. We received an MDL for this PMA in November 2018 for which we are currently in discussions with the FDA to address. Our OCS Lung EXPAND II Trial may also serve as supplemental clinical evidence to support our OCS Lung EXPAND PMA indication. The OCS Lung EXPAND II Trial is a prospective single-arm trial and has a design that is similar to the OCS Lung EXPAND Trial. Target enrollment for completion of the study is a total of 90 transplanted lung recipients. The trial is currently enrolling patients, with 34% of target enrollment completed at several active U.S. lung transplant centers as of November 21, 2018. We expect enrollment to be completed by the end of 2019.

OCS Lung Thoracic Organ Perfusion Post-Approval Study Registry

As a condition of approval for our currently marketed OCS Lung PMA, we are conducting a post-approval study known as the OCS Lung Thoracic Organ Perfusion Post-Approval Study Registry, or TOP Registry. The

TOP Registry will evaluate the short- and long-term safety and effectiveness of the OCS Lung for lung transplantation in a real-world environment. This registry will enroll all consenting patients who receive preserved double-lung transplants using the OCS Lung. A minimum of 500 double-lung transplant recipients transplanted with donor lungs preserved using the OCS Lung will be included in the registry. The first 289 eligible post-approval study consenting recipients transplanted with eligible donor lungs preserved on the OCS Lung will comprise the primary analysis population. The primary effectiveness endpoint is 12-month patient and graft survival post double-lung transplant. The safety endpoints are the number of lung graft-related serious adverse events through the longer of 30 days post-transplantation or initial hospital stay per patient, survival rate at 30 days post-transplantation and survival rate through initial transplant surgery hospital stay, if longer than 30 days. No patients have yet been enrolled.

OCS Lung INSPIRE Continuation Post-Approval Study

We also plan to enroll patients in our OCS Lung INSPIRE Continuation Post-Approval Study, which will evaluate long-term Bronchiolitis Obliterans Syndrome, or BOS, -free survival outcomes of OCS Lung INSPIRE Trial patients and is a condition of approval for our currently marketed OCS Lung PMA. This is a two-arm observational study limited to patients previously enrolled in the OCS Lung INSPIRE Trial in the United States and outside of the United States. The primary effectiveness endpoint is BOS-free survival, which measures freedom from BOS and mortality through five years post-transplantation. All patients in the OCS Lung INSPIRE Trial will be approached to seek their consent for collecting their long-term clinical diagnosis of BOS and survival status. In addition, the UNOS database will be queried to obtain BOS-free survival data on U.S. patients through five years of follow-up in an anonymized fashion by arm. The maximum number of patients to be enrolled is 349. No patients have yet been enrolled, but the last patient in the OCS Lung INSPIRE Trial will reach the five-year post-transplantation time point on November 24, 2019.

OCS Heart Clinical Trials

Below is a summary of our key clinical trials evaluating the OCS Heart.

	OCS Heart PROCEED II Trial in Current Donor Hearts	OCS Heart EXPAND Trial for Currently Unutilized DBD Donors
FDA Status	Potential PMA submission in Q1 2019	
Objectives	• International pivotal trial for FDA approval and market access for current heart transplant market • Compare OCS Heart clinical outcomes to cold storage and demonstrate non-inferiority of OCS Heart clinical outcomes to cold storage control	• U.S. pivotal trial for FDA approval and market access for currently unutilized DBD donors • Single arm trial to assess the ability of the OCS to improve donor heart utilization from currently unutilized DBD donors
Number of Patients	• 128 patients	• 75 patients
Length of Follow-up	• 30 days post-transplantation	• 12 months post-transplantation
Number of Centers	• 10 U.S. and international centers	• 9 U.S. centers
Summary Outcomes	• Met primary effectiveness and safety endpoints • Demonstrated significant reduction of injurious ischemic time on donor hearts compared to cold storage controls • In a post-hoc observational analysis of all-cause mortality, measured at 39 months post-transplant, graft-related deaths in the OCS group were similar to the number in the standard of care group, but overall deaths were higher in the OCS group.	• Demonstrated significant increase in donor heart utilization from currently unutilized DBD donors to 81% utilization • Demonstrated good patient survival at 6 months post-transplantation, which is ongoing; 12 months follow-up is also ongoing
Publication Status	• Pre-specified trial results published in Ardehali et al., The Lancet Journal, April 2015	• Pre-publication

The OCS Heart PROCEED II Trial was the first FDA trial for machine perfusion technologies for solid organ transplantation and helped identify several trial design and technology implementation opportunities. These opportunities were addressed in the design of the OCS Heart EXPAND Trial. As a result, we voluntarily withdrew our original PMA for OCS Heart in an effort to expand our data to include OCS Heart EXPAND Trial results as well as supplement our OCS Heart PROCEED II Trial results with long-term follow-up data that was not collected as part of the original trial protocol.

Summary Overview of OCS Heart PROCEED II Trial & Results

We sponsored the OCS Heart PROCEED II Trial, a randomized, controlled, multi-center study at 10 leading global academic heart transplant centers. The purpose of this trial was to demonstrate non-inferiority of the OCS Heart compared to cold storage. The trial inclusion criteria focused on current routine donor heart transplant criteria and the trial enrolled 128 heart transplant recipients randomized between the OCS Heart and the control arm, which used cold storage. Summary results of the OCS Heart PROCEED II Trial include:

- ***Met Primary Effectiveness Endpoint of Patient Survival at Day 30 post-Heart Transplantation:*** The OCS met the primary effectiveness endpoint in all analysis populations, demonstrating a greater than

90% survival rate at day 30 post-transplantation. These survival rates were not statistically different from those of the control arm, which potentially support that the OCS is effective in preserving donor hearts for transplantation.

- ***Met Principal Safety Endpoint of Cardiac-Graft Related Serious Adverse Events Relative to the Control Arm:*** The OCS Heart PROCEED II Trial met the secondary endpoint of cardiac-graft related serious adverse events, with no statistically significant difference relative to the control arm. These results support the safety of the OCS Heart for donor heart preservation.

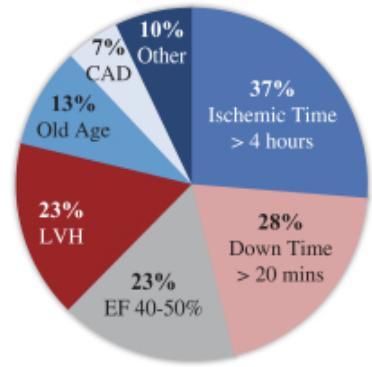
Summary Overview of OCS Heart EXPAND Trial & Results

We sponsored the OCS Heart EXPAND Trial, a single arm, multi-center U.S. FDA pivotal trial at nine leading academic U.S. heart transplant centers. The objective of the OCS Heart EXPAND Trial was to demonstrate the ability of the OCS Heart to improve donor heart utilization from currently unutilized DBD donors and to demonstrate reasonable assurance of effectiveness and safety required for U.S. FDA approval for this indication. The trial inclusion criteria focused on currently unutilized DBD donor hearts and enrolled 75 heart transplant recipients with donor hearts that would otherwise have been unutilized from DBD donors. In fact, data obtained from UNOS demonstrated that U.S. donor hearts used for the OCS Heart EXPAND Trial had been declined for transplantation an average of 66 times by other transplant centers before reaching a center participating in the OCS Heart EXPAND Trial due to variety of clinical and logistical reasons, including donor organ quality, donor age, expected injurious ischemic time or travel distance, or type of donor.

Summary results of the OCS Heart EXPAND Trial:

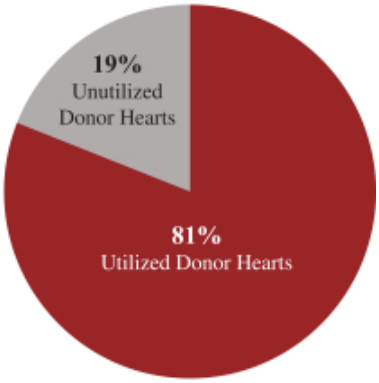
- ***Observed 81% Utilization Rate for Heart Transplantation Using OCS Heart Technology***: The OCS Heart EXPAND Trial included several clinical criteria that would typically result in the rejection of hearts from DBD donors, including older donor age, lower than acceptable cardiac ejection fraction, or EF, donor with prolonged cardiac arrest/down time requiring resuscitation, donor hearts with thick left ventricle hypertrophy, or LVH, donor hearts with non-specific coronary artery disease, or CAD, and long injurious ischemic time greater than four hours. Use of the OCS Heart resulted in successful utilization of 81% of these donor hearts that had been rejected for transplantation by other transplant centers using cold storage. The figure below demonstrates the donor heart characteristics and observed rates of successful transplantation in the OCS Heart EXPAND Trial.

OCS Heart EXPAND Trial Donors Type



25 patients had more than one inclusion criteria

OCS Heart EXPAND Trial Utilization Results



- ***Good Short- and Mid-Term Patient Survival at Six Months Post-Heart Transplantation:*** Despite the higher risk profile associated with the donor hearts used in the OCS Heart EXPAND Trial, the trial demonstrated short- and mid-term survival rates of 94.7% and 88.0% at 30 days and six months, respectively. The 12-month follow-up is ongoing.

Summary of Key Ex-U.S. Studies Supporting OCS Heart for DCD Donors

The OCS Heart is the only portable medical technology capable of resuscitating, preserving and assessing hearts from DCD donors. Outside of the United States, the OCS has been used to successfully transplant 102 hearts from DCD donors. As such, in addition to our clinical trials that potentially support the FDA approval process for the OCS Heart, there are several scientific and clinical publications from Australia and the U.K. that may provide additional support for demonstrating the safety and efficacy of the OCS Heart in the transplantation of DCD donor hearts.

A single-center observational matched cohort study in the U.K. compared the outcomes of consecutive patients who received transplants of DCD donor hearts between February 1, 2015 and March 31, 2017 to matched recipients who received transplants of DBD donor hearts between February 1, 2013 and March 31, 2017. The DCD donor hearts were transported and perfused on the OCS Heart, while the DBD hearts were preserved with cold storage. There was no difference in the protocol for implant technique or immunosuppressive regimens during this period. In this study, the use of the OCS Heart resulted in an 87% rate of successful utilization of DCD donor hearts for transplantation and resulted in one-year post-transplantation survival rates that were comparable to those of the matched DBD donor hearts that were transplanted with cold storage. This study was published in the Journal of Heart and Lung Transplantation in December 2017.

Similarly, a publication by Dhital et al. in April 2015 in The Lancet Journal described the experience of using the OCS Heart to preserve DCD donor hearts at St. Vincent's Hospital in Sydney, Australia. The DCD program at this institution began in July 2014 with all DCD donor hearts being perfused with the OCS Heart. As of October 2018, there have been 17 DCD donor heart transplants utilizing 71% of DCD donor hearts. Of the reported results available on 16 of the 17 patients, all 16 patients were alive and had normal biventricular function.

OCS Liver Clinical Trials

We are also actively enrolling patients in our U.S. pivotal IDE trial, the OCS Liver PROTECT Trial, to support U.S. FDA approval and market access for the OCS Liver. The OCS Liver PROTECT Trial is a prospective, randomized trial to evaluate the effectiveness of the OCS Liver to preserve and assess donor livers intended for transplantation. This is a two-armed, multi-center, randomized, controlled pivotal trial with participants assigned to the OCS treatment arm or the control arm, which uses cold storage. Target enrollment for completion of the study is a total of 300 patients. The trial is currently enrolling patients with 46% of target enrollment completed at leading academic U.S. liver transplant centers as of November 21, 2018.

Additionally, our OCS Liver European REVIVE Trial, which was a single arm, prospective trial of 25 transplanted liver recipients, evaluated the safety and performance of the OCS Liver. The primary performance endpoint was the number of donor livers preserved by the OCS Liver in a near-physiologic state. The primary safety endpoint was the number of events directly related to the use of the OCS Liver that led to the donor liver being deemed not clinically acceptable and, consequently, not transplanted. Results from the OCS Liver European REVIVE Trial demonstrated that the OCS Liver resulted in approximately 100% utilization of DBD and DCD donor livers. Long-term data collection is ongoing.

Intellectual Property

Patents and Trade Secrets

We rely on a combination of patent, trademark, copyright, trade secret and other intellectual property laws, nondisclosure and assignment of inventions agreements and other measures to protect our intellectual property. Our patent portfolio includes patents and patent applications that we own or license from third parties.

As of November 16, 2018, our owned and licensed patent portfolio consisted of approximately 182 issued patents and pending patent applications worldwide, including in Australia, Europe, Canada, China, Israel, New

Zealand and Japan. Our licensed portfolio includes one issued unexpired United States patent licensed from the VA. Several other licensed U.S. and international patents expired in 2018. The issued unexpired licensed VA patent includes claims directed to portable perfusion apparatus for preserving a harvested donor heart in a viable state. Our owned portfolio includes patents and applications related to one or more of the OCS Lung, OCS Heart, OCS Liver and solutions. In the United States, our owned portfolio includes about 20 issued patents and 9 pending applications. Worldwide, our owned portfolio includes about 94 issued patents and 58 pending applications. Issued patents in our portfolio are expected to expire between 2019 and 2035, excluding any potential additional patent term for patent term adjustments or patent term extensions, if applicable. If granted, the pending U.S. and foreign patent applications in our portfolio are expected to expire between 2023 and 2036, excluding any potential additional patent term for patent term adjustments or patent term extensions, if applicable.

As of November 16, 2018, our patent portfolio relating to the OCS Lung includes a family comprised of patents and patent applications with claims that are generally directed to certain methods and systems for preserving a lung *ex vivo* using both perfusion and ventilation. Such patents are issued in the United States, Australia, China, Israel, Japan, Hong Kong and New Zealand and patent applications are pending in the United States, Australia, Canada, China, Europe, Hong Kong, Israel, Japan and New Zealand. These patents, and any patents issued from pending patent applications, are expected to expire in 2028, excluding any potential additional patent term for patent term adjustments or patent term extensions, if applicable.

As of November 16, 2018, our patent portfolio relating to the OCS Heart includes a family comprised of patents and patent applications with claims that are generally directed to certain methods and systems for preserving a heart *ex vivo*. Such patents are issued in the United States, Australia, Belgium, China, Germany, Denmark, Europe, Spain, France, United Kingdom, Hong Kong, Ireland, Israel, Italy, Japan, The Netherlands, New Zealand and Sweden and patent applications are pending in the United States, Australia, Canada, Israel, Japan and New Zealand. These patents, and any patents issued from pending patent applications, are expected to expire in 2025, excluding any potential additional patent term for patent term adjustments or patent term extensions, if applicable.

As of November 16, 2018, our patent portfolio relating to the OCS Liver includes a family of allowed and pending patent applications with claims that are generally directed to certain systems, including perfusion circuits for perfusing a liver *ex vivo*. One patent in this family is issued in the United States, and applications are pending in the United States, Australia, Canada, China, Europe, Hong Kong, Israel, Japan and New Zealand. This patent and any patents issued from pending patent applications are expected to expire in 2035, excluding any potential additional patent term for patent term adjustments or patent term extensions, if applicable.

As of November 16, 2018, our patent portfolio relating to the OCS Solutions includes a family comprised of patents and patent applications with claims that are generally directed to compositions of certain perfusion fluids. Such patents are issued in the United States and patent applications are pending in the United States. These patents, and any patents issued from pending patent applications, are expected to expire in 2025, excluding any potential additional patent term for patent term adjustments or patent term extensions, if applicable.

The term of individual patents depends on the legal term for patents in the countries in which they are granted. In most countries, including the United States, the patent term is generally 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country. We cannot assure you that patents will be issued from any of our pending applications or that, if patents are issued, they will be of sufficient scope or strength to provide meaningful protection for our technology. Notwithstanding the scope of the patent protection available to us, a competitor could develop methods or devices that are not covered by our patents. Furthermore, numerous U.S. and foreign issued patents and patent applications owned by third parties exist in the fields in which we are developing products. Because patent applications can take many years to issue, there may be applications unknown to us, which applications may later result in issued patents that our existing or future products or proprietary technologies may be alleged to infringe.

There has been substantial litigation regarding patent and other intellectual property rights in the medical device industry. In the future, we may need to engage in litigation to enforce patents issued or licensed to us, to protect our trade secrets or know-how, to defend against claims of infringement of the rights of others or to determine the scope and validity of the proprietary rights of others. Litigation could be costly and could divert our attention from other functions and responsibilities. Adverse determinations in litigation could subject us to significant liabilities to third parties, could require us to seek licenses from third parties and could prevent us from manufacturing, selling or using the OCS, any of which could severely harm our business.

For more information, see "Risk Factors—Risks Related to Intellectual Property."

Department of Veterans Affairs License

In August 2002, we entered into a license agreement with the VA under which the VA granted us an exclusive, worldwide license under specified patents to make, use, sell and import perfusion apparatuses for our portable organ preservation systems and disposable perfusion modules for use in these apparatuses and a non-exclusive, worldwide license to make, use, sell and import solutions for use in or with those systems. Prior to September 23, 2017, our license rights under the VA patents included at least 20 issued United States and international patents and patent applications pending in the United States, Canada and Japan. Dr. Hassanein, our President and Chief Executive Officer and founder, is a co-inventor on all of these patents. During his cardiac surgery research fellowship at West Roxbury VA Medical Center prior to founding TransMedics, Dr. Hassanein performed much of the research and other work that resulted in the inventions and claims that subsequently became the subject of patents and patent applications currently held by the VA. The majority of the licensed U.S. patents expired in 2017, and the foreign patents expired in September 2018. However, we have requested patent term extension for one U.S. patent covered by the VA license agreement, U.S. Patent No. 6,100,082. We have been granted interim patent term extension for this patent. The maximum extension granted could be through May 2022; however, the length of the patent term extension is currently being determined by the United States Patent and Trademark Office. Our rights under the license agreement will continue until the expiration of the last to expire of the licensed patents, which will be the '082 patent. Our license includes the right to grant sublicenses, subject to approval by the VA and other restrictions, and is subject to the U.S. government's right to practice the licensed patents on its own behalf without payment of a royalty and an obligation to grant certain sublicenses as necessary to fulfill public health, welfare and safety needs. During its term, our license agreement with the VA also requires us to make our products covered by the licensed patents available to the public on reasonable terms and to provide the U.S. government such products at the lowest price. During the term, we must manufacture our products covered by the licensed patents in the United States to the extent practicable.

As consideration for the licenses granted by the VA, we paid a one-time five figure amount to the VA and are obligated to pay tiered royalties ranging from a low single-digit to a mid single-digit percentage on net sales of each product covered by a licensed patent (subject to a minimum aggregate royalty payment of less than $0.1 million per year during each of the first five years after the first commercial sale, after which no minimum is required). Royalties will be paid by us on a licensed product-by-licensed product and country-by-country basis, beginning on the first commercial sale of such licensed product in such country until expiration of the last valid patent claim covering such licensed product in such country. Our license agreement with the VA provides that so long as our license remains exclusive, we have the first right to amend, prosecute and maintain the licensed patents at our own expense, and, subject to prior written approval of the U.S. Department of Justice or, if required by law, jointly with the VA, the first right to enforce the licensed patents with respect to infringement relating to perfusion apparatuses. Our license agreement with the VA can be terminated by us or the VA only if the other party fails to cure its material breach within a specified period after receiving notice of such breach.

Research, Development and Clinical Trial Operations

Our research, development and clinical trial operations function consists of a dedicated clinical trial team that has trial management, data collection and biostatistics expertise. Our product engineering function consists

of a multi-disciplinary engineering team that has electrical, mechanical, systems and software engineering expertise. Our regulatory function includes a team with both U.S. and international medical device regulatory expertise and is supported by senior FDA regulatory advisors and legal counsel. For the fiscal years ended December 31, 2016 and December 30, 2017, our research, development and clinical trials expenses were $15.6 million and $15.0 million, respectively.

This team is focused on the following research, development and clinical trial activities:

- expanding the body of clinical evidence supporting the use of the OCS platform through pre-market clinical trials, post-market registries and scientific publications;
- improving incrementally the technology and manufacturing efficiency of our current platform;
- developing the next generation OCS; and
- conducting research to investigate new clinical applications and uses for the OCS platform.

Competition

Competition in organ preservation for transplantation can be classified into two main segments: (1) cold storage and cold perfusion technologies and (2) warm perfusion technologies. In both cold storage and cold perfusion, the organs are not functioning or metabolically inactive. The characteristics of cold storage and cold perfusion described above significantly limit donor organ utilization and are a primary driver of post-transplant complications. Supply of cold storage and cold perfusion products is fragmented with a number of companies mainly providing undifferentiated flush and perfusion solutions.

Warm perfusion preservation for solid organ transplant is an emerging alternative designed to address the limitations of cold storage and cold perfusion. In warm perfusion, the organs are functioning and metabolically active. We are aware of only two other companies providing warm perfusion systems, OrganOx Limited and XVIVO Perfusion AB, both of which offer single-organ systems for the liver and lung, respectively.

We believe that our principal competitive factors include:

- strong clinical evidence from large trials demonstrating safety, effectiveness and clinical benefits;
- regulatory approvals for broad clinical indications of use;
- ease of integration into current organ retrieval workflow, including system portability across all modes of transportation;
- platform capabilities designed to support multiple organ transplant programs;
- brand recognition among leading transplant programs worldwide;
- established clinical relationships and a core of committed clinical users;
- commercial reimbursement; and
- sophisticated clinical training and support program to users worldwide.

Manufacturing, Supply and Operations

We design and assemble our OCS Consoles and disposable OCS Perfusion Sets at our facility in Andover, Massachusetts. We believe our current facility’s capacity using a single shift is sufficient to cover the next two to three years of forecast demand, and we also have the ability to increase capacity significantly with additional shifts. We manufacture our sterilized disposable OCS Perfusion Sets in a class 10,000 cleanroom. We source many of the components for the OCS Console and OCS Perfusion Sets from third-party suppliers that are required to manufacture and test them according to our specifications. We purchase some of the components of the OCS Console and OCS Perfusion Set from single-source suppliers and, in a few cases, sole-source suppliers.

We source the OCS Solutions using our proprietary formulas from third-party suppliers. Fresenius is our single-source supplier of OCS Solutions for the OCS Lung and OCS Heart. Our agreement with Fresenius for the supply of OCS Lung Solution expires in April 2020 and automatically extends for subsequent periods of 24 months each, unless terminated by either party at least 12 months prior to the end of the initial term or the then-current extension term. We may also terminate this agreement with 12 months' notice if we request that Fresenius qualify a second manufacturing plant or qualify a reputable third party to manufacture the OCS Lung Solution and Fresenius fails to respond to this request. We are obligated to meet certain annual minimum purchase commitments based upon rolling order forecasts that we provide to Fresenius in accordance with this agreement. Our agreement with Fresenius for the supply of OCS Heart Solution has one-year evergreen terms, terminable by either party at least 12 months prior to the end of the then-current term.

Our operations team includes production and test employees, manufacturing engineers and field service technicians.

Facilities

Our corporate headquarters and manufacturing and clinical training facilities are located in Andover, Massachusetts, where we lease 54,000 square feet of space, including a 10,500 square foot laboratory and training facility and a 2,400 square foot class 10,000 re-configurable cleanroom facility. The leases for these facilities expire on December 31, 2021.

Employees

As of October 27, 2018, we employed 83 people globally. We believe the success of our business will depend, in part, on our ability to attract and retain qualified personnel. We are committed to developing our employees and providing them with opportunities to contribute to our growth and success. Except for certain European employees, our employees are not subject to collective bargaining agreements, and we believe that we have good relations with our employees.

Legal Proceedings

We are not currently a party to any material legal proceedings. From time to time, we may be involved in legal proceedings or investigations, which could have an adverse impact on our reputation, business and financial condition and divert the attention of our management from the operation of our business.

REGULATION

Our OCS products and our operations are subject to extensive regulation by the FDA and other federal and state authorities in the United States, as well as comparable authorities in the European Union. EU laws in relation to CE marking also apply in Norway, Lichtenstein, Iceland, Switzerland and Turkey due to mutual recognition agreements. Our products are subject to regulation as medical devices under the FDCA, as implemented and enforced by the FDA. The FDA regulates the development, design, non-clinical and clinical research, manufacturing, safety, effectiveness, labeling, packaging, storage, installation, servicing, recordkeeping, premarket clearance or approval, adverse event reporting, advertising, promotion, marketing and distribution, and import and export of medical devices to ensure that medical devices distributed domestically are safe and effective for their intended uses and otherwise meet the requirements of the FDCA.

In addition to U.S. regulations, we are subject to a variety of regulations in the European Union and other countries, governing medical devices, clinical investigations and commercial sales and distribution of our products. Whether or not we have or are required to obtain FDA clearance or approval for a product, we will be required to obtain authorization before commencing clinical trials and to obtain marketing authorization or approval of our products under the comparable regulatory authorities of countries outside of the United States before we can commence clinical trials or commercialize our products in those countries. The approval processes outside the European Union, although to a significant extent harmonized across the European Union, will vary from country to country and the time may be longer or shorter than that required for FDA clearance or approval.

FDA Premarket Clearance and Approval Requirements

Unless an exemption applies, each medical device commercially distributed in the United States requires either FDA clearance of a 510(k) premarket notification, approval of a PMA or issuance of a de novo classification order. Under the FDCA, medical devices are classified into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent and regulatory controls needed to ensure its safety and effectiveness. Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be assured by adherence to the FDA's General Controls for medical devices, which include compliance with the applicable portions of the QSR facility registration and product listing, reporting of adverse medical events, and truthful and non-misleading labeling, advertising, and promotional materials. Class II devices are subject to the FDA's General Controls, and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. These special controls can include performance standards, post-market surveillance, patient registries and FDA guidance documents. While most Class I devices are exempt from the 510(k) premarket notification requirement, manufacturers of most Class II devices are required to submit to the FDA a premarket notification under Section 510(k) of the FDCA requesting a classification determination that provides permission to commercially distribute the device. The FDA's permission to commercially distribute a device subject to a 510(k) premarket notification is generally known as 510(k) clearance. Under the 510(k) process, the manufacturer must submit to the FDA a premarket notification demonstrating that the device is "substantially equivalent" to either a device that was legally marketed prior to May 28, 1976, the date upon which the Medical Device Amendments of 1976 were enacted, or a device that was reclassified from Class III to Class II or I, or another commercially available device that was cleared through the 510(k) process or that was granted marketing authorization through the *De Novo* classification process under section 513(f)(2) of the FDCA.

Devices deemed by the FDA to pose the greatest risks, such as life-sustaining, life-supporting and most implantable devices, or devices that have been found not substantially equivalent to a legally marketed Class I or Class II predicate device, are placed in Class III, requiring approval of a PMA. Pre-amendment Class III devices require a PMA only after FDA publishes a regulation calling for PMA submissions, and prior to the PMA effective date are subject to the FDA's 510(k) premarket notification and clearance process in order to be commercially distributed.

We received PMA approval for the OCS Lung in March 2018 for the preservation of donor lungs for double-lung transplantation. In the future, we also hope to obtain PMA approvals for the OCS for preservation of donor lungs currently unutilized for transplantation, donor hearts currently utilized and unutilized for transplantation, and donor livers currently utilized and unutilized for transplantation.

PMA Pathway

Class III devices require an approved PMA before they can be marketed although some pre-amendment Class III devices for which the FDA has not yet required a PMA are cleared through the 510(k) process. The PMA process is more demanding than the 510(k) premarket notification process. In a PMA, the manufacturer must demonstrate that the device is safe and effective, and the PMA must be supported by extensive data, including data from preclinical studies and human clinical trials. The PMA must also contain a full description of the device and its components, a full description of the methods, facilities and controls used for manufacturing, and proposed labeling. Following receipt of a PMA, the FDA determines whether the application is sufficiently complete to permit a substantive review. If the FDA accepts the application for review, it has 180 days under the FDCA to complete its review of a PMA, although in practice, the FDA's review generally takes from one to three years, or even longer, from the time the PMA application is submitted to the FDA until an approval is obtained. An advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may not accept the panel's recommendation. In addition, the FDA will generally conduct a preapproval inspection of the applicant or its third-party manufacturers' and/or suppliers' manufacturing facility or facilities to ensure compliance with the QSR and, in some cases, will audit the applicant and clinical sites as part of its BioResearch Monitoring program.

During the PMA review, the FDA assesses whether the data and information in the PMA constitute valid scientific evidence to support a determination that there is a reasonable assurance that the device is safe and effective for its intended use(s) based on the proposed labeling. Grounds for PMA denial include the lack of a showing of reasonable assurance that the device is safe or effective under the conditions of use prescribed, recommended or suggested in the proposed labeling; a finding that the methods used in, or the facilities or controls used for, the manufacture, processing, packing or installation of such device do not conform to the requirements of the QSR; or a finding that the proposed labeling is false or misleading in any particular. If none of the grounds for PMA denial identified in FDA's laws and regulations exist, the FDA will approve the PMA. The FDA may approve a PMA with post-approval conditions intended to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution, and collection of long-term follow-up data from patients in the clinical study that supported a PMA or requirements to conduct additional clinical studies post-approval. The FDA may condition a PMA approval on some form of post-market surveillance when deemed necessary to protect the public health or to provide additional safety and effectiveness data for the device in a larger population or for a longer period of use. In such cases, the manufacturer might be required to follow certain patient groups for a number of years and to make periodic reports to the FDA on the clinical status of those patients. For our currently marketed OCS Lung, as part of the conditions of approval we must complete two PMA post-approval studies, the INSPIRE Continuation Post-Approval Study, which is a two-arm observational study intended to evaluate long-term outcomes of the OCS Lung INSPIRE Trial patients, and the TOP Registry, a prospective, single-arm, multi-center, observational study designed to evaluate the short- and long-term safety and effectiveness of the OCS Lung. Both the INSPIRE Continuation Post-Approval Study and the TOP Registry entail submission of regular reports to the FDA. Failure to comply with the conditions of approval can result in material adverse enforcement action, including withdrawal of the approval.

Certain changes to an approved device, such as changes in manufacturing facilities, methods, or quality control procedures, or changes in the design performance specifications, which affect the safety or effectiveness of the device, require submission and approval of a PMA supplement. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may not require as extensive

clinical data or the convening of an advisory panel. Certain other changes to an approved device require the submission and approval of a new PMA, such as when the design change causes a different intended use, mode of operation, and technical basis of operation, or when the design change is so significant that a new generation of the device will be developed, and the data that were submitted with the original PMA are not applicable for the change in demonstrating a reasonable assurance of safety and effectiveness.

Clinical Trials

Clinical trials are almost always required to support a PMA. All clinical investigations of investigational devices to determine safety and effectiveness must be conducted in accordance with the FDA's investigational device exemption, or IDE, regulations that govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a "significant risk" to human health, as defined by the FDA, the FDA requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical trials. A significant risk device is one that presents a potential for serious risk to the health, safety or welfare of a patient and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject. To be approved, an IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies the company that the investigation may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE for which it requires modification, the FDA may permit a clinical trial to proceed under a conditional approval.

In addition, the study must be approved by, and conducted under the oversight of, an Institutional Review Board, or IRB. The IRB is responsible for the initial and continuing review of the study, and may pose additional requirements for the conduct of the study. If an IDE application is approved by the FDA and one or more IRBs, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate approval from the FDA, but must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements. Acceptance of an IDE application for review does not guarantee that the FDA will allow the IDE to become effective and, if it does become effective, the FDA may or may not determine that the data derived from the trials support the safety and effectiveness of the device to support marketing approval or clearance, or to warrant the continuation of clinical trials. An IDE supplement must be submitted to, and approved by, the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study plan or the rights, safety or welfare of human subjects.

During a study, the sponsor is required to comply with the applicable FDA requirements, including, for example, trial monitoring, selecting clinical investigators and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims for them. The clinical investigators in the clinical study are also subject to FDA regulations and must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device, and comply with all reporting and recordkeeping requirements. Additionally, after a trial begins, we, the FDA or the IRB could suspend or terminate a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits or protocol violations.

Currently, pivotal trials are being initiated or conducted under IDEs that investigate (i) the safety and effectiveness of the OCS Heart for the preservation of certain donor hearts that do not meet the current standard donor heart acceptance criteria for transplantation; (ii) the safety and effectiveness of the OCS Lung for the

preservation of certain donor lungs that do not meet the current standard donor lung acceptance criteria for transplantation; and (iii) the safety and effectiveness of the OCS Liver for currently unutilized donor livers and certain donor livers that are currently unutilized for transplantation. In addition, we completed an IDE pivotal trial of the OCS Heart for donor hearts, and plans to submit IDEs for a Continued Access Protocol to the OCS Heart Study for the preservation of certain donor hearts that do not meet the current standard donor heart acceptance criteria for transplantation, and for a study of OCS Heart for donor hearts that are donated after circulatory death.

Post-market Regulation

After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include:

- establishment registration and device listing with the FDA;
- QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling and marketing regulations, which require that promotion is truthful, not misleading, fairly balanced and provide adequate directions for use and that all claims are substantiated, and also prohibit the promotion of products for unapproved or "off-label" uses and impose other restrictions on labeling;
- approval of a PMA supplement for certain modifications to PMA-approved devices that affect the safety or effectiveness of the device, or clearance of a new 510(k) premarket notification for modifications to 510(k) cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of the device;
- medical device reporting regulations, which require that a manufacturer report to the FDA information that reasonably suggests a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;
- correction, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;
- complying with the federal law and regulations requiring Unique Device Identifiers, on devices and also requiring the submission of certain information about each device to the FDA's Global Unique Device Identification Database;
- the FDA's recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations if the FDA finds that there is a reasonable probability that the device would cause serious, adverse health consequences or death; and
- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device.

Our manufacturing processes are required to comply with the applicable portions of the QSR, which cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master record, device history file, and complaint files. As a manufacturer, our facilities, records and manufacturing processes are subject to periodic scheduled or unscheduled inspections by the FDA. Our failure to maintain compliance with the QSR or other applicable regulatory requirements (for example, if we fail to re-certify our products under the new Medical Devices Regulation in time) could result in the shutdown of, or restrictions on, our manufacturing operations and

the recall or seizure of our products. The discovery of previously unknown problems with any of our products, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or off-label by a physician in the practice of medicine, could result in restrictions on the device, including the removal of the product from the market or voluntary or mandatory device recalls.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that we failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, which may result in any of the following sanctions:

- warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;
- recalls, withdrawals, or administrative detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for approvals of PMAs of new products or modified products;
- withdrawing a PMA approval that has already been granted;
- refusal to grant export or import approvals for our products; or
- criminal prosecution.

Regulation of Medical Devices in the European Union

In the European Union, our products are regulated as medical devices. Regulation of medical devices in the European Union is harmonized such that EU countries follow the standards set out in three medical devices directives (90/385/EEC, 93/42/EEC and 98/79/EC). However, the competent authorities in each member state have the right to enforce the standards set out in those directives against the manufacturer selling medical devices in the state.

All medical devices placed on the market in the European Union must meet the applicable essential requirements laid down in Directive 93/42/EEC concerning medical devices, or the Medical Devices Directive. Similar to the U.S. system, medical devices are classified into one of four classes: I, IIa, IIb and III, with class I representing the lowest risk products and class III the highest risk products. The most fundamental essential requirement is that a medical device must be designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients, or the safety and health of users and others. In addition, the device must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in a suitable manner. The European Commission has adopted various standards applicable to medical devices. These include standards governing common requirements, such as sterilization and safety of medical electrical equipment, and product standards for certain types of medical devices. There are also harmonized standards relating to design and manufacture. While not mandatory, compliance with these standards is often viewed as the easiest way to satisfy the essential requirements as a practical matter. Compliance with a standard developed to implement an essential requirement also creates a rebuttable presumption that the device satisfies that essential requirement.

To demonstrate compliance with the essential requirements laid down in Annex I to the Medical Devices Directive, medical device manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Conformity assessment procedures require an assessment of available clinical evidence, literature data for the product and post-market experience in respect of similar products already marketed.

Except for low-risk medical devices (Class I non-sterile, non-measuring devices), where the manufacturer can self-declare the conformity of its products with the essential requirements (except for any parts that relate to

sterility or metrology), a conformity assessment procedure requires the intervention of a notified body. Notified bodies are private entities and are authorized or licensed to perform such assessments by government authorities. The notified body must audit and examine a product's technical dossiers and the manufacturers' quality system. If satisfied that the relevant product conforms to the relevant essential requirements, the notified body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then apply the CE Mark to the device, which allows the device to be placed on the market throughout the European Union. Once the product has been placed on the market in the European Union, the manufacturer must comply with requirements for reporting incidents and field safety corrective actions associated with the medical device. The notified body has on-going audit rights and must be notified of all significant changes to the device.

Clinical Investigations

In order to demonstrate safety and efficacy for their medical devices, manufacturers must conduct clinical investigations in accordance with the requirements of Annex X to the Medical Devices Directive, and applicable European and International Organization for Standardization standards, as implemented or adopted in the European Union member states. Clinical investigations for medical devices cannot proceed without a positive opinion of an ethics committee and approval by or notification to the national regulatory authorities. Both regulators and ethics committees also require the submission of serious adverse event reports during a study and may request a copy of the final study report.

Post-marketing Requirements

In the European Union, we are currently required to comply with strict post-marketing obligations that accompany the affixing of the CE Mark to medical devices. These include the obligation to report serious adverse events within a specified time period and to provide periodic safety reports and updates. Authorities in the European Union also closely monitor the marketing programs implemented by device companies. The obligations that companies must fulfill concerning premarketing approval of promotional material vary among member states of the European Union as advertising and promotion law is not harmonized in the European Union.

New Developments: MDR

On April 5, 2017, the European Parliament passed the Medical Devices Regulation (Regulation 2017/745), which repeals and replaces the EU Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the EU member states, the regulations would be directly applicable without the need for adoption of EU member state laws implementing them, in all EU member states and are intended to eliminate current differences in the regulation of medical devices among EU member states. The Medical Devices Regulation, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the European Union for medical devices and ensure a high level of safety and health while supporting innovation.

The Medical Devices Regulation will become applicable May 2020. Once applicable, the new regulations will among other things:

- strengthen the rules on placing devices on the market, by requiring more evidence substantiating safety and efficacy of the device, and reinforce surveillance once they are available;
- establish explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market and new responsibilities for distributors and importers;
- improve the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;

- set up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the European Union; and
- strengthen rules for the assessment of certain high-risk devices, such as implants, which may have to undergo an additional check by experts before they are placed on the market.

We recognize that our products will have to be re-certified under the Medical Devices Regulation and we are in the process of updating internal procedures to ensure compliance with the new Medical Devices Regulation and have added international regulatory personnel to assist with the transition. Additional steps may include undertaking a gap analysis to determine the additional steps required to comply with MDR, including determining whether additional clinical trial or post market study data might be required to be obtained, other regulatory requirements to ensure that the technical file will be.

New Developments: Brexit

We recognize that we may need to revise our regulatory strategy in the European Union because following the U.K.'s withdrawal from the European Union, certificates issued by U.K. notified bodies will no longer be recognized. Our notified body, BSI, is currently headquartered in the U.K., but it is in the process of applying for designation as a Medical Device Notified Body in the Netherlands to ensure that CE marks are transferred without interruption, or minimal delay. If BSI is unable to issue certificates from its office in the Netherlands, we may be unable to sell products in the European Union and the U.K. following Brexit until we are able to obtain an authorized notified body.

Regulations Applicable to Transport of Organs Intended for Transplantation

In the European Union, the Directive 2010/53/EU (formerly Directive 2010/45/EU) sets out certain standards which the EU member states should apply in respect of procurement, preservation and transport of organs intended for transplantation. While we are not directly affected by this directive, our EU customers are, and our products may either help or impede their compliance with this Directive.

Regulation in Other Countries

We are subject to regulations and product registration requirements in many foreign countries in which we may sell our products, including in the areas of:

- design, development, manufacturing and testing (including with respect to significant changes to the products);
- product standards;
- product safety;
- product safety reporting;
- marketing, sales and distribution;
- packaging and storage requirements;
- labeling requirements;
- content and language of instructions for use;
- clinical trials;
- record keeping procedures;
- advertising and promotion;
- recalls and field corrective actions;

- post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury;
- import and export restrictions;
- tariff regulations, duties and tax requirements;
- registration for reimbursement, agreement of prices with government; and
- necessity of testing performed in country by distributors for licensees.

The time required to obtain clearance by foreign countries may be longer or shorter than that for FDA clearance, and requirements for licensing a product in a foreign country may differ significantly from FDA requirements.

Adverse events and potential adverse events are monitored closely by regulatory authorities. For example, if, as a result of manufacturing error, the efficacy of our products does not meet the standards claimed in the accompanying instructions for use, regulatory authorities could prevent our products from being placed on the market in the European Union.

Internationally, the approaches to product defects will vary. A product may be recalled in one country but not in others. However, within the European Union, competent authorities share adverse event information and cooperate with each other and a recall in one EU member state is more likely to lead to recalls in the rest of the European Union.

Federal, State and Foreign Fraud and Abuse and Physician Payment Transparency Laws

In addition to FDA restrictions on marketing and promotion of drugs and devices, other federal, state, international laws, as well as laws with extra-territorial effect and market practices restrict our business practices. These laws include, without limitation, U.S. and foreign laws intended to prohibit or otherwise regulate activities that might result in fraud, abuse and bribery.

U.S. Laws

U.S. federal healthcare fraud and abuse laws generally apply to our activities because our products are covered under federal healthcare programs such as Medicare and Medicaid. The principal U.S. federal healthcare fraud and abuse laws applicable to us and our activities include: (1) the Anti-Kickback Statute, which prohibits the knowing and willful offer, solicitation, payment or receipt of anything of value in order to generate business reimbursable by a federal healthcare program; (2) the False Claims Act, which prohibits the submission of false or otherwise improper claims for payment to a federally-funded healthcare program, including claims resulting from a violation of the Anti-Kickback Statute; and (3) healthcare fraud statutes that prohibit false statements and improper claims to any third-party payor. There are also similar state anti-kickback and false claims laws that apply to activities involving state-funded Medicaid and other healthcare programs as well as to private third-party payers.

The Anti-Kickback Statute is particularly relevant because of its broad applicability. Specifically, the Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving, or providing remuneration, directly or indirectly, in exchange for, or to induce, either the referral of an individual, or the furnishing, arranging for or recommending a good or service for which payment may be made in whole or part under federal healthcare programs, such as the Medicare and Medicaid programs. Almost any financial interaction with a healthcare provider, patient or customer will implicate the Anti-Kickback Statute. Statutory exceptions and regulatory safe harbors protect certain interactions if specific requirements are met. Only those interactions that represent fair market value exchanges, however, are generally protected by an exception or safe harbor. The government can exercise enforcement discretion in taking action against unprotected activities.

Many interactions in which we commonly engage, such as the provision of business courtesies to healthcare practitioners, could implicate the Anti-Kickback Statute and may not be protected by an exception or safe harbor. If the government determines that these activities are abusive, we could be subject to enforcement action. Penalties for Anti-Kickback Statute violations may include both criminal penalties such as imprisonment and civil sanctions such as fines and possible exclusion from Medicare, Medicaid, and other federal healthcare programs. Exclusion would mean that our products were no longer eligible for reimbursement under federal healthcare programs.

Laws and regulations have also been enacted by the federal government and various states to regulate the sales and marketing practices of medical device and pharmaceutical manufacturers. The laws and regulations generally limit financial interactions between manufacturers and healthcare providers; require pharmaceutical and medical device companies to comply with voluntary compliance standards issued by industry associations and the relevant compliance guidance promulgated by the U.S. federal government; and/or require disclosure to the government and/or public of financial interactions, so-called “sunshine laws”.

The healthcare laws and regulations applicable to us, including those described above, contain ambiguous requirements and are subject to evolving interpretations and enforcement discretion. Manufacturers must adopt reasonable interpretations of requirements if there is ambiguity and those interpretations could be challenged. If a governmental authority were to conclude that we are not in compliance with applicable laws and regulations, we and our officers and employees could be subject to severe criminal and civil financial penalties, including, for example, exclusion from participation as a supplier of product to beneficiaries covered by Medicare or Medicaid. Any failure to comply with laws and regulations relating to reimbursement and healthcare goods and services could adversely affect our reputation, business, financial condition and cash flows.

International Laws

Many foreign countries have similar laws relating to healthcare fraud and abuse. Foreign laws and regulations may vary greatly from country to country. For example, the advertising and promotion of our products is subject to EU Directives concerning misleading and comparative advertising and unfair commercial practices, as well as other EU member state legislation governing the advertising and promotion of medical devices. Sometimes the relevant rules are found in industry guidance rather than legislation—for example, relationships with healthcare professionals in the U.K. are governed by the code of Association of British Healthcare Industries, or the ABHI Code, and rules may limit or restrict the advertising and promotion of our products to the general public and impose limitations on our promotional activities with healthcare professionals.

In the European Union the consequences for failing to comply with advertising and promotional laws might lead to reputational damage, fines, exclusions from public tenders and actions for damages from competitors for unfair competition.

Laws with Extra-territorial Effect

Many countries in which we operate have laws with extra-territorial effect—those laws apply to our operations outside the relevant country, to the extent they are breached. Examples of such laws include: FCPA, Bribery Act and the GDRP.

The extra-territorial effect of those laws affects our sales and marketing strategy, since in many countries healthcare professionals are officers of the state. This is particularly important in the context of bribery offences, which in the U.K. and in the United States include the offence of bribing a foreign public official.

Data Privacy and Security Laws

We are, or in the future may, become subject to various U.S. federal and state as well as foreign laws that protect the confidentiality of certain patient health information, including patient medical records, and restrict the use and disclosure of patient health information by healthcare providers.

HIPAA proscribes the conduct of certain electronic healthcare transactions and requires certain entities, called covered entities, to handle and protect, among other things, the privacy and security of protected health information, or PHI, in certain ways. HIPAA also requires business associates to enter into business associate agreements with covered entities and to safeguard a covered entity's PHI against improper use and disclosure.

HIPAA privacy regulations cover the use and disclosure of protected health information by covered entities as well as business associates, which are defined to include subcontractors that create, receive, maintain, or transmit protected health information on behalf of a business associate. These regulations also set forth certain rights that an individual may have with respect to his or her protected health information maintained by a covered entity, including the right to access or amend certain records containing protected health information, or to request restrictions on the use or disclosure of protected health information. HIPAA security regulations set forth requirements for safeguarding the confidentiality, integrity, and availability of protected health information that is electronically transmitted or electronically stored. HITECH, among other things, provides certain health information security breach notification requirements. Under these laws, the covered entity must notify any individual whose protected health information is breached as required under the breach notification rule. Although we believe that we currently are neither a "covered entity" nor a "business associate" under HIPAA, a business associate relationship may be imputed from facts and circumstances even in the absence of an actual business associate agreement. In addition, HIPAA may affect our interactions with customers who are covered entities or their business associates. The HIPAA privacy and security regulations establish a uniform federal "floor" and do not supersede state laws that may be more stringent or provide individuals with greater rights with respect to the privacy or security of, and access to, their health and other personal information.

In the European Union, we may be subject to laws relating to our collection, control, processing and other use of personal data, such as data relating to an identifiable living individual. We process personal data in relation to our operations. We process data of both our employees and our customers, including health and medical information. The data privacy regime in the European Union includes the GDPR, regarding the processing of personal data and the free movement of such data, which became applicable on May 25, 2018, the E-Privacy Directive 2002/58/EC and national laws implementing each of them. Each EU member state has transposed the requirements laid down by the Data Protection Directive and E-Privacy Directive into its own national data privacy regime and therefore the laws may differ by jurisdiction, sometimes significantly. In addition, many EU member states have passed legislation addressing areas where the GDPR permits member states to derogate from the regulation's requirements, thus leading to divergent requirements between member states in spite of the GDPR's stated goal of creating a uniform privacy law for the entire EU. We need to ensure compliance with the rules in each jurisdiction where we are established or are otherwise subject to local privacy laws. For example, we may be subject to the GDPR for processing personal data in connection with offering goods or services to persons located in the European Union or monitoring the behavior of persons located in the European Union.

GDPR requirements include that personal data may only be collected for specified, explicit and legitimate purposes based on a legal grounds, and may only be processed in a manner consistent with those purposes. Processing of personal data also needs to be adequate, relevant, not excessive in relation to the purposes for which it is collected, secure, not be transferred outside of the European Union unless certain steps are taken to ensure an adequate level of protection and not be kept for longer than necessary for the purposes of collection. To the extent that we process, control or otherwise use sensitive data relating to living individuals (for example, patients' health or medical information), more stringent rules may apply, limiting the circumstances and the manner in which we are legally permitted to process that data and transfer that data outside of the European Union. In particular, in order to process such data, explicit consent to the processing (including any cross-border transfer) usually may be required from the data subject (being the person to whom the personal data relates), though in certain cases, and depending on the jurisdiction in which the data originate or are processed, such data may be processed absent explicit consent for purposes of medical diagnosis, public interest in the area of public health or scientific research.

The new EU-wide GDPR became applicable on May 25, 2018, replacing the current data protection laws issued by each EU member state based on the Directive 95/46/EC. Unlike the Directive, which needed to be transposed at national level, the GDPR text is directly applicable in each EU member state, resulting in a more uniform application of data privacy laws across the European Union. The GDPR also imposes potentially onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and policies. It requires data controllers to be transparent and disclose to data subjects (in a concise, intelligible and easily accessible form) how their personal information is to be used, imposes limitations on retention of information, increases requirements pertaining to pseudonymized (i.e., key-coded) data, introduces mandatory data breach notification requirements and sets higher standards for data controllers to demonstrate that they have obtained valid consent for certain data processing activities. Fines for non-compliance with the GDPR may be significant. The GDPR provides that EU member states may introduce further conditions, including limitations, to the processing of genetic, biometric or health data, which could limit our ability to collect, use and share personal data, or could cause our compliance costs to increase, ultimately having an adverse impact on our business.

We are subject to the supervision of local data protection authorities in those jurisdictions where we are established or otherwise subject to applicable law.

We depend on third parties in relation to provision of our services, a number of which process personal data on our behalf. With such providers we have a practice of entering into contractual arrangements to ensure that they process personal data only according to our instructions, and that they have adequate technical and organizational security measures in place. Where personal data is being transferred outside the European Union, our policy is that it is done so in compliance with applicable data export requirements. Any failure by us or third parties to follow these policies or practices, or otherwise comply with applicable data laws, could lead to a security or privacy breach, regulatory enforcement, or regulatory or financial harm.

U.S. Healthcare Reform

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. Current and future legislative proposals to further reform healthcare or reduce healthcare costs may limit coverage of or lower reimbursement for the procedures associated with the use of our products. The cost containment measures that payors and providers are instituting and the effect of any healthcare reform initiative implemented in the future could impact our revenue from the sale of our products.

The implementation of the Affordable Care Act in the United States, for example, has changed healthcare financing and delivery by both governmental and private insurers substantially, and affected medical device manufacturers significantly. The Affordable Care Act imposed, among other things, a 2.3% federal excise tax, with limited exceptions, on any entity that manufactures or imports Class I, II and III medical devices offered for sale in the United States that began on January 1, 2013. Through a series of legislative amendments, the tax was suspended for 2016 through 2019. Absent further legislative action, the device excise tax will be reinstated on medical device sales starting January 1, 2020. The Affordable Care Act also provided incentives to programs that increase the federal government’s comparative effectiveness research, and implemented payment system reforms, including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models. Additionally, the Affordable Care Act has expanded eligibility criteria for Medicaid programs and created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. We do not yet know the full impact that the Affordable Care Act will have on our business. There have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, and we expect additional challenges and amendments in

the future. Moreover, the Trump Administration and the U.S. Congress may take further action regarding the Affordable Care Act, including, but not limited to, repeal or replacement. Most recently, the Tax Cuts and Jobs Acts was enacted, which, among other things, removes penalties for not complying with the individual mandate to carry health insurance.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, the Budget Control Act of 2011, among other things, included reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2027 unless additional Congressional action is taken. Additionally, the American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

We expect additional state and federal healthcare reform measures to be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure.

MANAGEMENT

Officers and Directors

The following table sets forth information regarding our executive officers, key employees and directors as of , 2018:

Name	Age	Position
Executive Officers		
Waleed Hassanein, M.D.	50	President, Chief Executive Officer, Director
John Carey	55	Vice President of Operations
Stephen Gordon	51	Chief Financial Officer
Tamer Khayal, M.D.	49	Chief Commercial Officer
Miriam Provost, Ph.D	57	Vice President of U.S. Regulatory and FDA Relations
John Sullivan	53	Vice President of Engineering
Key Employees		
Jacqueline Sneve, MPA	50	Vice President, Healthcare Economics and Reimbursement
Brian Thomson	50	Vice President, Human Resources
Non-Employee Directors		
James R. Tobin	74	Chairman of Board of Directors
Edward M. Basile	71	Director
James Gilbert	61	Director
Thomas J. Gunderson	68	Director
Edwin M. Kania, Jr.	61	Director

(1) Member of audit committee.
(2) Member of compensation committee.
(3) Member of nominating and corporate governance committee.

Officers and Employee Directors

Waleed H. Hassanein, M.D., age 50, our founder, has served as our President and Chief Executive Officer and as a member of our board of directors since August 1998. Prior to founding TransMedics, Inc. Dr. Hassanein completed a three-year cardiac surgery research fellowship at West Roxbury VA Medical Center and Brigham and Women's Hospital, a Harvard Medical School affiliate. Prior to his research fellowship, Dr. Hassanein completed two years of general surgery residency at Georgetown University Medical Center. Dr. Hassanein earned his M.D. degree from Georgetown University in 1993. Prior to transferring to Georgetown University, Dr. Hassanein attended Cairo University School of Medicine from 1985 to 1989, and holds a General Certificate of Education from the University of London. We believe that Dr. Hassanein is qualified to serve on our board of directors because of his extensive experience in the medical field and his extensive knowledge of our company based on his role as founder and President and Chief Executive Officer.

John Carey, age 55, has been employed by us since February 2006 and has served as our Vice President of Operations since 2013. Prior to joining TransMedics, Mr. Carey held operations management positions at Vasca, Inc., a medical device company, from 1997 to 2006 and served as Vice President of Operations at Vasca from 2004 to 2006. Prior to joining Vasca, Mr. Carey held engineering and operations management positions at C. R. Bard, Inc. and Galileo Electro-Optics Corporation. Mr. Carey holds a Bachelor's of Science degree in Mechanical Engineering from the University of Massachusetts.

Stephen Gordon, age 51, has served as our Chief Financial Officer since March 2015. Prior to joining TransMedics, Mr. Gordon was the Vice President, Financial Planning & Analysis at Analogic Corporation, a medical device and security technology company from 2010 to 2015. Before joining Analogic, Mr. Gordon held various financial leadership positions at Hologic, Inc., Cytyc Corporation, Maxtor Corporation and Hewlett-Packard Company. Mr. Gordon holds a Bachelor's degree in Finance and Accounting from the Wharton School at the University of Pennsylvania and an MBA from Boston University.

Tamer Khayal, M.D., age 49, has served as our Chief Commercial Officer since January 2018. He served as our Chief Medical Officer and Vice President of Clinical Development from 2006 to 2017 and as our Director of Clinical Development from 2001 to 2006. Prior to joining TransMedics, Dr. Khayal served for six years as Director of Clinical Affairs for Zentiva Group, a.s., a pharmaceutical company, where he led clinical research, regulatory filings and clinical sales training for the company's Middle East and Africa operations. Prior to his employment in the pharmaceutical industry, Dr. Khayal was a practicing physician. Dr. Khayal received a General Certificate of Education from the University of London and a M.D. degree from Cairo University School of Medicine.

Miriam Provost, Ph.D., age 57, has served as our Vice President of U.S. Regulatory and FDA Relations since February 2018, after serving as a key regulatory consulting advisor for us for over three years. Dr. Provost has over 23 years of experience in medical device regulatory affairs. Prior to joining TransMedics, Dr. Provost was an internationally recognized expert in FDA Regulatory Affairs and provided strategic guidance and tactical support for large and small medical device companies as a Senior Regulatory Consultant at the Biologics Consulting Group, Inc. Her expertise stems from 13 years as a reviewer and manager at the FDA where she served in a variety of roles across the agency, gaining broad knowledge and familiarity with all matters related to FDA policies, procedures and decision making. Dr. Provost earned a Bachelor's degree in Chemical Engineering from the University of Dayton and M.S. and Ph.D. degrees in Chemical Engineering from the University of Pennsylvania.

John Sullivan, age 53, has served as our Vice President of Engineering since 2012. Prior to joining TransMedics, Mr. Sullivan served as Software Development Manager at Juniper Networks and designed patient monitoring systems at Siemens Medical Systems USA, Inc. He has also held a number of roles at startups and established companies, including ViaSat, Inc., Argon Networks and Raytheon Company. Mr. Sullivan holds a Bachelor's degree in Electrical Engineering and Computer Science from Princeton University and a M.S. in Computer Engineering from Boston University.

Key Employees

Jacqueline Sneve, age 50, has served as our Vice President of Healthcare Economics and Reimbursement since April 2012. Prior to joining TransMedics, Ms. Sneve served as Vice President of Strategic Alliances at Surgical Review Corporation from 2005 to 2011. Before joining Surgical Review and during her tenure, she was a senior consultant with the Transplant Management Group. She led the National Transplant Network for Humana, Inc. from 1996 to 2005. Ms. Sneve has a Master's Degree in Public Administration with a certificate degree in Health Administration from the University of Wisconsin-Madison.

Brian Thomson, age 50, has served as our Vice President, Human Resources since September, 2018. Prior to joining TransMedics, Mr. Thomson served as Executive Director, Human Resources at Aegerion Pharmaceuticals from 2014 to 2018. Aegerion Pharmaceuticals is an indirect subsidiary of Novelion Therapeutics. Before joining Aegerion, he was the Assistant Director of Recruiting for the Broad Institute, a biomedical and genomic research center having formal affiliations with Harvard University and MIT. Before joining the Broad Institute, he held a number of senior recruiting positions at other life science firms, including Biogen Idec and Philips. Mr. Thomson holds a Bachelor's degree from the University of Tampa and an MBA from Boston College.

Non-Employee Directors

James R. Tobin, age 74, has served as Chairman of our board of directors since 2011. Mr. Tobin is the retired President and CEO of Boston Scientific Corporation, a medical device company, where he served from

1999 to 2009. Prior to Boston Scientific, Mr. Tobin was the President and CEO of Biogen Inc., and, from 1994 to 1997, its President and Chief Operating Officer. Before Biogen, Mr. Tobin spent 22 years with Baxter International Inc., rising from Financial Analyst to President and Chief Operating Officer. Mr. Tobin currently serves as a director of Corindus Vascular Robotics, Globus Medical Inc., Oxford Immunotec, Inc., each of which are public companies, and Resolys Bio, Inc., a private company. Mr. Tobin has also served on the boards of Curis, Inc., from 1995 to 2015, Medical Simulation Corp, from 2012 to 2018, CardioDX, Inc., from 2014 to 2017, Chiasma, Inc., from 2015 to 2016, and Aptus Endosystems, Inc. from 2011 to 2015. Mr. Tobin holds an AB from Harvard College and an MBA from Harvard Business School. Mr. Tobin also served to Lieutenant in the U.S. Navy. We believe Mr. Tobin is qualified to serve on our Board of Directors because of his decades of experience as President and Chief Executive Officer or Chief Operating Officer of three large biotechnology and medical device companies.

Edward M. Basile, age 71, has served as a member of our board of directors since February 2016. He is currently retired. During his 25 year tenure with the law firm King & Spalding, Mr. Basile served as Chair of the firm's FDA and Life Sciences Practice and on the firm's Policy and Compensation Committees. Mr. Basile's law practice included representing large, medium and small medical device, pharmaceutical, and biotechnology companies before the U.S. Food and Drug Administration. Mr. Basile also served in the Chief Counsel's Office of FDA as Associate Chief Counsel for Drugs & Biologics and Associate Chief Counsel for Enforcement from 1975 to 1985. Mr. Basile received a BSME from Lafayette College and a JD from George Washington University Law School. We believe the Mr. Basile's decades of experience representing medical device, pharmaceutical and biotechnology companies qualify him to serve on our Board of Directors.

James Gilbert, age 61, has served a as a member of our board of directors since June 2016. Mr. Gilbert is a senior partner of Flagship Pioneering. Before joining Flagship Pioneering in 2016, Mr. Gilbert served as a senior advisor to the investment firm General Atlantic and as a senior operating executive at Welsh, Carson, Anderson & Stowe. In addition to representing Flagship on the TransMedics board, Mr. Gilbert is also a board member of ECG Management Consultants, National Dentex Corporation, Sigilon, KSQ Therapeutics and Kintai Therapeutics. He previously served on the boards of directors of Nestlé Health Science S.A. between 2012 and 2016 and Rubius Therapeutics from 2015 to 2016. Mr. Gilbert has a BS from Cornell University and an MBA from Harvard Business School. Mr. Gilbert was also an Executive Vice President and Cardiovascular Group President at Boston Scientific and a Partner/Managing Director of the Global Healthcare Practice at Bain Consulting. We believe that Mr. Gilbert is qualified to serve on our Board of Directors due to his extensive experience advising and investing in life sciences and healthcare companies, in addition to his experience gained through serving on public company and private company boards of directors.

Thomas J. Gunderson, age 68, has served as a member of our board of directors since August 2016. Mr. Gunderson has served as Chair of the Board of Directors at the Minneapolis Heart Institute Foundation from 2015 to present, as Executive in Residence at the University of Minnesota's Medical Industry Leadership Institute from 2016 to present, as a member of the Board of Directors of Merit Medical Systems, Inc. from 2017 to present, as a member of American Heart Association Science and Technology Accelerator Committee from 2015 to 2017 and as managing director and senior research analyst at Piper Jaffray (focus on medical technology companies) from 1992 to 2016. We believe Mr. Gunderson is qualified to serve on our board of directors because of his more than 25 years of substantive experience in the medical device industry, his seasoned perspective on the challenges, trends and opportunities of publicly-traded medical device manufacturers, and understanding of our competitive position within its industry, as well as his strong background in financial and economic analysis and valuable insights regarding business development and acquisition opportunities.

Edwin M. Kania, Jr., age 61, has served as a member of our board of directors since 2003. Mr. Kania is the co-founder of Flagship Pioneering. He served as Flagship's Chairman between 2001 and 2014 and continues as Managing Partner for the three Flagship funds raised during that period. Mr. Kania also serves as Managing Partner for the predecessor OneLiberty Funds that were an early lead investor in our company. During Mr. Kania's 35 years in the venture capital industry, he has served on the boards of numerous privately and

publicly held companies, including previous board positions at Acceleron Pharma and Selecta Biosciences. Mr. Kania earned his Bachelor's degree in physics from Dartmouth College and his MBA from Harvard Business School. We believe that Mr. Kania's significant experience investing in and then serving as a board member of numerous life science companies, including several that have emerged as significant revenue businesses, make him qualified to serve on our Board of Directors.

There are no family relationships among any of our directors or executive officers.

Composition of the Board of Directors

Upon the consummation of this offering, our board of directors will consist of members, of whom were elected as directors pursuant to the board composition provisions of our stockholders' agreement among us and some of our stockholders. The board composition provisions of our stockholders' agreement will terminate upon the closing of this offering and there will be no further contractual obligations regarding the election of our directors. Our directors hold office until their successors have been elected and qualified or until their earlier death, resignation or removal.

In accordance with the terms of our restated articles of organization and amended and restated bylaws that will become effective upon the closing of this offering, all of our directors will serve for one-year terms and will be elected annually. Section 8.06(c)(2) of the Massachusetts Business Corporation Act provides that our board of directors may opt into the staggered board of directors requirements of Section 8.06(b), which provides that unless a company decides otherwise, the terms of directors of a public Massachusetts company shall be staggered by dividing the directors into three groups, as nearly equal in number as possible, with only one group of directors being elected each year. Sections 8.06(d) and (e) of the Massachusetts Business Corporation Act provide that when directors are so classified, (i) shareholders may remove directors only for cause, (ii) the number of directors shall be fixed only by the vote of the board of directors, (iii) vacancies and newly created directorships shall be filled solely by the affirmative vote of a majority of the remaining directors, and (iv) a decrease in the number of directors will not shorten the term of any incumbent director.

Our restated articles of organization and amended and restated bylaws that will become effective upon the closing of this offering provide that our directors may be removed only for cause by the affirmative vote of the holders of at least a majority of the stock entitled to vote for the election of directors.

Director Independence

Under the rules of the Nasdaq Stock Market, independent directors must comprise a majority of a listed company's board of directors within one year of the completion of its initial public offering. In addition, the rules of the Nasdaq Stock Market require that, subject to specified exceptions, each member of a listed company's audit and compensation committees be independent and that director nominees be selected or recommended for the board's selection by independent directors constituting a majority of the independent directors or by a nominating and corporate governance committee comprised solely of independent directors. Under the rules of the Nasdaq Stock Market, a director will only qualify as "independent" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that such person is "independent" as defined under Nasdaq Stock Market and the Exchange Act rules.

Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act. In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors or any other board committee: (1) accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries or (2) be an affiliated person of the listed company or any of its subsidiaries.

Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our board of directors has determined that each of our directors, with the exception of Dr. Hassanein, is an "independent director" as defined under applicable rules of the Nasdaq Stock Market, including, in the case of all the members of our audit committee other than due to his beneficial ownership of greater than 10% of the shares of our common stock, the independence criteria set forth in Rule 10A-3 under the Exchange Act, and in the case of all the members of our compensation committee, the independence criteria set forth in Rule 10C-1 under the Exchange Act. In making such determination, our board of directors considered the relationships that each such non-employee director has with our Company and all other facts and circumstances that our board of directors deemed relevant in determining his or her independence, including the beneficial ownership of our capital stock by each non-employee director. Dr. Hassanein is not an independent director under these rules because he is our President and Chief Executive Officer.

Board Committees

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee, each of which will operate pursuant to a charter to be adopted by our board of directors and which will be effective upon the closing of this offering. The board of directors may also establish other committees from time to time to assist us and the board of directors in their duties. Upon the effectiveness of the registration statement of which this prospectus forms a part, the composition and functioning of all of our committees will comply with all applicable requirements of the Sarbanes-Oxley Act, the Nasdaq Stock Market and the Exchange Act. Upon our listing on Nasdaq, each committee's charter will be available on the corporate governance section of our website at www.transmedics.com. Information contained on our website is not incorporated by reference into this prospectus, and you should not consider information contained on our website to be part of this prospectus or in deciding whether to purchase shares of our common stock.

Audit Committee

The audit committee's responsibilities upon completion of this offering will include:

- appointing, approving the compensation of, and evaluating the qualifications, performance and independence of our registered public accounting firm;
- overseeing the work of our registered public accounting firm, including through the receipt and consideration of reports from such firm;
- reviewing and discussing with management and the registered public accounting firm our annual and quarterly financial statements and related disclosures;
- coordinating our board of directors' oversight of our internal control over financial reporting, disclosure controls and procedures, and code of business conduct and ethics;
- discussing our risk management policies with management;
- establishing policies regarding hiring employees from the registered public accounting firm and procedures for the receipt and retention of accounting related complaints and concerns;
- meeting independently with our registered public accounting firm and management;
- reviewing and approving or ratifying any related person transactions;
- overseeing the integrity of our information technology systems, process and data;
- preparing the audit committee report required by SEC rules;
- reviewing and assessing the adequacy of the audit committee's charter; and
- performing, on an annual basis, an evaluation of the performance of the audit committee.

All audit services and all non-audit services, other than de minimis non-audit services, to be provided to us by our independent registered public accounting firm must be approved in advance by our audit committee.

The members of our audit committee are , and . chairs the audit committee. Our board of directors has determined that and of the audit committee satisfies the independence standards for audit committee purposes as that term is defined by the applicable rules of the Nasdaq Stock Market and the Exchange Act, and that each has sufficient knowledge in financial and auditing matters to serve on the audit committee. Our board of directors has also determined is an "audit committee financial expert," as defined under Item 407 of Regulation S-K.

Compensation Committee

Our compensation committee's responsibilities upon completion of this offering will include:

- assisting our board of directors in developing and reviewing potential candidates for executive positions;
- reviewing our overall compensation strategy, including base salary, incentive compensation and equity-based grants;
- reviewing and approving corporate goals and objectives relevant to compensation of our chief executive officer and our other executive officers;
- reviewing and making recommendations to the board of directors with respect to director compensation;
- overseeing and administering our cash and equity incentive plans;
- reviewing, considering and selecting, to the extent determined to be advisable, a peer group of appropriate companies for purposing of benchmarking and analysis of compensation for our executive officers and directors;
- retaining, appointing or obtaining advice of a compensation consultant, legal counsel or other advisor, and determining the compensation and independence of such consultant or advisor;
- preparing the compensation committee report on executive compensation for inclusion in our annual proxy statement in accordance with the proxy rules;
- monitoring our compliance with the requirements of Sarbanes-Oxley relating to loans to directors and officers;
- overseeing our compliance with applicable SEC rules regarding shareholder approval of certain executive compensation matters;
- reviewing the risks associated with our compensation policies and practices;
- reviewing and assessing the adequacy of the compensation committee's charter; and
- performing, on an annual basis, an evaluation of the performance of the compensation committee.

The members of our compensation committee are , and . chairs the compensation committee. Prior to establishing a compensation committee, our board of directors made decisions relating to the compensation of our executive officers. Our board of directors has determined that each member of the compensation committee satisfies the independence standards of the applicable rules of the Nasdaq Stock Market and Rule 10C-1 of the Exchange Act and "non-employee directors" as defined in Section 16b-3 of the Exchange Act.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee's responsibilities upon completion of this offering will include:

- identifying individuals qualified to become members of our board of directors consistent with criteria approved by the board and receiving nominations for such qualified individuals;
- recommending to our board of directors the persons to be nominated for election as directors and to each committee of the board;
- establishing a policy under which our shareholders may recommend a candidate to the nominating and corporate governance committee for consideration for nomination as a director;
- articulating to each of our directors the expectations of serving on our board, including basic duties and responsibilities with respect to attendance and advance review of meeting materials;
- developing and recommending to our board of directors a set of corporate governance principals applicable to us and reviewing the principles on at least an annual basis;
- reviewing and making recommendations to our board with respect to our board leadership structure and board committee structure;
- reviewing, in concert with our board of directors, our policies with respect to significant issues of corporate public responsibility;
- making recommendations to our board of directors processes for annual evaluations of the performance of our board of directors, the chairman of our board of directors, our chief executive officer and committees of our board of directors;
- considering and reporting to our board of directors any questions of possible conflicts of interest of members of our board of directors;
- providing new director orientation and continuing education for existing directors on a periodic basis;
- overseeing the maintenance and presentation to the Board of management's plans for succession to senior management positions in the Company;
- reviewing and assessing the adequacy of the nominating and corporate governance committee's charter; and
- performing, on an annual basis, an evaluation of the performance of the nominating and corporate governance committee.

The members of our nominating and corporate governance committee are , and . chairs the nominating and corporate governance committee. Our board of directors has determined that each member of the nominating and corporate governance committee satisfies the independence standards of the applicable rules of the Nasdaq Stock Market.

Our board of directors may establish other committees from time to time.

Compensation Committee Interlocks and Insider Participation

None of the members of our compensation committee has at any time during the prior three years been one of our officers or employees. None of our executive officers currently serves, or in the past fiscal year has served, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving on our board of directors or compensation committee.

Code of Business Conduct and Ethics

Prior to the completion of this offering, we intend to adopt a written code of business conduct and ethics, which will become effective upon the closing of this offering, that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. Following this offering, we will post a current copy of the code on our website. In addition, we intend to post on our website all disclosures that are required by law or Nasdaq Stock Market rules concerning any amendments to, or waivers from, any provision of the code.

EXECUTIVE COMPENSATION

Introduction

This section provides an overview of the compensation of our principal executive officer and our next two most highly-compensated executive officers for our fiscal year ended December 30, 2017. These individuals, who we refer to as our "named executive officers" in this prospectus, are:

- Waleed Hassanein, M.D., our President and Chief Executive Officer;
- Tamer Khayal, M.D., our Chief Commercial Officer; and
- Stephen Gordon, our Chief Financial Officer.

This section also provides an overview of certain compensation arrangements that we currently anticipate adopting in connection with this offering. The actual compensation arrangements that we adopt in connection with this offering may materially differ from the arrangements described herein.

Summary Compensation Table

The following table sets forth the compensation awarded to, earned by, or paid to our named executive officers in respect of their service to TransMedics, Inc. during our fiscal year ended December 30, 2017.

Name and Principal Position	Year	Salary ($)	Bonus ($)(1)	Option Awards ($)(2)	Total ($)
Waleed Hassanein, M.D. *President and Chief Executive Officer*	2017	350,769	96,000	154,548	601,317
Tamer Khayal, M.D. *Chief Commercial Officer*	2017	304,615	94,500	33,117	432,232
Stephen Gordon *Chief Financial Officer*	2017	269,808	96,250	27,598	393,656

(1) The amounts reported in this column represent the annual bonuses paid to our named executive officers for our fiscal year ended December 30, 2017, as described in more detail under "Annual Bonuses" below.

(2) The amounts reported in this column represent the aggregate grant-date fair value of options to purchase our common stock granted to Drs. Hassanein and Khayal and Mr. Gordon in our fiscal year ended December 30, 2017, computed in accordance with FASB ASC 718, excluding the effect of estimated forfeitures. The assumptions used to value the options for this purpose are set forth in Note 11 to our consolidated financial statements included elsewhere in this prospectus.

Narrative Disclosure to Summary Compensation Table

Base Salaries

From January 1, 2017 until June 21, 2017, the annual base salaries for Drs. Hassanein and Khayal and Mr. Gordon were $320,000, $295,000 and $265,000, respectively. Effective June 22, 2017, the annual base salaries for Drs. Hassanein and Khayal and Mr. Gordon were increased to $384,000, $315,000 and $275,000, respectively. In connection with this offering, our board of directors anticipates increasing the annual base salaries for Drs. Hassanein and Khayal and Mr. Gordon to $484,000, $375,000 and $360,000, respectively.

Annual Bonuses

Each of our named executive officers is eligible to receive an annual bonus in the discretion of our compensation committee. The annual bonus targets for Dr. Khayal and Mr. Gordon for fiscal 2017 were 30% of

their annual base salaries. Dr. Hassanein did not have a formal annual bonus target for fiscal 2017. Our compensation committee determined the amount of the annual bonuses paid to our named executive officers for fiscal 2017 based on individual and Company performance. The amounts paid in respect of annual bonuses for fiscal 2017 is reported under the "Bonus" column in the Summary Compensation Table above. In connection with this offering, our board of directors anticipates increasing the annual bonus targets for Drs. Hassanein and Khayal and Mr. Gordon to 90%, 45% and 45%, respectively, of their annual base salaries.

Equity Compensation

On June 22, 2017, Dr. Hassanein was granted an option to purchase 798,287 shares of our common stock, Dr. Khayal was granted an option to purchase 171,061 shares of our common stock, and Mr. Gordon was granted an option to purchase 142,551 shares of our common stock. These stock options were granted under our 2014 Plan, described below, and vest on a monthly basis over four years, generally subject to the named executive officer's continued employment on each applicable vesting date. Our named executive officers also hold stock options that were granted in fiscal years prior to 2017. See the "Outstanding Equity Awards at Fiscal Year-End Table" below for more information regarding the outstanding stock options held by our named executive officers as of December 30, 2017.

Agreements with our Named Executive Officers

We have entered into offer letters with each of Dr. Khayal and Mr. Gordon that set forth the initial terms and conditions of his employment with us, including, with respect to Mr. Gordon, his eligibility for a discretionary annual bonus of up to 30% of his annual base salary. We have also entered into a retention agreement with each of our named executive officers that provides for severance payments and benefits in the event the named executive officer's employment is terminated in certain circumstances. In addition, each of our named executive officers has entered into an invention and non-disclosure disclosure agreement and a non-competition and non-solicitation agreement with us. The material terms of these agreements are summarized below. As used in the summary below, the terms "cause," "disability," "good reason" and "change in control" have the meanings set forth in the applicable agreement.

Dr. Hassanein. Pursuant to his retention agreement, Dr. Hassanein is entitled to severance benefits in the event we terminate his employment other than for cause or due to his death or disability or if Dr. Hassanein resigns for good reason. If his employment terminates in such circumstances, Dr. Hassanein will be entitled to receive (i) an amount equal to the sum of his highest annual base salary during the preceding three years and his highest annual bonus during the preceding three years, payable in 12 monthly installments; (ii) Company-provided benefits for up to 12 months; (iii) an additional 12 months of service credit for purposes of eligibility for any retiree benefits; and (iv) any accrued but unpaid compensation and benefits, including a prorated annual bonus for the year in which his employment terminates, based on Dr. Hassanein's annual bonus for the preceding year, subject, in each case, to his execution of a release of claims and compliance with the material provisions of any employment, consulting, advisory, nondisclosure, non-competition or similar agreement with us. If his employment terminates in such circumstances either in connection with or in anticipation of, or within 24 months following, a change in control, then, in lieu of the payments and benefits described above, Dr. Hassanein will be entitled to receive (A) an amount equal to one and one-half times (1.5x) the sum of his highest annual base salary during the preceding three years and his highest annual bonus during the preceding three years, payable in a lump sum; (B) Company-provided benefits for up to 18 months; (C) an additional 18 months of service credit for purposes of eligibility for any retiree benefits; (D) accelerated vesting of all of his then-outstanding and unvested stock options, restricted stock, and other equity-based awards; and (E) any accrued but unpaid compensation and benefits, including a prorated annual bonus for the year in which his employment terminates, based on Dr. Hassanein's annual bonus for the preceding year.

Dr. Khayal. Pursuant to his retention agreement, Dr. Khayal is entitled to severance benefits in the event we terminate his employment other than for cause or due to his death or disability or if Dr. Khayal resigns for good

reason. If his employment terminates in such circumstances, Dr. Khayal will be entitled to receive (i) an amount equal to three-fourths times (.75x) the sum of his highest annual base salary during the preceding three years and his highest annual bonus during the preceding three years, payable in nine monthly installments; (ii) Company-provided benefits for up to nine months; (iii) an additional nine months of service credit for purposes of eligibility for any retiree benefits; and (iv) any accrued but unpaid compensation and benefits, including a prorated annual bonus for the year in which his employment terminates, based on Dr. Khayal's annual bonus for the preceding year, subject, in each case, to his execution of a release of claims and compliance with the material provisions of any employment, consulting, advisory, nondisclosure, non-competition or similar agreement with us. If his employment terminates in such circumstances either in connection with or in anticipation of, or within 24 months following, a change in control, then, in lieu of the payments and benefits described above, Dr. Khayal will be entitled to receive (A) an amount equal to the sum of his highest annual base salary during the preceding three years and his highest annual bonus during the preceding three years, payable in a lump sum; (B) Company-provided benefits for up to 12 months; (C) an additional 12 months of service credit for purposes of eligibility for any retiree benefits; (D) accelerated vesting of all of his then-outstanding and unvested stock options, restricted stock, and other equity-based awards; and (E) any accrued but unpaid compensation and benefits, including a prorated annual bonus for the year in which his employment terminates, based on Dr. Khayal's annual bonus for the preceding year.

Mr. Gordon. Pursuant to his retention agreement, Mr. Gordon is entitled to severance benefits in the event we terminate his employment other than for cause or due to his death or disability or if Mr. Gordon resigns for good reason. If his employment terminates in such circumstances, Mr. Gordon will be entitled to receive (i) an amount equal to three-fourths times (.75x) the sum of his highest annual base salary during the preceding three years and his highest annual bonus during the preceding three years, payable in nine monthly installments; (ii) Company-provided group health insurance benefits for up to nine months; and (iii) any accrued but unpaid compensation and benefits, including a prorated annual bonus for the year in which his employment terminates, based on Mr. Gordon's annual bonus for the preceding year. If his employment terminates in such circumstances either in connection with or in anticipation of, or within 24 months following, a change in control, then, in lieu of the payments and benefits described above, Mr. Gordon will be entitled to receive (A) an amount equal to the sum of his highest annual base salary during the preceding three years and his highest annual bonus during the preceding three years, payable in a lump sum; (B) Company-provided group health insurance benefits for up to 12 months; (C) accelerated vesting of all of his then-outstanding and unvested stock options, restricted stock, and other equity-based awards; and (D) any accrued but unpaid compensation and benefits, including a prorated annual bonus for the year in which his employment terminates, based on Mr. Gordon's annual bonus for the preceding year. The foregoing severance payments and benefits are conditioned upon Mr. Gordon's execution of a release of claims and his compliance with the material provisions of any employment, consulting, advisory, nondisclosure, non-competition, or similar agreement with us.

Restrictive Covenants. Each of our named executive officers has entered into an invention and non-disclosure disclosure agreement and a non-competition and non-solicitation agreement with us that contains covenants relating to the disclosure of proprietary and confidential information and the assignment of inventions, and non-competition, no-hire and employee and customer non-solicitation covenants that apply for one year following the termination of the named executive officer's employment with us.

Severance and Change in Control Payments and Benefits

Each of our named executive officers is entitled to severance payments and benefits under his retention agreement upon a termination of employment in certain circumstances, including in connection with a change in control. These severance payments and benefits are described under "Agreements with our Named Executive Officers" above. Each of the retention agreements provides that we will not be obligated to provide any payments or benefits to the named executive officer that would constitute "excess parachute payments" within the meaning of Section 280G of the Code, unless such payments and benefits would result in a greater after-tax amount to the named executive officer.

Employee Benefits

We currently provide health and welfare benefits, including health, dental, vision, life and accidental death and dismemberment, and short- and long-term disability insurance, that are available to all of our full-time employees, including our named executive officers. In addition, we maintain a 401(k) retirement plan for the benefit of our full-time employees. We did not make any employer contributions to our 401(k) retirement plan for fiscal 2017. Our named executive officers are eligible to participate in these plans on the same basis as our other full-time employees.

Outstanding Equity Awards at Fiscal Year-End Table

The following table sets forth information about the equity awards held by our named executive officers as of December 30, 2017.

	Option Awards				
Name	Vesting Commencement Date	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Option exercise price ($)	Option expiration date
Waleed Hassanein, M.D.	06/30/2010	16,986(1)	—	16.50	06/30/2020
	09/27/2011	781,949(2)	—	0.11	09/27/2021
	05/28/2013	900,799(2)	—	0.08	05/29/2023
	06/22/2017	99,786(3)	698,501(3)	0.63	06/22/2027
Tamer Khayal, M.D.	06/30/2010	3,088(1)	—	16.50	06/30/2020
	09/27/2011	68,421(2)	—	0.11	09/27/2021
	05/28/2013	206,250(2)	—	0.08	05/29/2023
	06/22/2017	21,383(3)	149,678(2)	0.63	06/22/2027
Stephen Gordon	03/23/2015	206,250(4)	93,750(4)	0.19	04/01/2025
	06/22/2017	17,819(3)	124,732(3)	0.63	06/22/2027

(1) Represents options to purchase shares of our common stock that were granted on June 30, 2010 and were fully vested as of December 30, 2017.

(2) Represents options to purchase shares of our common stock that were granted ten years prior to the applicable expiration date listed in the table above and were fully vested as of December 30, 2017.

(3) Represents options to purchase shares of our common stock that were granted to our named executive officers on June 22, 2017. These options vest on a monthly basis over four years from the vesting commencement date set forth in the table above, generally subject to the named executive officer's continued employment. Under their retention agreements, as described under "Agreements with Named Executive Officers" above, these options will vest in full if the named executive officer's employment is terminated by us other than for cause or due to the named executive officer's death or disability or if the named executive officer resigns for good reason, in either case, in connection with or within 24 months following a change in control.

(4) Represents an option to purchase shares of our common stock that was granted to Mr. Gordon on April 1, 2015. The option vested as to 25% of the shares subject to the option on the first anniversary of the vesting commencement date set forth in the table above and vests as to the remainder of the shares on a monthly basis for three years thereafter, generally subject to Mr. Gordon's continued employment. Under his retention agreement, this option will vest in full if Mr. Gordon's employment is terminated by us other than for cause or due to his death or disability or if Mr. Gordon resigns for good reason, in either case, in connection with or within 24 months following a change in control.

Equity Plans

2004 Plan

Our 2004 Stock Incentive Plan, as amended and restated, or our 2004 Plan, provides for the grant of incentive stock options, non-statutory stock options, restricted stock and other stock-based awards to our employees, officers, directors, consultants and advisors. Our 2004 Plan is administered by our board of directors, which has the discretionary authority to, among other things, adopt, amend and repeal such administrative rules, guidelines and practices relating to the plan as it deems advisable.

As of , options to purchase shares of our common stock were outstanding under our 2004 Plan and there are no shares available for future issuance under the plan. Awards under our 2004 Plan may not be sold, assigned, transferred, pledged or otherwise encumbered other than by will or the laws of descent and distribution or (other than incentive stock options) pursuant to a qualified domestic relations order, except as otherwise determined by our board of directors.

In the event of a stock split, reverse stock split, stock dividend, recapitalization, combination of shares, reclassification of shares, spin-off or other similar change in capitalization or event, or any dividend or distribution other than an ordinary cash dividend, the number and class of securities available under the plan, the number and class of securities and the exercise price of outstanding options, the number of shares subject to outstanding restricted stock awards, and the terms of other outstanding awards shall be equitably adjusted in a manner determined by our board of directors. In the event of a reorganization event (generally, a merger or consolidation, exchange of all of our stock or a liquidation or dissolution of the Company), our board of directors shall provide that all outstanding options shall be assumed or substituted for, or, if not assumed or substituted for, or in the event of our liquidation or dissolution, our board of directors may provide for the termination of unexercised options (upon prior written notice), the accelerated vesting of options and/or the cash out of options. Further, in the event of a change of control event (generally, a change in beneficial ownership of 50% or more of our common stock or our voting power or the turnover of a majority of our board of directors), outstanding options that are assumed or substituted for will vest in full if a participant's employment is terminated without cause within 18 months following the change in control.

Our board of directors may amend, modify or terminate any outstanding award, subject to a participant's consent if such action materially and adversely affects the participant. Our board of directors may at any time amend, suspend or terminate our 2004 Plan or any portion thereof at any time.

2014 Plan

Our 2014 Stock Incentive Plan, as amended and restated, or our 2014 Plan, provides for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock, restricted stock units and other stock-based awards to our employees, officers, directors, consultants and advisors. Our 2014 Plan is administered by our board of directors, or, at the discretion of our board of directors, by a committee of our board of directors, which has the discretionary authority to, among other things, grant awards and adopt, amend and repeal such administrative rules, guidelines and practices relating to the plan as it deems advisable.

As of , options to purchase shares of our common stock were outstanding under our 2014 Plan and shares of our common stock remained available for future issuance under the plan. Shares of common stock that are subject to awards under our 2004 Plan or our 2014 Plan that expire, terminate or are otherwise surrendered, cancelled or forfeited without the issuance of stock will become available again for grant under our 2014 Plan. Awards under our 2014 Plan may not be sold, assigned or transferred, except that awards may be transferred to family members through gifts or (other than incentive stock options) domestic relations orders or to an executor or guardian upon death or disability.

In the event of a stock split, reverse stock split, stock dividend, recapitalization, reclassification of shares, spin-off or similar change in capitalization or event, or dividend or distribution other than an ordinary cash

dividend, the number and class of securities available under the plan or subject to outstanding awards and the exercise price, measurement price, purchase price or repurchase price, as the case may be, of outstanding awards, shall be equitably adjusted. In the event of a reorganization event (generally, a merger or consolidation, transfer or disposition of all of our stock or a dissolution or liquidation of the Company), our board of directors may provide for the assumption or substitution of awards, the termination of unexercised awards (upon prior written notice), the accelerated vesting of awards, the cash out of awards and/or, if applicable, the conversion of awards into the right to receive liquidation proceeds.

Our board of directors may at any time amend, modify or terminate any outstanding award, subject to a participant's consent if such action materially and adversely affects the participant's rights under the plan. Our board of directors may amend, suspend or terminate our 2014 Plan at any time.

2019 Compensation Plans

Prior to the completion of this offering, our board of directors intends to adopt the TransMedics Group, Inc. 2019 Stock Incentive Plan, or our 2019 Plan, the TransMedics Group, Inc. 2019 Employee Stock Purchase Plan, or our 2019 ESPP, and the TransMedics Group, Inc. 2019 Cash Incentive Plan, or our 2019 Cash Plan. We refer to these plans collectively as our "2019 Plans." The following summaries describe what we anticipate to be the material terms of our 2019 Plans. These summaries are not complete descriptions of all of the terms of our 2019 Plans and are qualified in their entirety by reference to our 2019 Plans, which will be filed as exhibits to the Registration Statement of which this prospectus forms a part.

2019 Plan

In General

Our 2019 Plan provides for the grant of stock and stock-based awards. The purposes of our 2019 Plan are to attract, retain and reward key employees and directors of, and consultants and advisors to, us and our subsidiaries, to incentivize them to generate stockholder value, to enable them to participate in our growth, and to align their interests with the interests of our shareholders. Following its adoption by our board of directors, our 2019 Plan will be the only plan under which we may grant stock and stock-based awards. Awards granted under our 2019 Plan are intended to be eligible for the post-initial public offering transition relief under Section 162(m) of the Code, as set forth in Section 1.162-27(f) of the Treasury Regulations, to the extent available.

Administration

Our 2019 Plan will generally be administered by our compensation committee, which will have the discretionary authority to administer and interpret the plan and any award granted under it; determine eligibility for and grant awards; determine the exercise price, base value or purchase price applicable to any awards; determine, modify and waive the terms and conditions of any award; determine the form of settlement of awards; prescribe forms, rules and procedures relating to the plan and awards; and otherwise do all things necessary or desirable to carry out the purposes of the plan or any award. Our compensation committee (or our board of directors, with respect to such matters over which it retains authority) may delegate to one or more of its members (or one or more members of our board of directors) such of its duties, powers and responsibilities as it may determine and, to the extent permitted by law, may delegate certain of its duties, powers and responsibilities to officers, employees and other persons. As used in this summary, the term "Administrator" refers to our compensation committee, our board of directors or any authorized delegates, as applicable.

Eligibility

Our and our subsidiaries' key employees, directors, consultants and advisors will be eligible to participate in our 2019 Plan. Eligibility for stock options intended to be incentive stock options, or ISOs, will be limited to our employees and those of certain of our affiliates. Eligibility for stock options other than ISOs and stock

appreciation rights, or SARs, will be limited to individuals who are providing direct services on the date of grant of the award to us or certain of our affiliates. As of , approximately employees, directors and consultants and advisors would be eligible to participate in our 2019 Plan, including all of our executive officers.

Authorized Shares

Subject to adjustment as described below, the number of shares of our common stock that may be issued in satisfaction of awards under our 2019 Plan will be shares, plus the number of shares underlying awards under our 2014 Plan (not to exceed shares) that on or after the date the 2019 Plan is adopted expire or are terminated, surrendered or cancelled without the delivery of shares, are forfeited to or repurchased by us, or otherwise become available again for grant under our 2014 Plan. The number of shares available for issuance under our 2019 Plan is referred to in this summary as the "Share Pool." A maximum of shares from the Share Pool may be issued in satisfaction of ISOs. For purposes of the Share Pool, shares will not be treated as issued, and will not reduce the Share Pool, unless and until, and to the extent, they are actually issued to a participant. Shares of stock withheld by us in payment of the exercise or purchase price of an award or in satisfaction of tax withholding requirements and shares underlying any portion of an award that is settled or that expires, becomes unexercisable, terminates or is forfeited to or repurchased by us without the issuance of stock will not reduce the Share Pool. Shares issued in substitution for equity awards of an acquired company that are converted, replaced or adjusted in connection with the acquisition will not reduce the Share Pool.

Shares that may be issued under our 2019 Plan may be authorized but unissued shares or shares acquired in an open-market transaction.

Individual Limits; Director Limits

With respect to any participant in any calendar year, the maximum number of shares subject to stock options that may be granted, the maximum number of shares subject to SARs that may be granted, and the maximum number of shares subject to awards other than stock options and SARs that may be granted is shares, shares and shares, respectively.

Types of Awards

Our 2019 Plan provides for the grant of stock options, SARs, restricted and unrestricted stock and stock units, performance awards, and other awards that are convertible into or otherwise based on our common stock. Dividend equivalents may also be provided in connection with awards under our 2019 Plan.

- *Stock Options and SARs.* The Administrator may grant stock options, including ISOs, and SARs. A stock option is a right entitling the holder to acquire shares of our common stock upon payment of the applicable exercise price. A SAR is a right entitling the holder upon exercise to receive an amount (payable in cash or shares of equivalent value) equal to the excess of the fair market value of the shares subject to the right over the base value from which appreciation is measured. The per share exercise price of each stock option, and the per share base value of each SAR, granted under our 2019 Plan may not be less than 100% of the fair market value of a share of our common stock on the date of grant (110% in the case of certain ISOs).
- *Restricted and Unrestricted Stock and Stock Units.* The Administrator may grant awards of stock, stock units, restricted stock and restricted stock units. A stock unit is an unfunded and unsecured promise, denominated in shares, to deliver shares or cash measured by the value of shares in the future, and a restricted stock unit is a stock unit that is subject to the satisfaction of specified performance or other vesting conditions. Restricted stock is stock subject to restrictions requiring that it be forfeited, redelivered or offered for sale to us if specified performance or other vesting conditions are not satisfied.

- *Performance Awards.* The Administrator may grant performance awards, which are awards subject to performance vesting conditions, including the performance criteria described below.
- *Other Stock-Based Awards*. The Administrator may grant other awards that are convertible into or otherwise based on shares of our common stock, subject to such terms and conditions as are determined by the Administrator.
- *Substitute Awards*. The Administrator may grant substitute awards, which may have terms and conditions that are inconsistent with the terms and conditions of our 2019 Plan.

Vesting; Terms and Conditions of Awards

The Administrator will determine the terms and conditions of all awards granted under our 2019 Plan, including the time or times an award vests or becomes exercisable, the terms and conditions on which an option or SAR remains exercisable, and the effect of termination of a participant's employment or service on awards. The Administrator may at any time accelerate the vesting or exercisability of an award.

Transfer Restrictions

Except as the Administrator may otherwise determine, awards may not be transferred other than by will or by the laws of descent and distribution.

Performance Criteria

Our 2019 Plan provides for grants of performance awards subject to "performance criteria." Performance criteria may be applied to a participant individually, to a business unit or division of ours or to us as a whole and may relate to any or any combination of the following or any other criterion or criteria determined by the Administrator (measured either absolutely or comparatively (including, without limitation, by reference to an index or indices or the performance of one or more companies) and determined either on a consolidated basis or, as the context permits, on a divisional, subsidiary, line of business, project or geographical basis or in combinations thereof and subject to such adjustments, if any, as the Administrator specifies): sales; revenues; assets; expenses; earnings before or after deduction for all or any portion of interest, taxes, depreciation, or amortization, whether or not on a continuing operations or an aggregate or per share basis; return on equity, investment, capital or assets; one or more operating ratios; borrowing levels, leverage ratios or credit rating; market share; capital expenditures; cash flow; stock price; stockholder return; sales of particular products or services; customer acquisition or retention; acquisitions and divestitures (in whole or in part); joint ventures and strategic alliances; spin-offs, split-ups and the like; reorganizations; recapitalizations, restructurings, financings (issuance of debt or equity) or refinancings; or strategic business criteria, consisting of one or more objectives based on: meeting specified market penetration or value added, product development or introduction (including, without limitation, any clinical trial accomplishments, regulatory or other filings or approvals, or other product development milestones), geographic business expansion, cost targets, cost reductions or savings, customer satisfaction, operating efficiency, acquisition or retention, employee satisfaction, information technology, corporate development (including, without limitation, licenses, innovation, research or establishment of third-party collaborations), manufacturing or process development, legal compliance or risk reduction, or patent application or issuance goals. Performance criteria may also be based on individual performance and/or subjective performance criteria not listed above and may be adjusted in a manner to reflect events occurring during the performance period that affect the performance criteria.

Effect of Certain Transactions

In the event of certain covered transactions (including a consolidation, merger or similar transaction, a sale of substantially all of our assets or common stock, a change in control, or a dissolution or liquidation of our

company, the Administrator may, with respect to outstanding awards, provide for (in each case, on such terms and conditions as it determines):

- The assumption, continuation or substitution for some or all awards (or any portion thereof) by the acquirer or surviving entity;
- The acceleration of exercisability or issuance of shares in respect of any award (or any portion thereof), in full or in part; and/or
- A cash payment in respect of some or all awards (or any portion thereof) equal to the difference between the fair market value of the shares subject to the award and its exercise or base price, if any.

Except as the Administrator may otherwise determine, each award will automatically terminate immediately upon the consummation of the covered transaction, other than awards that are substituted for, assumed or continued or awards that by their terms continue following the covered transaction.

Adjustment Provisions

In the event of a stock dividend, stock split or combination of shares (including a reverse stock split), recapitalization or other change in our capital structure, the Administrator will make appropriate adjustments to the maximum number of shares that may be issued under our 2019 Plan, the individual limits described above, the number and kind of securities subject to, and, if applicable, the exercise or purchase prices (or base values) of, outstanding awards, and any other provisions affected by such event. The Administrator may also make such adjustments to take into account other distributions to stockholders or any other event if it determines that adjustments are appropriate to avoid distortion in the operation of our 2019 Plan or any award.

Clawback

The Administrator may provide that any outstanding award or the proceeds from, or other amounts received in respect of, any award or stock acquired under any award will be subject to forfeiture and disgorgement to us, with interest and related earnings, if the participant to whom the award was granted is not in compliance with the plan or the applicable award or any non-competition, non-solicitation, no-hire, non-disparagement, confidentiality, invention assignment or other restrictive covenant. Each award will be subject to any of our policies or those of our subsidiaries that provides for the forfeiture, disgorgement or clawback with respect to incentive compensation that includes awards under the plan and will be subject to forfeiture and disgorgement to the extent required by law or applicable stock exchange listing standards.

Amendment and Termination

The Administrator may at any time amend our 2019 Plan or any outstanding award and may at any time terminate our 2019 Plan as to future grants. However, except as expressly provided in our 2019 Plan or the applicable award, the Administrator may not alter the terms of an award so as to materially and adversely affect a participant's rights without the participant's consent, unless the Administrator expressly reserved the right to do so at the time the award was granted. Any amendments to our 2019 Plan will be conditioned on shareholder approval to the extent required by law or applicable stock exchange requirements.

2019 ESPP

In General

Our 2019 ESPP is intended to enable eligible employees to use payroll deductions to purchase shares of our common stock, and thereby acquire an interest in us. Our 2019 ESPP will generally be implemented

by a series of separate offerings, which we refer to as option periods. On the first day of each option period, participating employees will be granted an option to purchase shares of our common stock, which will be automatically exercised on the last business day of the option period. Our 2019 ESPP is intended to satisfy the requirements of Section 423 of the Code. As of the date of this prospectus, no options to purchase shares of our common stock have been granted under our 2019 ESPP.

Administration

Our 2019 ESPP will generally be administered by our compensation committee, which will have the discretionary authority to interpret the plan; determine eligibility under the plan; prescribe forms, rules and procedures relating to the plan; and otherwise do all things necessary or appropriate to carry out the purposes of the plan. Our compensation committee (or our board of directors, with respect to such matters over which it retains authority) may delegate to one or more of its members (or one or more members of our board of directors) such of its duties, powers and responsibilities as it may determine and, to the extent permitted by law, may delegate certain of its duties, powers and responsibilities to officers, employees and other persons. As used in this summary, the term "Administrator" refers to our compensation committee, our board of directors or any authorized delegates, as applicable.

Eligibility

Participation in our 2019 ESPP will generally be limited to our employees and those of our participating subsidiaries (i) who have been continuously employed by us or our subsidiary, as applicable, for a period of at least ten business days as of the first day of an applicable option period; (ii) whose customary employment with us or our subsidiary, as applicable, is for more than five months per calendar year; (iii) who customarily work twenty hours or more per week; and (iv) who satisfy the requirements set forth in our 2019 ESPP. The Administrator may establish additional or other eligibility requirements, or change the requirements described in this paragraph, to the extent consistent with Section 423 of the Code. No employee may be granted an option under our 2019 ESPP if, immediately after the option is granted, the employee would own (or would be deemed to own) shares of our common stock possessing five percent or more of the total combined voting power or value of all classes of shares of us or our subsidiaries, if any. As of , approximately employees would be eligible to participate in our 2019 ESPP, including all of our executive officers.

Authorized Shares

Subject to adjustment as described below, the number of shares of our common stock that are available for issuance under our 2019 ESPP will be shares. The number of shares available for issuance under our 2019 ESPP is referred to in this summary as the "Share Pool." For purposes of the Share Pool, shares will not be treated as issued, and will not reduce the Share Pool, unless and until, and to the extent, they are actually issued to a participant. If any option expires or terminates for any reason without having been exercised in full or ceases for any reason to be exercisable in whole or in part, the unpurchased shares subject to such option will not reduce the Share Pool.

Shares that may be issued under our 2019 ESPP may be authorized but unissued shares or shares acquired in an open-market transaction.

Participation

Eligible employees may participate in an option period under our 2019 ESPP by delivering a payroll deduction authorization to the Administrator authorizing a whole percentage of the employee's eligible compensation, between one percent and ten percent of the employee's eligible compensation, to be deducted from the employee's pay during the option period. The payroll deduction authorization must be delivered no later

than ten business days prior to the first day of the option period (or such other period specified by the Administrator). A payroll deduction authorization under our 2019 ESPP will remain in effect for subsequent option periods unless a participant delivers a new payroll deduction authorization or the participant's participation in our 2019 ESPP is terminated.

Option Periods

Unless otherwise determined by the Administrator, option periods under our 2019 ESPP will be six months in duration and commence on the first business day of January and July of each year.

Options

Subject to the limitations in our 2019 ESPP, as described in this summary, on the first day of each option period, participating employees will be granted an option to purchase shares of our common stock, except that no participant will be granted an option under our 2019 ESPP that permits the participant's right to purchase shares of our common stock under our 2019 ESPP and under all of our other employee stock purchase plans or those of our subsidiaries, if any, to accrue at a rate that exceeds $25,000 in fair market value (or such other maximum as may be prescribed by the Code) for each calendar year during which any option granted to the participant is outstanding at any time, determined in accordance with Section 423 of the Code.

Each option granted under our 2019 ESPP for an option period, unless earlier cancelled, will be automatically exercised on the last business day of the option period. Upon exercise, shares will be purchased using the participant's accumulated payroll deductions for the option period, which will be maintained on our books in a notional account. A participant may purchase a maximum of shares of our common stock with respect to any option period (or such lesser number of shares as the Administrator may prescribe).

Purchase Price

The purchase price of each share issued pursuant to the exercise of an option under our 2019 ESPP on an exercise date will be 85% (or such greater percentage as specified by the Administrator) of the lesser of (i) the fair market value of a share on the date the option is granted and (ii) the fair market value of a share on the exercise date.

Termination

A participant may cancel his or her option and terminate his or her participation in our 2019 ESPP by timely delivering a notice to the Administrator. Upon termination of a participant's employment prior to an exercise date for an option period, or if a participant ceases to be eligible to participate in the plan, the participant's option will be cancelled automatically. Upon cancellation, the balance of the participant's account will be returned to the participant, without interest, as soon as administratively practicable.

Transfer Restrictions

For participants who have purchased shares under our 2019 ESPP, the Administrator may impose restrictions prohibiting the transfer, sale, pledge or alienation of such shares, other than by will or by the laws of descent and distribution, for such period as may be determined by the Administrator.

Effect of Certain Transactions

In the event of certain covered transactions (including a consolidation, merger or similar transaction, a sale of substantially all of our assets or common stock, a change in control, or a dissolution or liquidation of our company

or such other corporate transaction as is determined by the Administrator), the Administrator may (i) provide that each outstanding option will be assumed or exchanged for a substitute option; (ii) cancel each outstanding option and return the participants' accounts; and/or (iii) terminate the option period on or before the date of the covered transaction.

Adjustment Provisions

In the event of a stock dividend, stock split or combination of shares (including a reverse stock split), recapitalization or other change in our capital structure, the Administrator will make appropriate adjustments to the aggregate number and type of shares available for purchase under our 2019 ESPP, the maximum number and type of shares purchasable under any outstanding option, and/or the purchase price under any outstanding option.

Amendment and Termination

The Administrator has the discretion to change the commencement and exercise dates of option periods, the purchase price, the maximum number of shares that may be purchased with respect to any option period, the duration of any option periods and other terms of our 2019 ESPP, in each case, without shareholder approval, except as required by law. The Administrator may at any time amend, suspend or terminate our 2019 ESPP, provided that any amendment that would be treated as the adoption of a new plan for purposes of Section 423 of the Code will require shareholder approval.

2019 Cash Plan

In General

Our 2019 Cash Plan provides for the grant of cash-based incentive awards to our executive officers and key employees and those of our subsidiaries. The purposes of our 2019 Cash Plan are to attract, retain and reward our executive officers and key employees and those of our subsidiaries, to incentivize them to generate stockholder value, and to enable them to participate in our growth. For fiscal years beginning following its adoption by our board of directors, our 2019 Cash Plan is intended to be the only plan under which we grant cash-based incentive awards to our executive officers. Awards granted under our 2019 Cash Plan are intended to be eligible for the post-initial public offering transition relief under Section 162(m) of the Code, as set forth in Section 1.162-27(f) of the Treasury Regulations, to the extent available.

Administration

Our 2019 Cash Plan will generally be administered by our compensation committee, which will have the discretionary authority to administer and interpret the plan and any award granted under it; determine eligibility for and grant awards; adjust the performance criteria applicable to awards; determine, modify or waive the terms and conditions of any award; prescribe forms, rules and procedures relating to the plan and awards; and otherwise do all things necessary or desirable to carry out the purposes of the plan or any award. Our compensation committee (or our board of directors, with respect to such matters over which it retains authority) may delegate to one or more of its members (or one or more members of our board of directors) such of its duties, powers and responsibilities as it may determine and, to the extent permitted by law, may delegate certain of its duties, powers and responsibilities to officers, employees and other persons. As used in this summary, the term "Administrator" refers to our compensation committee, our board of directors or any authorized delegates, as applicable.

Eligibility and Participation

Our and our subsidiaries' executive officers and key employees will be eligible to participate in our 2019 Cash Plan. As of , approximately employees would be eligible to participate in our 2019 Cash Plan, including all of our executive officers.

Individual Limits

The maximum amount paid to any participant in any calendar year pursuant to awards granted under our 2019 Cash Plan will be $, determined without regard to any elective deferrals of any award payments.

Awards

The Administrator will select the participants who receive awards for each performance period under the plan and, for each award, will establish (i) the performance criteria applicable to the award; (ii) the amount payable if the performance criteria are achieved in whole or in part; and (iii) such other terms and conditions as it determines.

Performance Criteria

Awards under our Cash Plan will be made based on, and subject to achieving, specified criteria established by the Administrator. Performance criteria may be applied to a participant individually, to a business unit or division of ours or to us as a whole and may relate to any or any combination of the performance criteria described under "2019 Plan—Performance Criteria."

Determination of Performance; Amounts Payable under Awards

As soon as practicable following the end of a performance period, the Administrator will determine whether and to what extent the performance criteria applicable to each award have been satisfied and the amount payable under each award. The Administrator may adjust the actual payment to be made with respect to any award in its discretion.

Clawback

The Administrator may provide that any outstanding award and any amounts received in respect of any award will be subject to forfeiture and disgorgement, with interest and other related earnings, to us if the participant to whom the award was granted is not in compliance with the plan or any applicable award or any non-competition, non-solicitation, no-hire, non-disparagement, confidentiality, invention assignment or other restrictive covenant. Each award will be subject to any of our policies or those of our subsidiaries that provides for the forfeiture, disgorgement or clawback with respect to incentive compensation that includes awards under the plan and will be subject to forfeiture and disgorgement to the extent required by law or applicable stock exchange listing standards.

Amendment and Termination

The Administrator may amend our 2019 Cash Plan or any outstanding award at any time, and may terminate our 2019 Cash Plan as to future grants of awards at any time.

Director Compensation

None of our directors was paid any fees, granted any equity awards, or otherwise compensated for their service as a director during fiscal 2017. The compensation received by Dr. Hassanein for his services as an employee in fiscal 2017 is included in the "Summary Compensation Table" above and described in the accompanying narrative description. Messrs. Basile and Gunderson, were each granted an option to purchase 67,500 shares of our common stock in connection with joining our board of directors in fiscal 2016. These stock options were granted under our 2014 Plan, described above, and vest on a monthly basis over three years, generally subject to the director's continued service through the applicable vesting date. These stock options were outstanding as of December 30, 2017.

Prior to the completion of this offering, our board of directors intends to adopt a non-employee director compensation policy covering non-employee directors who are not affiliated with the Flagship Funds, as referred to in "Principal Shareholders," which policy is expected to become effective upon the completion of this offering. Non-employee directors who are affiliated with the Flagship Funds are not expected to be eligible to receive any compensation in respect of their service to our board of directors. The following summary describes what we anticipate to be the material terms of our non-employee director compensation policy.

Each non-employee director who is not affiliated with the Flagship Funds will receive an annual cash retainer for service to our board of directors and an additional annual cash retainer for service on any committee of our board of directors or for serving as the chair of our board of directors or any of its committees, in each case, pro-rated for partial years of service, as follows:

	Board or Committee Member	Board or Committee Chair
Annual cash retainer	$ 40,000	$ 75,000
Additional annual cash retainer for compensation committee	$ 7,500	$ 15,000
Additional annual cash retainer for governance committee	$ 5,000	$ 10,000
Additional annual cash retainer for audit committee	$ 10,000	$ 20,000

In connection with this offering, each non-employee director who is not affiliated with the Flagship Funds and who has not previously been granted an option to purchase shares of our common stock will be granted an option to purchase shares of our common stock having a grant date value of approximately $176,100, such option to vest as to one-third of the shares subject to the option on the first anniversary of the vesting commencement date and as to the remainder of the shares subject to the option in equal monthly installments over two years thereafter, generally subject to the non-employee director's continued service through the applicable vesting date.

Each non-employee director who is not affiliated with the Flagship Funds and is first elected to our board of directors following the completion of this offering will be granted an option to purchase shares of our common stock having a grant date value of approximately $176,100, such option to vest as to one-third of the shares subject to the option on the first anniversary of the vesting commencement date and as to the remainder of the shares subject to the option in equal monthly installments over two years thereafter, generally subject to the non-employee director's continued service through the applicable vesting date.

Commencing in 2019, each non-employee director who is not affiliated with the Flagship Funds will annually be granted an option to purchase shares of our common stock having a grant date value of approximately $111,200, such option to vest in full on the first anniversary of the vesting commencement date, generally subject to the non-employee director's continued service through the applicable vesting date.

All options granted to our non-employee directors will have a per share exercise price equal to the fair market value of a share of our common stock on the date of grant and will expire not later than ten years after the date of grant. All cash retainers will be paid quarterly, in arrears, or upon the earlier resignation or removal of the non-employee director.

CORPORATE REORGANIZATION

TransMedics Group, Inc., a recently formed Massachusetts corporation, is currently a direct, wholly-owned subsidiary of TransMedics, Inc., a Delaware corporation. Immediately prior to or concurrently with the closing of this initial public offering, TMDX, Inc., a direct, wholly-owned subsidiary of TransMedics Group, will merge with and into TransMedics, Inc. with TransMedics, Inc. as the surviving corporation.

As a result of the merger, pursuant to the terms of the Agreement and Plan of Merger and Reorganization filed as an exhibit to the Registration Statement of which this prospectus forms a part:

- each outstanding share of Series A-1 preferred stock of TransMedics, Inc. will be converted into shares of common stock of TransMedics Group;
- each outstanding share of Series B and Series B-1 preferred stock of TransMedics, Inc. will be converted into shares of common stock of TransMedics Group;
- each outstanding share of Series C, Series D, Series E and Series F preferred stock of TransMedics, Inc. will be converted into shares of common stock of TransMedics Group;
- each outstanding share of common stock of TransMedics, Inc. will be converted into shares of common stock of TransMedics Group;
- each outstanding option to purchase shares of common stock of TransMedics, Inc. will be converted into an outstanding option to purchase shares of common stock of TransMedics Group (as appropriately adjusted); and
- each outstanding warrant to purchase shares of preferred stock of TransMedics, Inc. will be converted into a warrant to purchase shares of common stock of TransMedics Group (as appropriately adjusted).

Immediately following the Corporate Reorganization, (1) TransMedics Group will be a holding company with no material assets other than 100% of the equity interests in TransMedics, Inc., (2) the holders of capital stock in TransMedics, Inc. will become shareholders of TransMedics Group and (3) the historical consolidated financial statements of TransMedics, Inc. will become the historical consolidated financial statements of TransMedics Group because the Corporate Reorganization will be accounted for as a reorganization of entities under common control. Prior to the Corporate Reorganization, TransMedics Group has not conducted any activities other than in connection with its formation and in preparation for this offering and has no material assets other than 100% of the equity interests in TMDX, Inc.

Except as otherwise noted or the context otherwise requires, all information in this prospectus gives effect to the Corporate Reorganization.

CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

Other than compensation arrangements for our executive officers and directors that are described elsewhere in this prospectus, below we describe transactions since December 28, 2014 to which we were or will be a participant and in which:

- the amounts involved exceeded or will exceed $120,000; and
- any of our directors, executive officers or holders of more than 5% of our capital stock, or any member of the immediate family of, or person sharing the household with, the foregoing persons, had or will have a direct or indirect material interest

Series F Preferred Stock Financing

In May 2015, we issued and sold an aggregate of 4,008,934 shares of our Series F preferred stock at a price per share of $4.99, for an aggregate purchase price of $20.0 million. In May 2016, we issued and sold an aggregate of 10,266,480 shares our Series F preferred stock at a price per share of $4.99, for an aggregate purchase price of $51.2 million. The following table sets forth the number of shares of our Series F preferred stock purchased by our directors, executive officers and 5% stockholders and their respective affiliates and the aggregate purchase price paid for such shares in each of the initial closing in May 2015 and the extension closing in May 2016.

Name(1)	Number of Shares of Series F Preferred Stock Purchased in Initial Closing	Aggregate Purchase Price of Series F Preferred Stock Purchased in Initial Closing	Number of Shares of Series F Preferred Stock Purchased in Extension Closing	Aggregate Purchase Price of Series F Preferred Stock Purchased in Extension Closing
Lung Biotechnology PBC (successor-in-interest to Lung LLC)	845,099	$ 4,217,044	1,529,010	$ 7,629,760
Abrams Capital Partners II, L.P.(2)	764,581	3,815,259	465,014	2,320,420
Abrams Capital Partners I, L.P.(2)	56,770	283,282	34,527	172,290
Great Hollow International, L.P.(2)	56,221	280,543	34,193	170,623
Riva Capital Partners III, L.P.(2)	686,461	3,425,440	417,502	2,083,335
Whitecrest Partners, L.P.(2)	83,474	416,535	50,768	253,332
Flagship Ventures Fund 2007, L.P.(3)	250,558	1,250,284	200,400	999,996
Flagship Ventures IV, L.P.(3)	551,229	2,750,633	440,881	2,199,996
OneLiberty Ventures 2000, L.P.(4)	200,447	1,000,231	300,601	1,499,999
KPCB Holdings, Inc., as nominee	372,434	1,858,446	200,400	999,996
James R. Tobin 2012 Trust(5)	141,660	706,883	80,160	399,998
Fayerweather Fund 1, L.P.	—	—	2,505,010	12,500,000
Edward Basile(6)	—	—	50,100	249,999
Total	4,008,934	$ 20,004,580	6,308,566	$ 31,479,744

(1) See “Principal Shareholders” for more information about shares held by these entities.
(2) David Abrams, who previously served on our board of directors until , 2018, is a Managing Partner of Abrams Capital Management, LLC, which is the general partner to Abrams Capital Management, LP., which manages Abrams Capital Partners II, L.P., Abrams Capital Partners I, L.P., Great Hollow International, L.P., Riva Capital Partners III, L.P. and Whitecrest Partners, L.P.
(3) Mr. Kania, who serves on our board of directors, is a manager of each of Flagship 2007 LLC, which manages Flagship Ventures Fund 2007, L.P., and Flagship Fund IV GP, which manages Flagship Ventures IV, L.P.
(4) Mr. Kania, who serves on our board of directors, is a manager of OneLiberty Partners 2000, LLC, which manages OneLiberty Ventures 2000, L.P.
(5) James Tobin is the chairman of our board of directors.
(6) Edward Basile is a member of our board of directors.

In addition, in June 2016, we issued and sold an aggregate of 2,505,010 shares of our Series F preferred stock to Fayerweather Fund 1, L.P. at a price per share of $4.99, for an aggregate purchase price of $12.5 million.

Investor Rights Agreement

We are a party to an amended and restated investor rights agreement, dated as of June 14, 2013, as amended on May 29, 2015 and May 12, 2016, or the Investor Rights Agreement, with holders of our preferred stock, including some of our directors and 5% stockholders and their affiliates and entities affiliated with our officers and directors, which will be further amended and restated upon consummation of the Corporate Reorganization. The Investor Rights Agreement provides these holders the right, following the completion of this offering, to demand that we file a registration statement or request that their shares be covered by a registration statement that we are otherwise filing. In addition, under the Investor Rights Agreement, certain holders of warrants to purchase shares of our preferred stock following exercise of the warrants will have, with respect to the shares acquired on exercise of the warrants, the same rights to require us to register those shares as the other investor parties to the Investor Rights Agreement. See “Description of Capital Stock—Registration Rights” for additional information regarding these registration rights.

Stockholders’ Agreement

We are party to an amended and restated stockholders’ agreement, dated as of June 14, 2013, as amended on May 29, 2015, February 17, 2016 and May 12, 2016, or the Stockholders’ Agreement, with certain of our stockholders, pursuant to which the following directors were elected to serve as members on our board of directors and, as of the date of this prospectus, continue to so serve: Dr. Hassanein, Mr. Tobin, Mr. Basile, Mr. Gilbert and Mr. Kania.

The Stockholders’ Agreement will terminate upon consummation of the Corporate Reorganization and the closing of this offering, and members previously elected to our board of directors pursuant to this agreement will continue to serve as directors until they resign, are removed or their successors are duly elected by the holders of our common stock. The composition of our board of directors after this offering is described in more detail under “Management—Composition of the Board of Directors.”

Board Observer

In connection with this offering, the Abrams Capital Funds, as referred to in “Principal Shareholders”, will have the right to appoint to observe and attend meetings of the board of directors in a non-voting capacity provided that the Abrams Capital Funds collectively retain at least % of the shares it owns at the time of the closing of the offering.

Employment Arrangements

See the “Executive Compensation—Agreements with Our Named Executive Officers” section of this prospectus for a further discussion of these arrangements.

Dr. Amira Hassanein, the sister of Dr. Waleed Hassanein, our President and Chief Executive Officer, is employed by us as Product Director for OCS Lung Program and reports to our Chief Commercial Officer. Her compensation, including salary and bonus, earned in fiscal 2015 was $171,734, in fiscal 2016 was $180,000, in fiscal 2017 was $221,303 and for the fiscal nine months ended September 29, 2018 was $133,046, consistent with other employees at her level and responsibility. She also participated and currently participates in company benefit plans generally available to similarly situated employees.

Indemnification Agreements

Our restated articles of organization provides that we will indemnify our directors and officers to the fullest extent permitted by Massachusetts law. In addition, we have entered into indemnification agreements with our directors and officers.

Related Person Transactions

Our board of directors has adopted a written related person transaction policy, to be effective upon the effectiveness of the registration statement of which this prospectus forms a part, setting forth the policies and procedures for the review and approval or ratification of related person transactions. This policy will cover, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act of 1933, as amended, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we were or are to be a participant, where the amount involved exceeds $120,000 in any fiscal year and a related person had, has or will have a direct or indirect material interest, including without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our audit committee is tasked to consider all relevant facts and circumstances, including, but not limited to, whether the transaction is on terms comparable to those that could be obtained in an arm's length transaction and the extent of the related person's interest in the transaction. All of the transactions described in this section occurred prior to the adoption of this policy.

PRINCIPAL SHAREHOLDERS

The following table sets forth information with respect to the beneficial ownership of our capital stock, as of , 2018, by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our common stock;
- each of our directors;
- each of our named executive officers; and
- all of our executive officers and directors as a group.

The number of shares beneficially owned by each shareholder is determined under rules of the SEC and includes voting or investment power with respect to securities. Under these rules, beneficial ownership includes any shares as to which the individual or entity has sole or shared voting power or investment power. In computing the number of shares beneficially owned by an individual or entity and the percentage ownership of that person, shares of common stock subject to options, warrants or other rights held by such person that are currently exercisable or will become exercisable within 60 days after , 2018 are considered outstanding, although these shares are not considered outstanding for purposes of computing the percentage ownership of any other person.

We have based our calculation of the percentage of beneficial ownership prior to this offering on shares of common stock outstanding as of , 2018 (assuming the completion of the Corporate Reorganization). We have based our calculation of the percentage of beneficial ownership after this offering on shares of common stock (assuming the completion of the Corporation Reorganization and the closing of this offering) outstanding immediately after the completion of this offering, assuming that the underwriters do not exercise their option to purchase up to an additional shares of our common stock from us.

Unless otherwise indicated, the address of all listed shareholders is c/o TransMedics Group, Inc., 200 Minuteman Road, Andover, MA 01810. Each of the shareholders listed has sole voting and investment power with respect to the shares beneficially owned by the shareholder unless noted otherwise, subject to community property laws where applicable.

Name and Address of Beneficial Owner	Shares Beneficially Owned Prior to Offering		Shares Beneficially Owned After Offering	
	Number	Percentage	Number	Percentage
5% or Greater Shareholders:				
Abrams Capital Partners and affiliated entities(1)		%		%
Flagship Pioneering and affiliated entities(2)		%		%
Lung Biotechnology(3)		%		%
Fayerweather Fund I, L.P.(4)		%		%
OneLiberty Funds(5)		%		%
KPCB Holdings, Inc.(6)		%		%
Directors and Named Executive Officers:				
Waleed H. Hassanein, M.D.(7)		%		%
James Tobin(8)		%		%
Edward M. Basile(9)		%		%
James Gilbert		%		%
Thomas Gunderson(10)		%		%
Edwin M. Kania, Jr.(11)		%		%
Stephen Gordon(12)		%		%
Tamer Khayal, M.D.(13)		%		%
All executive officers and directors as a group (11 persons)(14)		%		%

* Less than 1%.

(1) Consists of (i) shares of our common stock held by Abrams Capital Partners I, L.P. (“Abrams Capital I”), (ii) shares of our common stock held by Abram Capital Partners II, L.P. (“Abrams Capital II”), (iii) shares of common stock held by Great Hollow International, L.P. (“Great Hollow”), (iv) shares of our common stock held by Riva Capital Partners III, L.P. (“Riva Capital”) and (v) shares of common stock held by Whitecrest Partners, L.P. (“Whitecrest Partners” and, together with Abrams Capital I, Abrams Capital II, Great Hollow and Riva Capital, the “Abrams Capital Funds”). David Abrams, who previously served on our board of directors until 2018, is the Managing Member of Abrams Capital Management, LLC, which is the general partner to Abrams Capital Management, L.P., the investment manager of the Abrams Capital Funds, and may be deemed to share voting and investment power with respect to all shares held by those entities. The address for the Abrams Capital Funds is 222 Berkeley Street, 22nd Floor, Boston, Massachusetts 02116.

(2) Consists of (i) shares of common stock held by Flagship Ventures Fund 2007, L.P. (“Flagship Fund 2007”), and (ii) shares of common stock held by Flagship Ventures Fund IV, L.P. (“Flagship Fund IV” and together with Flagship Fund 2007, the “Flagship Funds”). The general partner of Flagship Fund 2007 is Flagship Ventures 2007 General Partner, LLC (“Flagship 2007 LLC”), and the general partner of Flagship Fund IV is Flagship Ventures Fund IV General Partner LLC (“Flagship Fund IV GP” and together with Flagship 2007 LLC, the “Flagship General Partners”). Edwin M. Kania, Jr. serves on our board of directors. Noubar B. Afeyan, Ph.D. and Mr. Kania, Jr. are the managers of the Flagship General Partners, and each of these individuals may be deemed to share voting and investment power with respect to all shares held by the Flagship Funds. None of the Flagship General Partners, Edwin M Kania, Jr. or Noubar B. Afeyan, Ph.D. directly own any of the shares held by the Flagship Funds and each of the Flagship General Partners, Edwin M. Kania Jr. and Noubar B. Afeyan, Ph.D. disclaims beneficial ownership of such shares except to the extent of its or his pecuniary interest therein. The mailing address of the Flagship Funds is 55 Cambridge Parkway, Suite 800E, Cambridge, Massachusetts 02142.

(3) Lung Biotechnology PBC is deemed to have sole voting and investment power with respect to all shares held by Lung Biotechnology PBC. The address for Lung Biotechnology PBC is 1040 Spring Street, Silver Spring, MD 20910.

(4) The general partner of Fayerweather Fund 1, L.P. is Fayerweather Management, LLC. The managing members of Fayerweather Management, LLC are Andrew Stevenson and Howard Stevenson. Each of these individuals exercises shared voting and investment power over the shares held of record by Fayerweather Fund 1, L.P. The address for Fayerweather Fund 1, L.P. is 138 Mt. Auburn St., Cambridge, Massachusetts 02138.

(5) Consists of (i) shares of common stock held by OneLiberty Ventures 2000, L.P. ("OneLiberty 2000"), (ii) shares of common stock held by OneLiberty Advisors Fund 2000, L.P. ("OneLiberty Advisors 2000") and (iii) shares of common stock held by OneLiberty Ventures, Inc. ("OneLiberty Ventures" and, together with OneLiberty 2000 and OneLiberty Advisors Fund 2000, the "OneLiberty Entities"). OneLiberty Partners 2000, LLC ("OneLiberty 2000 LLC") is the general partner of OneLiberty 2000 and OneLiberty Advisors 2000. OneLiberty Ventures is the management company for and operates as an affiliate of OneLiberty 2000 LLC and provides services in connection with the investment activities of OneLiberty 2000 and OneLiberty Advisors 2000. Edwin M. Kania, Jr. and Stephen J. Ricci are the managers of OneLiberty 2000 LLC, and each of these individuals may be deemed to share voting and investment power with respect to the shares held by OneLiberty 2000 and OneLiberty Advisors 2000. Neither Mr. Kania nor Mr. Ricci directly own any of the shares held by OneLiberty 2000 or OneLiberty Advisors 2000 and each disclaims beneficial ownership of such shares. Mr. Kania is the principal of OneLiberty Ventures, and Mr. Kania may be deemed to have voting and investment power with respect to the shares held by OneLiberty Ventures. Mr. Kania does not directly own any of the shares held by OneLiberty Ventures and disclaims beneficial ownership of such shares. The mailing address of the OneLiberty Entities is c/o Edwin M. Kania, Jr., 55 Cambridge Parkway, Suite 800E, Cambridge, Massachusetts 02142.

(6) Consists of shares held by Kleiner Perkins Caufield & Byers XIII, LLC. All shares are held for convenience in the name of "KPCB Holdings, Inc., as nominee," for the accounts of such individuals and entities who each exercise their own voting and dispositive power over such shares. KPCB XIII Associates, LLC is the managing member of Kleiner Perkins Caufield & Byers XIII, LLC. The voting and dispositive control over such shares is shared by individual managing directors of KPCB XIII Associates, LLC, none of whom has veto power. Each such managing director disclaims beneficial ownership of such shares. Excludes 233,528 shares in the aggregate beneficially owned by individuals and entities associated with Kleiner Perkins Caufield & Byers XIII, LLC and held for convenience in the name of "KPCB Holdings, Inc. as nominee," for the accounts of such individuals and entities, each of whom exercise their own voting and dispositive control over such shares. The address for KPCB Holdings, Inc. is 2750 Sand Hill Road, Menlo Park, California 94025.

(7) Consists of (i) shares held, and (ii) shares of common stock underlying outstanding stock options exercisable within 60 days of .

(8) Consists of shares of our common stock held by a revocable trust for which Mr. Tobin is the grantor.

(9) Consists of (i) shares held, and (ii) shares of common stock underlying outstanding stock options exercisable within 60 days of .

(10) Consists of shares of common stock underlying outstanding stock options exercisable within 60 days of .

(11) Mr. Kania is a manager of each of the Flagship General Partners and may be considered to have beneficial ownership of the shares held by the Flagship Funds. Mr. Kania expressly disclaims beneficial ownership of such shares, except to the extent of his pecuniary interest therein. See note 2 above. Mr. Kania is also a manager of OneLiberty 2000 LLC and principal of OneLiberty Ventures and may be considered to have beneficial ownership of the shares held by the OneLiberty Entities. Mr. Kania expressly disclaims beneficial ownership of such shares, except to the extent of his pecuniary interest therein. See note 5 above.

(12) Consists of shares of common stock underlying outstanding stock options exercisable within 60 days of .

(13) Consists of (i) shares held, and (ii) shares of common stock underlying outstanding stock options exercisable within 60 days of .

(14) Consists of (i) shares held, and (ii) shares of common stock underlying outstanding stock options exercisable within 60 days of .

DESCRIPTION OF CAPITAL STOCK

General

Following the closing of this offering, our authorized capital stock will consist of shares of common stock, no par value per share, and shares of preferred stock, no par value per share, all of which preferred stock will be undesignated. The following description of our capital stock and provisions of our restated articles of organization and amended and restated bylaws are summaries and are qualified by reference to the restated articles of organization and amended and restated bylaws that will become effective upon the closing of this offering, and to the applicable provisions of the Massachusetts Business Corporation Act, or the MBCA. The following description of our capital stock reflects changes to our capital structure that will occur upon the closing of this offering.

As of , 2018, assuming the Corporate Reorganization, including the conversion of all outstanding shares of preferred stock of TransMedics, Inc. into an aggregate of shares of common stock of TransMedics Group and the closing of this offering, there were shares of common stock outstanding, held by shareholders of record, and no shares of preferred stock outstanding.

The following summary describes all material provisions of our capital stock. We urge you to read our restated articles of organization and our amended and restated bylaws, which are included as exhibits to the registration statement of which this prospectus forms a part.

Our restated articles of organization and amended and restated bylaws will contain provisions that are intended to enhance the likelihood of continuity and stability in the composition of the board of directors and which may have the effect of delaying, deferring or preventing a future takeover or change in control of our company unless such takeover or change in control is approved by our board of directors.

Common Stock

Dividend Rights

Subject to preferences that may apply to shares of preferred stock outstanding at the time, holders of outstanding shares of common stock will be entitled to receive dividends out of assets legally available at the times and in the amounts as our board of directors may from time to time determine.

Voting Rights

Holders of common stock are entitled to one vote for each share of common stock held on all matters submitted to a vote of shareholders, unless otherwise provided by our restated articles of organization. An election of directors by our shareholders will be determined by a of the votes cast by the shareholders entitled to vote in the election. Other matters shall be decided by an affirmative vote of our shareholders having a majority in voting power of the votes cast by the shareholders present or represented and voting on such matter, except as otherwise disclosed below.

No Preemptive Rights

Our common stock will not be entitled to preemptive or other similar subscription rights to purchase any of our securities.

Conversion or Redemption Rights

Our common stock will be neither convertible nor redeemable.

Liquidation Rights

Upon our voluntary or involuntary liquidation, dissolution or winding up, the holders of our common stock will be entitled to receive pro rata our net assets which are legally available for distribution, after payment of all debts and other liabilities and subject to the preferential rights of any holders of preferred stock then outstanding.

Preferred Stock

As part of the Corporate Reorganization, all outstanding shares of preferred stock of TransMedics, Inc. will be converted into an aggregate of shares of common stock of TransMedics Group.

Subsequent to the consummation of the Corporate Reorganization and this offering, our board of directors may, without further action by our shareholders, from time to time, direct the issuance of shares of preferred stock in series and may, at the time of issuance, determine the designations, powers, preferences, privileges, and relative participating, optional or special rights as well as the qualifications, limitations or restrictions thereof, including dividend rights, conversion rights, voting rights, terms of redemption and liquidation preferences, any or all of which may be greater than the rights of the common stock. Satisfaction of any dividend preferences of outstanding shares of preferred stock would reduce the amount of funds available for the payment of dividends on shares of our common stock. Holders of shares of preferred stock may be entitled to receive a preference payment in the event of our liquidation before any payment is made to the holders of shares of our common stock. Under certain circumstances, the issuance of shares of preferred stock may render more difficult or tend to discourage a merger, tender offer or proxy contest, the assumption of control by a holder of a large block of our securities or the removal of incumbent management. Upon the affirmative vote of a majority of the total number of directors then in office, our board of directors, without shareholder approval, may issue shares of preferred stock with voting and conversion rights, which could adversely affect the holders of shares of our common stock and the market value of our common stock. Upon consummation of the Corporate Reorganization, there will be no shares of preferred stock outstanding, and we have no present intention to issue any shares of preferred stock.

Stock Options

As of October 27, 2018, options to purchase 5,704,293 shares of common stock were outstanding at a weighted average exercise price of $0.50 per share.

Warrants

As of October 27, 2018, we had the following warrants to purchase capital stock outstanding: warrants to purchase 175,000 shares of our Series D preferred stock, at an exercise price of $2.50 per share; and warrants to purchase 50,544 shares of our Series F preferred stock, at an exercise price of $4.99 per share.

Effective upon the consummation of the Corporate Reorganization and the closing of this offering, the warrants to purchase shares of Series D preferred stock will become exercisable for shares of common stock at an exercise price of $ per share, and the warrants to purchase shares of Series F preferred stock will become exercisable for shares of common stock at an exercise price of $ per share. The holder of these warrants to purchase Series D and Series F preferred stock has registration rights as described below under the heading “Registration Rights.”

Registration Rights

Pursuant to the Investor Rights Agreement, certain of our shareholders have the right, 180 days following the closing of this offering, to demand that we file a registration statement or request that their shares be included in a registration statement that we file otherwise. We refer to the shares held by holders having rights under this agreement as registrable securities. As of October 27, 2018, the holders of shares of registrable securities, including shares issuable upon the conversion of all outstanding preferred stock upon the consummation of the Corporate Reorganization have registration rights under the Investor Rights Agreement.

Demand Registration Rights

Pursuant to the Investor Rights Agreement, until the fifth anniversary of the consummation of this offering, the holders of at least 50% of the registrable securities then outstanding can demand that we file up to two registration statements on Form S-1 registering their registrable securities, if the aggregate anticipated offering price is at least $5.0 million. Under specified circumstances, we also have the right to defer filing of a requested registration statement for a period of not more than 90 days, which right may not be exercised more than once during any 12-month period. These registration rights are subject to additional conditions and limitations, including the right of the underwriters to limit the number of shares included in any such registration under certain circumstances.

Form S-3 Registration Rights

Pursuant to the Investor Rights Agreement, if we are eligible to file a registration statement on Form S-3, the holders of at least 30% of the registrable securities then outstanding will have the right to demand that we file additional registration statements, including a shelf registration statement, for such holders on Form S-3, if the aggregate anticipated offering price is at least $1.0 million. These holders can demand up to two such registrations in any 12-month period.

Piggyback Registration Rights

Pursuant to the Investor Rights Agreement, if we propose to file a registration statement under the Securities Act (other than with respect to a registration statement on Form S-8 or Form S-4, or their successors, or any other form for a similar limited purpose, or any registration statement covering only securities proposed to be issued in exchange for securities or assets of another corporation), the holders of all registrable securities are entitled to receive notice of the registration and to include their registrable securities in such registration. The underwriters of any underwritten offering will have the right to limit the number of the number of registrable securities that may be included in the registration statement.

Expenses of Registration

We are required to pay all expenses relating to any demand, Form S-3 or piggyback registration, other than the underwriting discount, subject to certain limited exceptions. We will not pay for any expenses of any demand registration if the request is subsequently withdrawn by the holders of a majority of the shares requested to be included in such a registration statement, subject to limited exceptions.

Anti-takeover Effects of Our Restated Articles of Organization and Our Amended and Restated Bylaws

Upon consummation of the Corporate Reorganization and the closing of this offering, our restated articles of organization and amended and restated bylaws will contain certain provisions that are intended to enhance the likelihood of continuity and stability in the composition of our board of directors but which may have the effect of delaying, deferring or preventing a future takeover or change in control of us unless such takeover or change in control is approved by our board of directors.

These provisions include:

Action by written consent; special meetings of shareholders. Our amended and restated bylaws will provide that shareholder action can be taken only at an annual or special meeting of shareholders or by the unanimous written consent of all shareholders entitled to vote on the matter in lieu of such a meeting. Our restated articles of organization and amended and restated bylaws will also provide that, except as otherwise required by law, special meetings of the shareholders can only be called pursuant to a resolution adopted by a majority of our board of directors or holders of at least 25% of all the votes entitled to be cast on any issuer to be considered at the proposed special meeting. Except as described above, shareholders will not be permitted to call a special meeting or to require our board of directors to call a special meeting.

Advance notice procedures. Our amended and restated bylaws will establish an advance notice procedure for shareholder proposals to be brought before an annual meeting of our shareholders, including proposed nominations of persons for election to the board of directors. Shareholders at an annual meeting will only be able to consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of our board of directors or by a shareholder who was a shareholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has given timely written notice, in proper form, of the shareholder's intention to bring that business before the meeting. Although the amended and restated bylaws will not give our board of directors the power to approve or disapprove shareholder nominations of candidates or proposals regarding other business to be conducted at a special or annual meeting, the amended and restated bylaws may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed or may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect its own slate of directors or otherwise attempting to obtain control of us.

Number of directors and filling vacancies. Our restated articles of organization will provide that the number of directors will be established by the board of directors. Furthermore, any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of our board, may only be filled by the affirmative vote of a majority of our directors then in office. The ability of our board of directors to increase the number of directors and fill any vacancies may make it more difficult for our shareholders to change the composition of our board of directors.

Authorized but unissued shares. Our authorized but unissued shares of common stock and preferred stock will be available for future issuance without shareholder approval. These additional shares may be utilized for a variety of corporate purposes, including future public offerings to raise additional capital, corporate acquisitions and employee benefit plans. The existence of authorized but unissued shares of common stock and preferred stock could render more difficult or discourage an attempt to obtain control of a majority of our common stock by means of a proxy contest, tender offer, merger or otherwise.

Exclusive forum. Our restated articles of organization will require, to the fullest extent permitted by law, that derivative actions brought in the name of TransMedics Group, Inc., actions against directors, officers and employees for breach of a fiduciary duty and other similar actions may be brought only in specified courts in the Commonwealth of Massachusetts. Although we believe this provision benefits us by providing increased consistency in the application of Massachusetts law in the types of lawsuits to which it applies, the provision may have the effect of discouraging lawsuits against our directors and officers. See "Risk Factors—Our restated articles of organization will designate the state and federal courts located within the Commonwealth of Massachusetts as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our shareholders, which could discourage lawsuits against us and our directors and officers."

Anti-Takeover Provisions under Massachusetts Law

Provisions Regarding Business Combinations

Upon consummation of the Corporate Reorganization, we will be subject to the provisions of Chapter 110F of the MBCA. In general, Chapter 110F prohibits a publicly held Massachusetts corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. A "business combination" includes, among other things, a merger, asset or stock sale or other transaction resulting in a financial benefit to the interested stockholder. An "interested stockholder" is a person who, together with affiliates and associates, owns, or did own within three years prior to the determination of interested stockholder status, five percent% or more of the corporation's voting stock.

Under Chapter 110F, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions: before the stockholder became interested, our board

of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder; upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 90% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances; or at or after the time the stockholder became interested, the business combination was approved by our board of directors of the corporation and authorized at an annual or special meeting of the shareholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

A Massachusetts corporation may "opt out" of these provisions with an express provision in its original articles of organization or an express provision in its articles of organization or bylaws resulting from a shareholders' amendment approved by at least a majority of the outstanding voting shares. We have not opted out of these provisions. As a result, mergers or other takeover or change in control attempts of us may be discouraged or prevented.

Provisions Regarding a Classified Board of Directors

Section 8.06(b) of the MBCA provides that, unless a company opts out of such provision, the terms of directors of a public Massachusetts company shall be staggered by dividing the directors into three groups, as nearly equal in number as possible, with only one group of directors being elected each year. Our board of directors has opted out of this default requirement for a classified board of directors, and following the consummation of the Corporate Reorganization we expect that all of our directors will serve for one-year terms and will be elected annually.

However, pursuant to Section 8.06(c)(2) of the MBCA, our board of directors may unilaterally opt back into default requirements under Section 8.06(b) of the MBCA and become a classified board of directors without the approval of our shareholders. Sections 8.06(d) and (e) of the MBCA provide that when a board of directors is so classified, (i) shareholders may remove directors only for cause, (ii) the number of directors shall be fixed only by the vote of the board of directors, (iii) vacancies and newly created directorships shall be filled solely by the affirmative vote of a majority of the remaining directors, and (iv) a decrease in the number of directors will not shorten the term of any incumbent director. If our board of directors opts into this classified structure in the future, these provisions are likely to increase the time required for shareholders to change the composition of our board of directors. For example, at least two annual meetings would generally be necessary for shareholders to effect a change in a majority of the members of our board of directors. As a result, the ability of our board of directors to adopt a classified structure in the future without the approval of our shareholders could have the effect of discouraging a potential acquirer from making a tender offer for a majority of the outstanding voting interest of our capital stock or otherwise attempting to obtain control of TransMedics Group, Inc.

Transfer Agent and Registrar

The transfer agent and registrar for the common stock will be .

Nasdaq Global Market

We have applied to list our common stock on the Nasdaq Global Market under the symbol "TMDX".

DESCRIPTION OF CERTAIN INDEBTEDNESS

The following is a summary of certain of our indebtedness that is currently outstanding. The following description does not purport to be complete and is qualified in its entirety by reference to the agreements and related documents referred to herein, copies of which have been filed as exhibits to the registration statement of which this prospectus forms a part, and may be obtained as described under "Where You Can Find More Information" in this prospectus.

Credit Agreement

On June 22, 2018, TransMedics, Inc., or the Borrower, entered into the Credit Agreement with OrbiMed Royalty Opportunities II, LP, as lender, pursuant to which OrbiMed made certain term loans available to us. The Credit Agreement provides for aggregate maximum borrowings of up to $65.0 million. On the initial closing date of June 22, 2018, or the Closing Date, the Borrower borrowed $35.0 million and used $7.3 million to repay in full outstanding indebtedness and pay related fees and expenses. Under the terms of the Credit Agreement, the remaining $30.0 million is available to be drawn in three tranches, each, a Tranche. The loans drawn under the Credit Agreement mature on June 22, 2023, or the Maturity Date.

Tranches and Conditions to Draw

The first tranche of $5.0 million, or Tranche A, may be drawn by the Borrower at any time but no later than April 30, 2019, the second tranche of $5.0 million, or Tranche B, may also be drawn by the Borrower at any time but no later than April 30, 2019 and the third tranche of $20.0 million, or Tranche C, may be drawn by the Borrower at any time but no later than April 30, 2020, in each case provided that the Borrower satisfies certain conditions described in the Credit Agreement, including:

- in the case of Tranche A, that the Borrower's Revenue Base, as described below, for the period comprising the 12 months preceding the month during which Tranche A is drawn was at least $12.0 million (of which at least $7.0 million was derived from sales in the United States);
- in the case of Tranche B, that the Borrower's Revenue Base for the period comprising the 12 months preceding the month during which Tranche B is drawn was at least $12.0 million (of which at least $9.5 million was derived from sales in the United States); and
- in the case of Tranche C, that (x) the Borrower's Revenue Base for the period comprising the 12 months preceding the month during which Tranche C is drawn was at least $20.0 million and (y) the Borrower has received final FDA approval of the Borrower's PMA for the OCS Heart for preservation of donor hearts in a near physiologic, beating and perfused state for heart transplantation.

Under the terms of the Credit Agreement, the Borrower's Revenue Base is equal to the net sales, distribution income, service payments, license income and other forms of consideration from commercial sales of the Borrower's products (excluding any sales, distribution income, service payments, license income and other forms of consideration received in connection with any clinical trial).

OrbiMed's obligation to fund each Tranche is cancelled (i) in the case of Tranche A or Tranche B, on April 30, 2019, if either such Tranche had not previously been drawn, and (ii) in the case of Tranche C, on the earlier of (A) April 30, 2020, if such Tranche had not previously been drawn, or (B) April 30, 2019, if Tranche A has not been drawn by such date.

Interest Rates and Fees

Borrowings under the Credit Agreement bear interest at an annual rate equal to LIBOR, subject to a minimum of 1.0% and a maximum of 4.0%, plus 8.5%, or the Applicable Margin, subject in the aggregate to a

maximum interest rate of 11.5%. In addition, borrowings under the Credit Agreement bear PIK interest at an annual rate equal to the amount by which LIBOR plus the Applicable Margin exceeds 11.5%, not to exceed 12.5%. The PIK interest is added to the principal amount of the borrowings outstanding at the end of each quarter until the Maturity Date.

Upon the prepayment or repayment of all or any portion of outstanding loans under the Credit Agreement, the Borrower will pay OrbiMed an exit fee equal to 3% of the principal amount of loans being prepaid or repaid, in addition to any repayment premium described below.

Prepayments

Voluntary prepayments of borrowings under the Credit Agreement are permitted at any time, in whole or in part, subject to payment of a repayment premium, which is equal to (i) if prepayment is made prior to the 12-month anniversary of the Closing Date, the Make-Whole Amount as described below, (ii) if prepayment is made following the 12-month anniversary of the Closing Date but prior to the 24-month anniversary of the Closing Date, 9% of the principal amount of loans prepaid, and (iii) if prepayment is made following the 24-month anniversary of the Closing Date but prior to the 36-month anniversary of the Closing Date, 4.5% of the principal amount of loans prepaid. There is no prepayment premium for any amount of loans prepaid after the 36-month anniversary of the Closing Date. Under the Credit Agreement, "Make-Whole Amount" means the amount, if any, by which (x) the present value as of such date of determination of (A) 109% of the principal amount of the loans prepaid plus (B) all interest required to be paid through and including the 12-month anniversary of the Closing Date, in each case computed using a discount rate equal to the three-month U.S. Treasury rate plus 0.50%, exceeds (y) the principal amount of loans prepaid.

Upon the Borrower's receipt of any net asset sale proceeds (except proceeds from certain permitted dispositions) or net casualty proceeds (each as defined in the Credit Agreement), if requested by OrbiMed, the Borrower must make a mandatory prepayment in an amount equal to 100% of such proceeds, or a lesser amount requested by OrbiMed, plus the applicable repayment premium.

Guarantee; Security

All obligations under the Credit Agreement are guaranteed by the Borrower and each of its material subsidiaries. Upon the consummation of this offering, TransMedics Group will also be a guarantor under the Credit Agreement.

All obligations of the Borrower and each guarantor are secured by substantially all of the Borrower's and each guarantor's assets, including their intellectual property, subject to certain exceptions, including, a perfected security interest in substantially all tangible and intangible assets of the Borrower and each guarantor, including the capital stock of the Borrower and the capital stock of each direct material U.S. subsidiary of the Borrower and each guarantor, and 65% of each series of capital stock of any non-U.S. subsidiary held directly by the Borrower or any guarantor

Covenants, Representations and Warranties

The Credit Agreement contains a number of representations and warranties and a number of affirmative and negative covenants. The negative covenants limit the ability of the Borrower to:

- incur additional indebtedness;
- pay dividends, redeem stock or make other distributions;
- repurchase, prepay or redeem subordinated indebtedness;
- make certain investments;

- create restrictions on the ability of the Borrower's subsidiaries to pay dividends;
- create liens;
- transfer or sell assets;
- liquidate, consolidate, merge, purchase all or substantially all of the assets of any other Person, sell or otherwise dispose of all or substantially all of the Borrower's assets;
- modify organizational documents or any agreement governing permitted subordinated indebtedness;
- enter into a sale-leaseback arrangement;
- enter into any agreement concerning the Organ Care System or any current or future product or service of the Borrower;
- engage in business activities other than those engaged in as of the date of the Credit Agreement and any reasonable extensions or activities reasonably related or incidental thereto; and
- enter into certain transactions with affiliates.

The negative covenants are subject to certain exceptions. In addition, the Borrower must maintain liquidity of no less than $3.0 million at all times. There are no other financial covenants included in the Credit Agreement.

Events of Default

Events of default under the Credit Agreement include, in each case subject to certain thresholds, notice and grace period provisions:

- nonpayment of principal when due, nonpayment of interest or other amounts;
- breach of representations or warranties in any material respect;
- violation of covenants;
- certain defaults under other material debt;
- occurrence of circumstances that has or could reasonably be expected to have a material adverse effect on the Borrower;
- change in control event;
- certain bankruptcy or insolvency events;
- certain material judgments, termination of any key permit or any of the Borrower's material rights or interests thereunder or any amendment to any key permit in a manner adverse to the Borrower in any material respect;
- assertion by the FDA, CMS, European Medicines Agency or other governmental authority by letter or other communication that any of the Borrower's products lacks regulatory authorization and that causes the discontinuance of marketing or withdrawal of any products or causes delay in manufacturing;
- the initiation of a regulatory enforcement action or issuance of a warning letter with respect to the Borrower or any of its products or manufacturing facilities that causes the discontinuance of marketing or withdrawal of any products or causes delay in manufacturing; and
- termination or invalidity of the security interests granted to secure the Credit Agreement.

In addition, an event of default occurs if Waleed Hassanein ceases to be employed by the Borrower full time and actively working as the Borrower's President and Chief Executive Officer, unless within 120 days after his employment ceases, the Borrower hires a replacement reasonably acceptable to OrbiMed.

Upon the occurrence of an event of default and until such event of default is no longer continuing, the Applicable Margin will increase by 4.0% per annum. If an event of default (other than certain events of bankruptcy or insolvency) occurs and is continuing, OrbiMed may declare all or any portion of the outstanding principal amount of the borrowings plus accrued and unpaid interest to be due and payable. Upon the occurrence of certain events of bankruptcy or insolvency, all of the outstanding principal amount of the borrowings plus accrued and unpaid interest will automatically become due and payable.

As of September 29, 2018, the Borrower was in compliance with all of its covenants under the Credit Agreement.

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there was no public market for our common stock. Future sales of substantial amounts of our common stock in the public market, or the perception that such sales may occur, could materially and adversely affect the market price of our common stock and could impair our future ability to raise capital through the sale of our equity or equity-related securities at a time and price that we deem appropriate. Although we intend to apply to list our common stock on the Nasdaq Global Market, we cannot assure you that there will be an active public market for our common stock.

Upon completion of this offering, we will have shares of our common stock outstanding (or shares, if the underwriters exercise their option to purchase additional shares in full). Of the outstanding shares, all shares sold in this offering will be freely tradable without further restriction or registration under the Securities Act, except that any shares purchased by our affiliates, as that term is defined in Rule 144 under the Securities Act, may be sold only in compliance with the limitations described below. The remaining outstanding shares of common stock will be deemed "restricted securities" under the Securities Act. Restricted securities may be sold in the public market only if registered or if they qualify for an exemption from registration under Rules 144 or 701 under the Securities Act, which are described below. of these shares will be subject to lock-up agreements described below.

Taking into account the lock-up agreements described below, and assuming the representatives of the underwriters do not release shareholders from these agreements, the following shares will be eligible for sale in the public market at the following times, subject to the provisions of Rule 144 and Rule 701:

Date Available for Resale	Number of Shares Eligible for Resale	Comment
On the date of this offering (,)		Shares eligible for sale under Rule 144 and Rule 701
180 days after the date of this offering (,)		Lock-up released, shares eligible for sale under Rule 144 (subject, in some instances, to volume limitations) and Rule 701

Rule 144

In general, under Rule 144, beginning 90 days after the date of this prospectus, a person who is not our affiliate and has not been our affiliate at any time during the preceding three months will be entitled to sell any shares of our common stock that such person has beneficially owned for at least six months, including the holding period of any prior owner other than one of our affiliates, without regard to volume limitations. Sales of our common stock by any such person would be subject to the availability of current public information about us if the shares to be sold were beneficially owned by such person for less than one year. In addition, under Rule 144, any person who is not our affiliate and has not been our affiliate at any time during the preceding three months and has held their shares for at least one year, including the holding period of any prior owner other than one of our affiliates, would be entitled to sell an unlimited number of shares immediately upon the closing of this offering without regard to whether current public information about us is available.

Approximately shares of our common stock that are not subject to the lock-up agreements described below will be eligible for sale under Rule 144 immediately upon the consummation of this offering.

Beginning 90 days after the date of this prospectus, our affiliates who have beneficially owned shares of our common stock for at least six months, including the holding period of any prior owner other than one of our affiliates, would be entitled to sell within any three-month period a number of shares that does not exceed the greater of:

- 1% of the total number of then-outstanding shares of the class of security sold, which will equal, immediately after this offering, approximately shares of common stock, assuming an initial

public offering price of $ per share, which is the midpoint of the price range set forth on the cover page of this prospectus; or

- the average weekly trading volume in the class of security sold on the Nasdaq Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Sales under Rule 144 by our affiliates are also subject to manner of sale provisions and notice requirements and to the availability of current public information about us.

Rule 701

In general, under Rule 701 as currently in effect, any of our employees, directors, officers, consultants or advisors who purchase shares from us in connection with a compensatory stock or option plan or other written agreement before the effective date of this offering is entitled to sell such shares 90 days after the effective date of this offering in reliance on Rule 144, in the case of affiliates, without having to comply with the holding period requirements of Rule 144 and, in the case of non-affiliates, without having to comply with the public information, holding period, volume limitation or notice filing requirements of Rule 144.

Lock-Up Agreements

Our officers, directors and other shareholders owning an aggregate of shares of our common stock will be subject to lock-up agreements with Morgan Stanley & Co. LLC and J.P. Morgan Securities LLC, as representatives of the underwriters, that will restrict the sale of the shares of our common stock held by them for 180 days, subject to certain exceptions. See “Underwriting” for a description of these lock-up agreements.

Registration Statements on Form S-8

Immediately after the consummation of this offering, we intend to file a registration statement on Form S-8 under the Securities Act to register all of the shares of our common stock issued or reserved for future issuance under our equity incentive plans. This registration statement would cover approximately shares. Shares registered under the registration statement will generally be available for sale in the open market after the 180-day lock-up period immediately following the date of this prospectus.

Registration Rights

Upon the closing of this offering, the holders of shares of common stock will be entitled to the registration of these shares under the Securities Act. See “Description of Capital Stock—Registration Rights” for additional information. Registration of these shares under the Securities Act would result in these shares becoming freely tradable without restriction under the Securities Act immediately upon effectiveness of the registration.

MATERIAL U.S. FEDERAL INCOME AND ESTATE TAX CONSIDERATIONS FOR NON-U.S. HOLDERS OF COMMON STOCK

The following discussion is a summary of the material U.S. federal income and estate tax consequences to Non-U.S. Holders (as defined below) of the purchase, ownership and disposition of our common stock issued pursuant to this offering, but does not purport to be a complete analysis of all potential tax effects. The effects of other U.S. federal tax laws and any applicable state, local or non-U.S. tax laws are not discussed. This discussion is based on the Code, Treasury Regulations promulgated thereunder, judicial decisions and published rulings and administrative pronouncements of the U.S. Internal Revenue Service, or the IRS, in each case, in effect as of the date hereof. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a Non-U.S. Holder of our common stock. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position to that discussed below regarding the tax consequences of the purchase, ownership and disposition of our common stock.

This discussion is limited to Non-U.S. Holders that hold our common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a Non-U.S. Holder's particular circumstances, including the impact of the Medicare contribution tax on net investment income. In addition, it does not address consequences relevant to Non-U.S. Holders subject to special rules, including, without limitation:

- U.S. expatriates and former citizens or long-term residents of the United States;
- persons subject to the alternative minimum tax;
- persons holding our common stock as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies and other financial institutions;
- brokers, dealers or traders in securities;
- "controlled foreign corporations," "passive foreign investment companies," and corporations that accumulate earnings to avoid U.S. federal income tax;
- partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and investors therein);
- tax-exempt organizations or governmental organizations;
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- tax-qualified retirement plans;
- "qualified foreign pension funds" as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds; and
- persons subject to special tax accounting rules as a result of any item of gross income with respect to our common stock being taken into account in an applicable financial statement.

This discussion does not address the tax treatment of partnerships or other pass-through entities, or persons who hold our common stock through partnerships or other pass-through entities, for U.S. federal income tax purposes. If an entity or arrangement treated as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Accordingly, partnerships holding our common stock and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

INVESTORS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS, AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.

Definition of a Non-U.S. Holder

For purposes of this discussion, a "Non-U.S. Holder" is any beneficial owner of our common stock that is neither a "U.S. person" nor an entity or arrangement treated as a partnership for U.S. federal income tax purposes. A U.S. person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (1) is subject to the primary supervision of a U.S. court and the control of one or more "United States persons" (within the meaning of Section 7701(a)(30) of the Code) or (2) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

Distributions

As described in the section entitled "Dividend Policy," we do not anticipate declaring or paying any distributions to holders of our common stock in the foreseeable future. However, if we do make distributions of cash or property on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and first be applied against and reduce a Non-U.S. Holder's adjusted tax basis in its common stock, but not below zero. Any excess will be treated as capital gain and will be treated as described below under "—Sale or Other Taxable Disposition."

Subject to the discussions below on effectively connected income, FATCA, and backup withholding, dividends paid to a Non-U.S. Holder of our common stock will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends or such lower rate specified by an applicable income tax treaty, provided the Non-U.S. Holder furnishes a valid IRS Form W-8BEN or W-8BEN-E (or other applicable documentation) certifying qualification for the lower treaty rate. A Non-U.S. Holder that does not timely furnish the required documentation, but that qualifies for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. Holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

If dividends paid to a Non-U.S. Holder are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such dividends are attributable), the Non-U.S. Holder will be exempt from the U.S. federal withholding tax described above. To claim the exemption, the Non-U.S. Holder must furnish to the applicable withholding agent a valid IRS Form W-8ECI, certifying that the dividends are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States.

Any such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the regular graduated rates. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at

a rate of 30% (or such lower rate specified by an applicable income tax treaty) on its effectively connected earnings and profits attributable to such dividends, as adjusted for certain items. Non-U.S. Holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules.

Sale or Other Taxable Disposition

Subject to the discussions below on backup withholding and FATCA, a Non-U.S. Holder will not be subject to U.S. federal income tax on any gain realized upon the sale or other taxable disposition of our common stock unless:

- the gain is effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such gain is attributable);
- the Non-U.S. Holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met; or
- our common stock constitutes a U.S. real property interest, or USRPI, by reason of our status as a U.S. real property holding corporation, or USRPHC, for U.S. federal income tax purposes.

If a Non-U.S. Holder is engaged in a trade or business in the United States and gain recognized by the Non-U.S. Holder on a sale or other disposition of our common stock is effectively connected with the conduct of such trade or business, the Non-U.S. Holder generally will be subject to U.S. federal income tax on a net income basis at the regular graduated rates. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected gain, as adjusted for certain items.

We believe we currently are not, and we do not anticipate becoming, a USRPHC. Because the determination of whether we are a USRPHC depends on the fair market value of our USRPIs relative to the fair market value of our non-U.S. real property interests and our other business assets, there can be no assurance we currently are not a USRPHC or will not become one in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition by a Non-U.S. Holder of our common stock will not be subject to U.S. federal income tax if our common stock is "regularly traded" (as defined by applicable Treasury Regulations) on an established securities market, and such Non-U.S. Holder owned, actually and constructively, 5% or less of our common stock throughout the shorter of the five-year period ending on the date of the sale or other taxable disposition or the Non-U.S. Holder's holding period.

A nonresident alien who is subject to U.S. federal income tax because such individual was present in the United States for 183 days or more in the taxable year of the taxable disposition of our common stock will be subject to a flat 30% tax on the gain derived from such disposition, which may be offset by U.S. source capital loss. Non-U.S. Holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

Information Reporting and Backup Withholding

Payments of dividends on our common stock will not be subject to backup withholding, provided the applicable withholding agent does not have actual knowledge or reason to know the holder is a United States person and the holder either certifies its non-U.S. status, such as by furnishing a valid IRS Form W-8BEN, W-8BEN-E or W-8ECI, or otherwise establishes an exemption. However, information returns are required to be filed with the IRS in connection with any dividends on our common stock paid to the Non-U.S. Holder, regardless of whether any tax was actually withheld. In addition, proceeds of the sale or other taxable disposition of our common stock within the United States or conducted through certain U.S.-related brokers generally will not be subject to backup withholding or information reporting, if the applicable withholding agent receives the

certification described above and does not have actual knowledge or reason to know that such holder is a United States person, or the holder otherwise establishes an exemption. Proceeds of a disposition of our common stock conducted through a non-U.S. office of a non-U.S. broker generally will not be subject to backup withholding or information reporting.

Copies of information returns that are filed with the IRS may also be made available under the provisions of an applicable treaty or agreement to the tax authorities of the country in which the Non-U.S. Holder resides or is established.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a Non-U.S. Holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

Additional Withholding and Information Reporting Requirements

Sections 1471 through 1474 of the Code and related Treasury Regulations, together with other Treasury Department or IRS guidance issued thereunder, and intergovernmental agreements, legislation, rules and other official guidance adopted pursuant to such intergovernmental agreements (commonly referred to as "FATCA") generally impose a U.S. federal withholding tax of 30% on payments to certain non-U.S. entities (including certain intermediaries), including dividends on our common stock and, on or after January 1, 2019, the gross proceeds from a sale or other disposition of shares of our common stock, unless such persons comply with a complicated U.S. information reporting, disclosure and certification regime or an exemption applies. This regime requires, among other things, a broad class of persons to enter into agreements with the IRS to obtain, disclose and report information about their investors and account holders. An intergovernmental agreement between the U.S. and an applicable foreign country may, however, modify these requirements. Prospective investors should consult their own tax advisors regarding the possible impact of these rules on their investment in our common stock, and the possible impact of these rules on the entities through which they hold our common stock, including, without limitation, the process and deadlines for meeting the applicable requirements to prevent the imposition of this 30% withholding tax under FATCA.

U.S. Federal Estate Tax

Common stock owned or treated as owned by an individual who is a Non-U.S. Holder at the time of death generally will be included in the individual's gross estate for U.S. federal estate tax purposes and may be subject to U.S. federal estate tax unless an applicable estate or other tax treaty provides otherwise.

UNDERWRITING

Under the terms and subject to the conditions in an underwriting agreement dated the date of this prospectus, the underwriters named below, for whom Morgan Stanley & Co. LLC and J.P. Morgan Securities LLC are acting as representatives, have severally agreed to purchase, and we have agreed to sell to them, severally, the number of shares indicated below:

Underwriters	Number of Shares
Morgan Stanley & Co. LLC	
J.P. Morgan Securities LLC	
Cowen and Company, LLC	
Canaccord Genuity LLC	
Total	

The underwriters and the representatives are collectively referred to as the "underwriters" and the "representatives," respectively. The underwriters are offering the shares of common stock subject to their acceptance of the shares from us and subject to prior sale. The underwriting agreement provides that the obligations of the several underwriters to pay for and accept delivery of the shares of common stock offered by this prospectus are subject to the approval of certain legal matters by their counsel and to certain other conditions. The underwriting agreement provides for a firm commitment underwriting, and the underwriters are obligated to take and pay for all of the shares of common stock offered by this prospectus if any such shares are taken. However, the underwriters are not required to take or pay for the shares covered by the underwriters' over-allotment option described below.

The underwriters initially propose to offer part of the shares of common stock directly to the public at the offering price listed on the cover page of this prospectus and part to certain dealers at a price that represents a concession not in excess of $ a share under the public offering price. After the initial offering of the shares of common stock, the offering price and other selling terms may from time to time be varied by the representatives. Sales of shares made outside of the United States may be made by affiliates of the underwriters.

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to additional shares of common stock at the public offering price listed on the cover page of this prospectus, less underwriting discounts and commissions. The underwriters may exercise this option solely for the purpose of covering over-allotments, if any, made in connection with the offering of the shares of common stock offered by this prospectus. To the extent the option is exercised, each underwriter will become obligated, subject to certain conditions, to purchase about the same percentage of the additional shares of common stock as the number listed next to the underwriter's name in the preceding table bears to the total number of shares of common stock listed next to the names of all underwriters in the preceding table.

The following table shows the per share and total public offering price, underwriting discounts and commissions, and proceeds before expenses to us. These amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase up to an additional shares of common stock.

	Per Share	Total	
		No Exercise	Full Exercise
Public offering price	$	$	$
Underwriting discounts and commissions to be paid by us	$	$	$
Proceeds, before expenses, to us	$	$	$

The estimated offering expenses payable by us, exclusive of the underwriting discounts and commissions, are approximately $. We have agreed to reimburse the underwriters for expenses relating to clearance of this offering with the Financial Industry Regulatory Authority, or FINRA, for up to $.

The underwriters have informed us that they do not intend sales to discretionary accounts to exceed 5% of the total number of shares of common stock offered by them.

We have applied to list our common stock on the Nasdaq Global Market under the trading symbol “TMDX.”

We and all directors and officers and the holders of substantially all of our outstanding stock and stock options have agreed that, without the prior written consent of Morgan Stanley & Co. LLC and J.P. Morgan Securities LLC on behalf of the underwriters, we and they will not, during the period ending 180 days after the date of this prospectus, or the restricted period, subject to certain exceptions, dispose of or hedge any of common stock or securities convertible into or exchangeable for shares of common stock.

Morgan Stanley & Co. LLC and J.P. Morgan Securities LLC, in their sole discretion, may release the common stock and other securities subject to the lock-up agreements described above in whole or in part at any time.

In order to facilitate the offering of the common stock, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of the common stock. Specifically, the underwriters may sell more shares than they are obligated to purchase under the underwriting agreement, creating a short position. A short sale is covered if the short position is no greater than the number of shares available for purchase by the underwriters under the over-allotment option. The underwriters can close out a covered short sale by exercising the over-allotment option or purchasing shares in the open market. In determining the source of shares to close out a covered short sale, the underwriters will consider, among other things, the open market price of shares compared to the price available under the over-allotment option. The underwriters may also sell shares in excess of the over-allotment option, creating a naked short position. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in this offering. As an additional means of facilitating this offering, the underwriters may bid for, and purchase, shares of common stock in the open market to stabilize the price of the common stock. These activities may raise or maintain the market price of the common stock above independent market levels or prevent or retard a decline in the market price of the common stock. The underwriters are not required to engage in these activities and may end any of these activities at any time.

We and the underwriters have agreed to indemnify each other against certain liabilities, including liabilities under the Securities Act.

A prospectus in electronic format may be made available on websites maintained by one or more underwriters, or selling group members, if any, participating in this offering. The representatives may agree to allocate a number of shares of common stock to underwriters for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters that may make Internet distributions on the same basis as other allocations.

Relationships

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. Certain of the underwriters and their respective affiliates may in the future perform various financial advisory and investment banking services for us, for which they will receive customary fees and expenses.

In addition, in the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers and may at any time hold long and short positions in such securities and instruments. Such investment and securities activities may involve our securities and instruments. The underwriters and their respective affiliates may also make investment recommendations or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long or short positions in such securities and instruments.

Pricing of the Offering

Prior to this offering, there has been no public market for our common stock. The initial public offering price was determined by negotiations between us and the representatives. Among the factors considered in determining the initial public offering price were our future prospects and those of our industry in general, our sales, earnings and certain other financial and operating information in recent periods, and the price-earnings ratios, price-sales ratios, market prices of securities, and certain financial and operating information of companies engaged in activities similar to ours.

Selling Restrictions

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

Australia

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission, or ASIC, in relation to the offering. This prospectus does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001, or the Corporations Act, and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the shares may only be made to persons, or the Exempt Investors, who are “sophisticated investors” (within the meaning of section 708(8) of the Corporations Act), “professional investors” (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the shares without disclosure to investors under Chapter 6D of the Corporations Act.

The shares applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring shares must observe such Australian on-sale restrictions.

This prospectus contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

Canada

The shares of our common stock may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the shares of our common stock must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Dubai International Finance Centre

This prospectus relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority, or the DFSA. This prospectus is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for the prospectus. The shares to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the shares offered should conduct their own due diligence on the shares. If you do not understand the contents of this prospectus you should consult an authorized financial advisor.

European Economic Area

In relation to each member state of the European Economic Area which has implemented the Prospectus Directive (each, a "Relevant Member State"), each underwriter has represented and agreed that with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State it has not made and will not make an offer of common stock which are the subject of the offering contemplated by this prospectus to the public in that Relevant Member State other than:

- to any legal entity which is a "qualified investor" as defined in the Prospectus Directive;
- to fewer than 150 natural or legal persons (other than "qualified investors" as defined in the Prospectus Directive), per Relevant Member State, subject to obtaining the prior consent of the underwriters; or
- in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of common stock shall result in a requirement for us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Directive or a supplemental prospectus pursuant to Article 16 of the Prospectus Directive.

For the purposes of this provision, the expression an "offer of common stock to the public" in relation to any common stock in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the common stock to be offered so as to enable an investor to decide to purchase or subscribe for the common stock, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State. The expression "Prospectus Directive" means Directive 2003/71/EC (as amended, including by Directive 2010/73/EU), and includes any relevant implementing measure in the Relevant Member State.

Hong Kong

The common stock has not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or (b) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of that Ordinance. No advertisement, invitation or document relating to the common stock has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to common stock which is or is intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance.

Japan

The common stock has not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended) and, accordingly, will not be offered or sold, directly or indirectly, in Japan, or for the benefit of any Japanese Person or to others for re-offering or resale, directly or indirectly, in Japan or to any Japanese Person, except in compliance with all applicable laws, regulations and ministerial guidelines promulgated by relevant Japanese governmental or regulatory authorities in effect at the relevant time. For the purposes of this paragraph, "Japanese Person" shall mean any person resident in Japan, including any corporation or other entity organized under the laws of Japan.

People's Republic of China

This prospectus may not be circulated or distributed in the People's Republic of China, or the PRC, and the common stock may not be offered or sold to any person for re-offering or resale directly or indirectly to any resident of the PRC, except pursuant to applicable laws, rules and regulations of the PRC. For the purpose of this paragraph only, the PRC does not include Taiwan and the special administrative regions of Hong Kong and Macau.

Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the common stock may not be circulated or distributed, nor may the common stock be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA, (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275, of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the common stock is subscribed or purchased under Section 275 of the SFA by a relevant person which is:

a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or

b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares pursuant to an offer made under Section 275 of the SFA except:

a) to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;

b) where no consideration is or will be given for the transfer;

c) where the transfer is by operation of law;

d) as specified in Section 276(7) of the SFA; or

e) as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.

Singapore Securities and Futures Act Product Classification

Solely for the purposes of its obligations pursuant to Sections 309B(1)(a) and 309B(1)(c) of the SFA, the company has determined, and hereby notify all relevant persons (as defined in Section 309A of the SFA) that the shares are "prescribed capital markets products" (as defined in the Securities and Futures (Capital Markets Products) Regulations 2018) and Excluded Investment Products (as defined in MAS Notice SFA 04-N12: Notice on the Sale of Investment Products and MAS Notice FAA-N16: Notice on Recommendations on Investment Products).

Switzerland

This document is not intended to constitute an offer or solicitation to purchase or invest in the common stock described herein. The common stock may not be publicly offered, sold or advertised, directly or indirectly, in, into or from Switzerland and will not be listed on the SIX Swiss Exchange or on any other exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the common stock constitutes a prospectus as such term is understood pursuant to article 652a or article 1156 of the Swiss Code of Obligations or a listing prospectus within the meaning of the listing rules of the SIX Swiss Exchange or any other regulated trading facility in Switzerland, and neither this document nor any other offering or marketing material relating to the common stock may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, nor the Company nor the common stock have been or will be filed with or approved by any Swiss regulatory authority. The common stock is not subject to the supervision by any Swiss regulatory authority, e.g., the Swiss Financial Markets Supervisory Authority FINMAXX, and investors in the common stock will not benefit from protection or supervision by such authority.

United Kingdom

This document is only being distributed to and is only directed at (i) persons who are outside the United Kingdom or (ii) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, or the Order, or (iii) high net worth entities, and other persons to whom it may lawfully be communicated, falling with Article 49(2)(a) to (d) of the Order (all such persons together being referred to as "relevant persons"). The common stock is only available to, and any invitation, offer or agreement to subscribe, purchase or otherwise acquire such securities will be engaged in only with, relevant persons. Any person who is not a relevant person should not act or rely on this document or any of its contents.

LEGAL MATTERS

The validity of the shares of common stock offered hereby will be passed upon for us by Ropes & Gray LLP. Certain legal matters in connection with this offering will be passed upon for the underwriters by Davis Polk & Wardwell LLP, New York, New York.

EXPERTS

The financial statements as of December 30, 2017 and December 31, 2016 and for the years then ended included in this prospectus have been so included in reliance on the report (which contains an explanatory paragraph relating to the Company's ability to continue as a going concern as described in Note 1 to the consolidated financial statements) of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 (File Number 333-) under the Securities Act with respect to the shares of common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed therewith. For further information about us and the common stock offered hereby, we refer you to the registration statement and the exhibits and schedules filed thereto. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement.

You may read the registration statement for this offering at the SEC's internet website, which is located at www.sec.gov and which also contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC.

We are not currently subject to the informational requirements of the Exchange Act. As a result of this offering, we will become subject to the informational requirements of the Exchange Act and, in accordance therewith, will file reports and other information with the SEC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of TransMedics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of TransMedics, Inc. and its subsidiaries as of December 30, 2017 and December 31, 2016, and the related consolidated statements of operations, of comprehensive loss, of convertible preferred stock and stockholders' deficit and of cash flows for the years then ended, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 30, 2017 and December 31, 2016, and the results of their operations and their cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Substantial Doubt About the Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred recurring losses from operations since inception and will require additional financing to fund future operations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts
October 19, 2018

We have served as the Company's auditor since 2001.

TRANSMEDICS, INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share amounts)

	December 31, 2016	December 30, 2017	September 29, 2018 (unaudited)	Pro Forma September 29, 2018 (unaudited)
Assets				
Current assets:				
Cash and cash equivalents	$ 9,837	$ 11,936	$ 28,890	$ 28,890
Marketable securities	38,001	12,727	—	—
Accounts receivable	1,379	925	3,904	3,904
Inventory	6,335	7,971	9,621	9,621
Prepaid expenses and other current assets	311	477	666	666
Total current assets	55,863	34,036	43,081	43,081
Property and equipment, net	1,723	2,459	3,342	3,342
Deferred offering costs	—	—	1,468	1,468
Restricted cash	500	500	500	500
Other long-term assets	18	6	6	6
Total assets	$ 58,104	$ 37,001	$ 48,397	$ 48,397
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)				
Current liabilities:				
Accounts payable	$ 4,250	$ 3,515	$ 3,689	$ 3,689
Accrued expenses and other current liabilities	4,733	5,010	7,170	7,170
Deferred revenue	177	239	185	185
Current portion of long-term debt	—	1,805	—	—
Current portion of deferred rent	311	330	315	315
Total current liabilities	9,471	10,899	11,359	11,359
Preferred stock warrant liability	512	353	776	—
Long-term debt, net of discount and current portion	8,407	6,847	33,564	33,564
Deferred rent, net of current portion	1,437	1,107	876	876
Total liabilities	19,827	19,206	46,575	45,799
Commitments and contingencies (Note 13)				
Convertible preferred stock (Series A-1, B, B-1, C, D, E and F), $0.0001 par value; 50,776,054 shares authorized at December 31, 2016 and December 30, 2017 and September 29, 2018 (unaudited); 50,404,140 shares issued and outstanding at December 31, 2016 and December 30, 2017 and September 29, 2018 (unaudited); aggregate liquidation preference of $223,681 at December 30, 2017 and September 29, 2018 (unaudited); no shares issued or outstanding, pro forma at September 29, 2018 (unaudited)	186,519	186,519	186,519	—
Stockholders' equity (deficit):				
Common stock, $0.0001 par value; 60,000,000 shares authorized at December 31, 2016 and December 30, 2017, 60,000,000 shares authorized at September 29, 2018 (unaudited); 4,641,728 shares and 4,657,483 shares issued and outstanding at December 31, 2016 and December 30, 2017, respectively, 4,878,364 shares issued and 4,877,288 shares outstanding at September 29, 2018 (unaudited); no shares issued or outstanding, pro forma at September 29, 2018 (unaudited)	1	1	1	—
Common stock, no par value; no shares authorized, issued or outstanding at December 31, 2016, December 30, 2017 or September 29, 2018 (unaudited); shares issued and outstanding, pro forma at September 29, 2018 (unaudited)	—	—	—	331,037
Additional paid-in capital	143,531	143,604	143,741	—
Accumulated other comprehensive loss	(417)	(149)	(138)	(138)
Accumulated deficit	(291,357)	(312,180)	(328,301)	(328,301)
Total stockholders' equity (deficit)	(148,242)	(168,724)	(184,697)	2,598
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 58,104	$ 37,001	$ 48,397	$ 48,397

The accompanying notes are an integral part of these consolidated financial statements.

TRANSMEDICS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except share and per share amounts)

	Fiscal Year Ended		Fiscal Nine Months Ended	
	December 31, 2016	December 30, 2017	September 30, 2017	September 29, 2018
			(unaudited)	
Net revenue	$ 6,209	$ 7,685	$ 5,579	$ 9,473
Cost of revenue	5,443	5,548	3,971	5,238
Gross profit	766	2,137	1,608	4,235
Operating expenses:				
Research, development and clinical trials	15,637	14,957	11,555	10,170
Selling, general and administrative	8,115	7,606	5,973	7,941
Total operating expenses	23,752	22,563	17,528	18,111
Loss from operations	(22,986)	(20,426)	(15,920)	(13,876)
Other income (expense):				
Interest expense	(979)	(1,072)	(804)	(1,647)
Change in fair value of preferred stock warrant liability	(105)	159	156	(423)
Other income (expense), net	5	548	421	(152)
Total other expense, net	(1,079)	(365)	(227)	(2,222)
Loss before income taxes	(24,065)	(20,791)	(16,147)	(16,098)
Provision for income taxes	—	(32)	(28)	(23)
Net loss	$ (24,065)	$ (20,823)	$ (16,175)	$ (16,121)
Net loss per share attributable to common stockholders, basic and diluted	$ (5.35)	$ (4.48)	$ (3.48)	$ (3.42)
Weighted average common shares outstanding, basic and diluted	4,502,099	4,647,495	4,646,570	4,714,298
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)		$		$
Pro forma weighted average common shares outstanding, basic and diluted (unaudited)				

The accompanying notes are an integral part of these consolidated financial statements.

TRANSMEDICS, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)

	Fiscal Year Ended		Fiscal Nine Months Ended	
	December 31, 2016	December 30, 2017	September 30, 2017	September 29, 2018
			(unaudited)	
Net loss	$ (24,065)	$ (20,823)	$ (16,175)	$ (16,121)
Other comprehensive income (loss):				
Foreign currency translation adjustment	(5)	269	127	4
Unrealized gains (losses) on marketable securities, net of tax of $0	(6)	(1)	(4)	7
Total other comprehensive income (loss)	(11)	268	123	11
Comprehensive loss	$ (24,076)	$ (20,555)	$ (16,052)	$ (16,110)

The accompanying notes are an integral part of these consolidated financial statements.

TRANSMEDICS, INC.

CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT

(In thousands, except share amounts)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehen-sive Loss	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Par Value				
Balances at December 26, 2015	37,632,650	$122,911	4,423,748	$ 1	$ 143,465	$ (406)	$ (267,292)	$ (124,232)
Issuance of Series F convertible preferred stock, net of issuance costs of $122	12,771,490	63,608	—	—	—	—	—	—
Issuance of common stock upon the exercise of common stock options	—	—	217,980	—	21	—	—	21
Stock-based compensation expense	—	—	—	—	45	—	—	45
Foreign currency translation adjustment	—	—	—	—	—	(5)	—	(5)
Unrealized loss on marketable securities	—	—	—	—	—	(6)	—	(6)
Net loss	—	—	—	—	—	—	(24,065)	(24,065)
Balances at December 31, 2016	50,404,140	186,519	4,641,728	1	143,531	(417)	(291,357)	(148,242)
Issuance of common stock upon the exercise of common stock options	—	—	15,755	—	3	—	—	3
Stock-based compensation expense	—	—	—	—	70	—	—	70
Foreign currency translation adjustment	—	—	—	—	—	269	—	269
Unrealized loss on marketable securities	—	—	—	—	—	(1)	—	(1)
Net loss	—	—	—	—	—	—	(20,823)	(20,823)
Balances at December 30, 2017	50,404,140	186,519	4,657,483	1	143,604	(149)	(312,180)	(168,724)
Issuance of common stock upon the exercise of common stock options	—	—	220,881	—	45	—	—	45
Abandonment of shares of common stock by stockholders	—	—	(1,076)	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	92	—	—	92
Foreign currency translation adjustment	—	—	—	—	—	4	—	4
Unrealized gain on marketable securities	—	—	—	—	—	7	—	7
Net loss	—	—	—	—	—	—	(16,121)	(16,121)
Balances at September 29, 2018 (unaudited)	50,404,140	$186,519	4,877,288	$ 1	$ 143,741	$ (138)	$ (328,301)	$ (184,697)

TRANSMEDICS, INC.

CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT (Continued)

(In thousands, except share amounts)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehen-sive Loss	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Par Value				
Balances at December 31, 2016	50,404,140	186,519	4,641,728	$ 1	$ 143,531	$ (417)	$ (291,357)	$ (148,242)
Issuance of common stock upon the exercise of common stock options	—	—	5,866	—	1	—	—	1
Stock-based compensation expense	—	—	—	—	47	—	—	47
Foreign currency translation adjustment	—	—	—	—	—	127	—	127
Unrealized loss on marketable securities	—	—	—	—	—	(4)	—	(4)
Net loss	—	—	—	—	—	—	(16,175)	(16,175)
Balances at September 30, 2017 (unaudited)	50,404,140	186,519	4,647,594	$ 1	$ 143,579	$ (294)	$ (307,532)	$ (164,246)

The accompanying notes are an integral part of these consolidated financial statements.

TRANSMEDICS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Fiscal Year Ended		Fiscal Nine Months Ended	
	December 31, 2016	December 30, 2017	September 30, 2017	September 29, 2018
			(unaudited)	
Cash flows from operating activities:				
Net loss	$ (24,065)	$ (20,823)	$ (16,175)	$ (16,121)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization expense	426	630	461	550
Stock-based compensation expense	45	70	47	92
Change in fair value of preferred stock warrant liability	105	(159)	(156)	423
Non-cash interest expense	65	93	69	116
Net amortization of premiums on marketable securities	187	151	133	9
Loss on extinguishment of debt	—	—	—	305
Unrealized foreign currency transaction (gains) losses	—	(308)	(238)	(10)
Changes in operating assets and liabilities:				
Accounts receivable	(758)	454	279	(2,979)
Inventory	(1,587)	(2,497)	(1,365)	(2,818)
Prepaid expenses and other current assets	(108)	(166)	(31)	(183)
Other long-term assets	(5)	12	11	—
Accounts payable	1,062	(735)	(1,602)	(753)
Accrued expenses and other current liabilities	805	429	954	1,805
Deferred revenue	12	62	32	(54)
Deferred rent	(293)	(311)	(232)	(246)
Net cash used in operating activities	(24,109)	(23,098)	(17,813)	(19,864)
Cash flows from investing activities:				
Purchases of property and equipment	(1,478)	(263)	(144)	(284)
Purchases of marketable securities	(46,534)	(19,187)	(15,466)	—
Proceeds from sales and maturities of marketable securities	8,340	44,309	34,616	12,725
Net cash provided by (used in) investing activities	(39,672)	24,859	19,006	12,441
Cash flows from financing activities:				
Proceeds from issuance of convertible preferred stock, net of issuance costs	63,608	—	—	—
Proceeds from issuance of long-term debt, net of issuance costs	—	—	—	33,436
Repayments of long-term debt	—	—	—	(9,076)
Payment of additional debt issuance costs	(85)	—	—	—
Payments of initial public offering costs	—	—	—	(61)
Proceeds from issuance of common stock upon exercise of stock options	21	3	1	45
Net cash provided by financing activities	63,544	3	1	24,344
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(6)	335	339	33
Net increase (decrease) in cash, cash equivalents and restricted cash	(243)	2,099	1,533	16,954
Cash, cash equivalents and restricted cash, beginning of period	10,580	10,337	10,337	12,436
Cash, cash equivalents and restricted cash, end of period	$ 10,337	$ 12,436	$ 11,870	$ 29,390
Supplemental disclosure of cash flow information:				
Cash paid for interest	$ 825	$ 823	$ 618	$ 1,473
Supplemental disclosure of non-cash investing and financing activities:				
Transfers of inventory to property and equipment	$ —	$ 1,130	$ 950	$ 1,168
Issuance of preferred stock warrants in connection with amended loan agreement	$ 82	$ —	$ —	$ —
Deferred offering costs included in accounts payable and accrued expenses	$ —	$ —	$ —	$ 1,407

The accompanying notes are an integral part of these consolidated financial statements.

TRANSMEDICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of the Business and Basis of Presentation

TransMedics, Inc. (the "Company") was incorporated in the State of Delaware in August 1998. The Company is a commercial-stage medical technology company transforming organ transplant therapy for end-stage organ failure patients across multiple disease states. The Company developed the Organ Care System ("OCS") to replace a decades-old standard of care. The OCS represents a paradigm shift that transforms organ preservation for transplantation from a static state to a dynamic environment that enables new capabilities, including organ optimization and assessment. The Company's OCS technology replicates many aspects of the organ's natural living and functioning environment outside of the human body.

The Company is subject to risks and uncertainties common to companies in the medical device industry and of similar size, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, uncertainty of market acceptance of products, and the need to obtain additional financing to fund operations. Products currently under development will require additional research and development efforts, including additional clinical testing and regulatory approval, prior to commercialization. These efforts require additional capital, adequate personnel, infrastructure and extensive compliance-reporting capabilities. There can be no assurance that the Company's research and development will be successfully completed, that adequate protection for the Company's technology will be obtained, that any products will obtain necessary government regulatory approval or that any approved products will be commercially viable. The Company operates in an environment of rapid change in technology and competition from other medical device companies.

Basis of Presentation

The Company's fiscal year ends on the Saturday nearest December 31, and the Company reports fiscal years using a 52/53-week convention. Under this convention, certain fiscal years contain 53 weeks. Each fiscal year is typically composed of four 13-week fiscal quarters, but in years with 53 weeks, the fourth quarter is a 14-week period. The fiscal year ended December 31, 2016 included 53 weeks, while the fiscal year ended December 30, 2017 included 52 weeks.

The Company's consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

Going Concern

In accordance with Accounting Standards Update ("ASU") No. 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (Subtopic 205-40)*, the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the consolidated financial statements are issued.

Since its inception, the Company has funded its operations primarily with proceeds from sales of preferred stock and borrowings under loan agreements. The Company has incurred recurring losses since inception, including net losses of $24.1 million and $20.8 million for the fiscal years ended December 31, 2016 and December 30, 2017, respectively, and $16.1 million for the fiscal nine months ended September 29, 2018 (unaudited). In addition, as of December 30, 2017 and September 29, 2018 (unaudited), the Company had an accumulated deficit of $312.2 million and $328.3 million, respectively. The Company expects to continue to generate operating losses for the foreseeable future. As of October 19, 2018, the issuance date of the annual

TRANSMEDICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

consolidated financial statements for the fiscal year ended December 30, 2017, the Company expected that its cash, cash equivalents and marketable securities would be sufficient to fund its operating expenses, capital expenditure requirements and debt service payments through September 2019, without considering potential additional borrowings of up to $30.0 million that may become available to the Company under its credit agreement with OrbiMed Royalty Opportunities II, L.P. upon the achievement of specified revenue thresholds and a regulatory milestone (see Note 7). In addition, as of December 12, 2018, the issuance date of the interim consolidated financial statements for the fiscal nine months ended September 29, 2018 (unaudited), the Company expects that its cash and cash equivalents will be sufficient to fund its operating expenses, capital expenditure requirements and debt service payments through September 2019, without considering potential additional borrowings of up to $30.0 million that may become available to the Company under its credit agreement with OrbiMed Royalty Opportunities II, L.P. upon the achievement of specified revenue thresholds and a regulatory milestone. The future viability of the Company beyond that point is dependent on its ability to raise additional capital to finance its operations.

The Company is seeking to complete an initial public offering ("IPO") of the common stock of its wholly-owned subsidiary, TransMedics Group, Inc. ("TransMedics Group"), which will become the direct parent of the Company immediately prior to or concurrently with the closing of the IPO. In the event an IPO of the common stock of TransMedics Group is not completed (see "The Corporate Reorganization" below), the Company expects to seek additional funding through private equity financings, debt financings or strategic alliances. The Company may not be able to obtain financing on acceptable terms, or at all, and the terms of any financing may adversely affect the holdings or the rights of the Company's stockholders.

If the Company is unable to obtain funding, the Company will be required to delay, reduce or eliminate some or all of its research and development programs, product expansion or commercialization efforts, or the Company may be unable to continue operations. Although management continues to pursue these financing plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all.

Based on its recurring losses from operations incurred since inception, expectation of continuing operating losses for the foreseeable future, and need to raise additional capital to finance its future operations, as of October 19, 2018, the issuance date of the annual consolidated financial statements for the fiscal year ended December 30, 2017, and as of December 12, 2018, the issuance date of the interim consolidated financial statements for the fiscal nine months ended September 29, 2018 (unaudited), the Company has concluded that there is substantial doubt about its ability to continue as a going concern within one year after the date that these consolidated financial statements are issued.

The accompanying consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. Accordingly, the consolidated financial statements have been prepared on a basis that assumes the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

The Corporate Reorganization

TransMedics Group, a recently formed Massachusetts corporation, is currently a direct, wholly-owned subsidiary of the Company, a Delaware corporation. Immediately prior to or concurrently with the closing of the IPO, TMDX, Inc., a direct, wholly-owned subsidiary of TransMedics Group, will merge with and into the Company with the Company as the surviving corporation. As a result of the merger, each outstanding share of capital stock of the Company will be converted into shares of common stock of TransMedics Group, each outstanding option to purchase shares of common stock of the Company will be converted into an outstanding

option to purchase shares of common stock of TransMedics Group, and each outstanding warrant to purchase shares of preferred stock of the Company will be converted into a warrant to purchase shares of common stock of TransMedics Group, pursuant to the terms of an agreement and plan of merger and reorganization. This is referred to as the "Corporate Reorganization."

Immediately following the Corporate Reorganization, (i) TransMedics Group will be a holding company with no material assets other than 100% of the equity interests in the Company, (ii) the holders of capital stock in the Company will become shareholders of TransMedics Group and (iii) the historical consolidated financial statements of the Company will become the historical consolidated financial statements of TransMedics Group because the Corporate Reorganization will be accounted for as a reorganization of entities under common control. Prior to the Corporate Reorganization, TransMedics Group has not conducted any activities other than in connection with its formation and in preparation for the IPO and has no material assets other than 100% of the equity interests in TMDX, Inc.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenue and expenses during the reporting periods. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, revenue recognition, the valuation of inventory, the valuation of common stock, the valuation of stock-based awards and the valuation of the preferred stock warrant liability. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates as there are changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results may differ from those estimates or assumptions.

Unaudited Interim Financial Information

The accompanying consolidated balance sheet as of September 29, 2018, the consolidated statements of operations, of comprehensive loss and of cash flows for the fiscal nine months ended September 30, 2017 and September 29, 2018, and the consolidated statements of convertible preferred stock and stockholders' deficit for the fiscal nine months ended September 30, 2017 and September 29, 2018 are unaudited. The unaudited interim consolidated financial statements have been prepared on the same basis as the audited annual consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company's financial position as of September 29, 2018 and the results of its operations and its cash flows for the fiscal nine months ended September 30, 2017 and September 29, 2018. The financial data and other information disclosed in these notes related to the fiscal nine months ended September 30, 2017 and September 29, 2018 are also unaudited. The results for the fiscal nine months ended September 29, 2018 are not necessarily indicative of results to be expected for the fiscal year ending December 29, 2018, any other interim periods, or any future year or period.

Unaudited Pro Forma Information

The accompanying unaudited pro forma consolidated balance sheet as of September 29, 2018 has been prepared to give effect to the Corporate Reorganization, including (i) the conversion of all outstanding shares of convertible preferred stock of the Company into an aggregate of shares of common stock of

TRANSMEDICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

TransMedics Group, (ii) the conversion of all outstanding shares of common stock of the Company into an aggregate of shares of common stock of TransMedics Group and (iii) the conversion of all outstanding warrants to purchase shares of convertible preferred stock of the Company into warrants to purchase shares of common stock of TransMedics Group as if the Corporate Reorganization had occurred on September 29, 2018.

In the accompanying consolidated statements of operations, the unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the fiscal year ended December 30, 2017 and fiscal nine months ended September 29, 2018 have been prepared to give effect to the Corporate Reorganization, including (i) the conversion of all outstanding shares of convertible preferred stock of the Company into shares of common stock of TransMedics Group, (ii) the conversion of all outstanding shares of common stock of the Company into an aggregate of shares of common stock of TransMedics Group and (iii) the conversion of all outstanding warrants to purchase shares of convertible preferred stock of the Company into warrants to purchase shares of common stock of TransMedics Group as if the Corporate Reorganization had occurred on the later of January 1, 2017 or the issuance date of the convertible preferred stock, common stock or preferred stock warrants.

Risk of Concentrations of Credit, Significant Customers and Significant Suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents, marketable securities and accounts receivable. As of December 31, 2016 and December 30, 2017, the Company maintained its cash, cash equivalents and marketable securities with financial institutions that management believes to be of high credit quality. As of September 29, 2018 (unaudited), the Company maintained its cash and cash equivalents with financial institutions that management believes to be of high credit quality. The Company has not experienced any other-than-temporary losses with respect to its cash, cash equivalents and marketable securities and does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships. The Company's marketable securities as of December 31, 2016 and December 30, 2017 consisted of U.S. Treasury securities and U.S. government agency bonds. The Company had no marketable securities as of September 29, 2018 (unaudited).

Significant customers are those that accounted for 10% or more of the Company's total revenue or accounts receivable (see Note 16).

Certain of the components and subassemblies included in the Company's products are obtained from a sole source, a single source or a limited group of suppliers. Although the Company seeks to reduce dependence on those limited sources of suppliers and manufacturers, the partial or complete loss of certain of these sources could have a material adverse effect on the Company's operating results, financial condition and cash flows and damage its customer relationships.

Deferred Offering Costs

The Company capitalizes certain legal, accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of an equity financing, these costs are recorded in stockholders' equity (deficit) as a reduction of additional paid-in capital generated as a result of the offering. Should the in-process equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the consolidated statements of operations. The Company had no deferred offering costs recorded as of December 31, 2016 and December 30, 2017. The Company recorded deferred offering costs of $1.5 million as of September 29, 2018 (unaudited).

TRANSMEDICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Deferred Financing Costs

Deferred financing costs related to a recognized debt liability are recorded as a reduction of the carrying amount of the debt liability and amortized to interest expense using the effective interest method over the repayment term of the debt.

Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less at the date of purchase to be cash equivalents.

Restricted Cash

As of December 31, 2016, December 30, 2017 and September 29, 2018 (unaudited), the Company maintained two letters of credit totaling $0.5 million for the benefit of the landlord of its leased property. The Company was required to maintain a separate cash balance of $0.5 million to secure the letters of credit. Related to this separate cash balance, the Company classified $0.5 million as restricted cash (non-current) on its consolidated balance sheets as of December 31, 2016, December 30, 2017 and September 29, 2018 (unaudited).

Accounts Receivable

Accounts receivable are presented net of a provision for doubtful accounts, which is an estimate of amounts that may not be collectible. The Company performs ongoing credit evaluations of its customers and, if necessary, provides an allowance for doubtful accounts and expected losses. The Company writes off accounts receivable against the allowance when it determines a balance is uncollectible and no longer actively pursues collection of the receivable. As of December 31, 2016, December 30, 2017 and September 29, 2018 (unaudited), the Company had no allowance for doubtful accounts. During the fiscal years ended December 31, 2016 and December 30, 2017 and the fiscal nine months ended September 30, 2017 and September 29, 2018 (unaudited), the Company did not record any provisions for doubtful accounts and did not write off any accounts receivable balances.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation and amortization expense is recognized using the straight-line method over the estimated useful life of each asset as follows:

	Estimated Useful Life
Manufacturing equipment	5 years
OCS Consoles loaned to customers	5 years
Computer equipment and software	3 years
Laboratory equipment	3 years
Office and trade show equipment	5 years
Leasehold improvements	Shorter of life of lease or 15 years

Costs incurred for OCS Consoles are recorded as inventory unless and until the Company determines that an OCS Console will be loaned to a customer for its use. When an OCS Console is loaned to a customer, the Company reclassifies the cost of the OCS Console from inventory to property and equipment and begins to depreciate the loaned OCS Console over its estimated life. Related depreciation expense for the loaned OCS Console is classified as a cost of revenue. If an OCS Console is returned to the Company, it will continue to be classified as property and equipment and depreciated over its remaining useful life. The Company retains title to all OCS Consoles loaned to customers.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Other than for OCS Consoles loaned to customers, costs for capital assets not yet placed into service are capitalized as construction-in-progress and depreciated once placed into service. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation and amortization are removed from the accounts and any resulting gain or loss is included in loss from operations. Expenditures for repairs and maintenance are charged to expense as incurred.

Impairment of Long-Lived Assets

Long-lived assets consist of property and equipment. Long-lived assets to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset group for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset group to its carrying value. An impairment loss would be recognized in loss from operations when estimated undiscounted future cash flows expected to result from the use of an asset group are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset group over its fair value, determined based on discounted cash flows. The Company did not record any impairment losses on long-lived assets during the fiscal years ended December 31, 2016 and December 30, 2017 and the fiscal nine months ended September 30, 2017 and September 29, 2018 (unaudited).

Software Development Costs

The Company incurs costs to develop computer software that is embedded in the hardware components of the Company's OCS Console and OCS Perfusion Sets. Research and development costs related to this software are expensed as incurred, except for costs of internally developed or externally purchased software that qualify for capitalization. Software development costs incurred subsequent to the establishment of technological feasibility, but prior to the general release of the product, are capitalized and, upon general release, are amortized based upon the pattern in which economic benefits related to such assets are realized. Due to the short time period between achieving technological feasibility and product release and the insignificant amount of costs incurred during such periods, the Company did not capitalize any software development costs during the fiscal years ended December 31, 2016 and December 30, 2017 and the fiscal nine months ended September 30, 2017 and September 29, 2018 (unaudited), respectively.

Inventory

Inventory is valued at the lower of cost or net realizable value. Cost is computed using the first-in, first-out method. The Company regularly reviews inventory quantities on-hand for excess and obsolete inventory and, when circumstances indicate, records charges to write down inventories to their estimated net realizable value, after evaluating historical sales, future demand, market conditions and expected product life cycles. Such charges are classified as cost of revenue in the consolidated statements of operations. Any write-down of inventory to net realizable value creates a new cost basis.

At the end of each reporting period, the Company assesses whether losses should be accrued on long-term manufacturing purchase commitments in accordance with Accounting Standards Codification ("ASC") 330, *Inventory*, which requires that losses that are expected to arise from firm, noncancelable and unhedged commitments for the future purchase of inventory, measured in the same way as inventory losses, should be recognized in the current period in the statement of operations unless they are deemed recoverable through firm sales contacts or when there are other circumstances that reasonably assure continuing sales without price

decline. As of the end of each reporting period presented in the accompanying consolidated financial statements, the Company did not identify any potential losses arising from remaining future purchase commitments as compared to estimated future customer sales through the remainder of the term of the manufacturing purchase commitment and, as a result, did not recognize in a current period any loss provision for future-period remaining purchase commitments.

Deferred Rent

The Company's lease agreements include payment escalations, rent holidays and other lease incentives, which are accrued or deferred as appropriate such that rent expense for each lease is recognized on a straight-line basis over the respective lease term. Adjustments for such items, consisting primarily of payment escalations, are recorded as deferred rent and amortized over the respective lease terms.

Fair Value Measurements

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company's cash equivalents and marketable securities, consisting of money market funds, U.S. Treasury securities and U.S. government agency bonds, and its preferred stock warrant liability are carried at fair value, determined according to the fair value hierarchy described above (see Note 3). The carrying values of the Company's accounts receivable, accounts payable and accrued expenses approximate their fair values due to the short-term nature of these assets and liabilities. The carrying value of the Company's long-term debt approximates its fair value at each balance sheet date due to its variable interest rate, which approximates a market interest rate.

Marketable Securities

The Company's marketable securities are classified as available-for-sale and are carried at fair value, with the unrealized gains and losses reported as a component of accumulated other comprehensive income (loss) in stockholders' equity (deficit). Realized gains and losses and declines in value determined to be other than temporary are based on the specific identification method and are included as a component of other income (expense), net in the consolidated statements of operations.

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The Company evaluates its marketable securities with unrealized losses for other-than-temporary impairment. When assessing marketable securities for other-than-temporary declines in value, the Company considers such factors as, among other things, how significant the decline in value is as a percentage of the original cost, how long the market value of the investment has been less than its original cost, the Company's ability and intent to retain the investment for a period of time sufficient to allow for any anticipated recovery in fair value and market conditions in general. If any adjustment to fair value reflects a decline in the value of the investment that the Company considers to be "other than temporary," the Company reduces the investment to fair value through a charge recorded in the consolidated statements of operations. No such adjustments were necessary during the periods presented.

Classification of Convertible Preferred Stock

The Company's convertible preferred stock is classified outside of stockholders' equity (deficit) on the consolidated balance sheet because the holders of such shares have liquidation rights in the event of a deemed liquidation that, in certain situations, is not solely within the control of the Company.

Preferred Stock Warrant Liability

The Company classifies warrants for the purchase of shares of its convertible preferred stock (see Notes 3 and 9) as a liability on its consolidated balance sheets as these warrants are freestanding financial instruments that may require the Company to transfer assets upon exercise. The warrant liability is initially recorded at fair value upon the date of issuance of each warrant and is subsequently remeasured to fair value at each reporting date. Changes in the fair value of the warrant liability are recognized as a component of other income (expense) in the consolidated statements of operations. Changes in the fair value of the preferred stock warrant liability will continue to be recognized until the warrants are exercised, expire or qualify for equity classification.

Segment Information

The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. The Company is developing and commercializing a proprietary system to preserve human organs for transplant in a near-physiologic condition to address the limitations of cold storage organ preservation. Operating segments are defined as components of an enterprise for which separate financial information is regularly evaluated by the Company's chief operating decision maker, or decision-making group, in deciding how to allocate resources and assess performance. The Company has determined that its chief operating decision maker is its Chief Executive Officer. The Company's chief operating decision maker reviews the Company's financial information on a consolidated basis for purposes of allocating resources and assessing financial performance.

Product Warranties

The Company provides a one-year warranty on its OCS Consoles and disposable sets and replaces or repairs any OCS Console or disposable set that does not function in accordance with the product specifications. OCS Consoles returned to the Company may be refurbished and redeployed. Estimated warranty costs are recorded at the time of shipment of the OCS Console or disposable set. Warranty costs are estimated based on the current expected product replacement or repair cost and expected replacement or repair rates based on historical experience. The Company evaluates its warranty accrual at the end of each reporting period and makes adjustments as necessary. As of December 31, 2016, December 30, 2017 and September 29, 2018 (unaudited), the warranty accrual was less than $0.1 million.

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Revenue Recognition

The Company generates revenue primarily from sales of its single-use, organ-specific disposable sets (i.e., its organ-specific OCS Perfusion Sets sold together with its organ-specific OCS Solutions) used on its organ-specific OCS Consoles, each being a component of the Company's OCS products. To a lesser extent, the Company also generates revenue from the sale of OCS Consoles to customers and from the implied rental of OCS Consoles loaned to customers at no charge. For each new transplant procedure, customers purchase an additional disposable set for use on the customer's existing organ-specific OCS Console.

The Company recognizes revenue from sales to customers when all of the following criteria are met: persuasive evidence of an arrangement exists, delivery has occurred (based on contractual shipping terms), the sales price is fixed or determinable, and collectability is reasonably assured. Revenue is recognized upon delivery to the customer or upon the later receipt of customer acceptance, if such acceptance is required. Because all elements of a customer order are delivered and recognized as revenue at the same time and because revenue allocated to elements other than OCS disposable sets, such as implied rental income and service revenue, is insignificant, all elements of revenue from customer arrangements are classified as a single category of revenue in the Company's consolidated statement of operations.

The Company's products have both software and non-software (e.g., hardware) components that function together to deliver the products' essential functionality. In addition, the hardware sold cannot be used apart from the embedded software. As a result, all of the Company's product offerings are excluded from the scope of software revenue recognition requirements and instead fall within the scope of ASC Topic 605, *Revenue Recognition*.

Substantially all of the Company's customer arrangements are multiple-element arrangements that contain deliverables consisting of OCS Perfusion Sets and OCS Solutions. In some of those multiple-element arrangements, the deliverables also include an OCS Console, whether sold or loaned to the customer. The Company evaluates each element within a multiple-element arrangement to determine whether it represents a separate unit of accounting. An element constitutes a separate unit of accounting when the delivered item has standalone value to the customer and delivery of any undelivered element is probable and within the Company's control.

When a customer order includes an OCS Console, whether sold or loaned, the Company has determined that customer training and the equipment set-up of the OCS Console, each performed by the Company, lack standalone value to the customer because they are not sold on a standalone basis and can only be performed by the Company in conjunction with a sale or loan of its OCS Console. As a result, the Company has concluded that training, OCS Console equipment set-up and the OCS Console itself represent a single unit of accounting. Consequently, the Company does not recognize any revenue from any element of a customer order that includes an OCS Console, whether sold or loaned, until the OCS Console has been delivered and the training and equipment set-up have been completed by the Company. Further, the Company deems that "delivery" of an OCS Console occurs only after the console has been delivered and the training and equipment set-up have been completed by the Company.

Some of the Company's revenue has been generated from products sold in conjunction with the clinical trials conducted for the Company's OCS products, under arrangements referred to as customer clinical trial agreements. Under most of these customer clinical trial agreements, the Company places an organ-specific OCS Console at the customer site for its use free of charge for the duration of the clinical trial, and the customer separately purchases from the Company the OCS disposable sets used in each transplant procedure during the clinical trial. When the Company loans the OCS Console to the customer, it retains title to the console at all times

and does not require minimum purchase commitments from the customer related to any OCS products. In such cases, the Company invoices the customer for OCS disposable sets based on customer orders received for each new transplant procedure and the prices set forth in the customer agreement. Over time, the Company typically recovers the cost of the loaned OCS Console through the customer's continued purchasing and use of additional disposable sets. For these reasons, the Company has determined that part of the arrangement consideration for the disposable set is an implied rental payment for use of the OCS Console.

When the Company's customer arrangements are multiple-element arrangements that contain a loan of an OCS Console for the customer's use at its customer site as well as OCS disposable sets that are delivered simultaneously, the Company allocates the arrangement consideration between the lease deliverables (i.e., the OCS Console) and non-lease deliverables (i.e., the disposable sets) based on the relative selling price of each deliverable, determined using the selling price hierarchy. To date, the amounts allocated to lease deliverables have been insignificant. The selling price hierarchy includes (1) vendor-specific objective evidence ("VSOE"), if available, (2) third-party evidence ("TPE"), if VSOE is not available, or (3) best estimate of selling price ("BESP"), if neither VSOE nor TPE is available. The Company has not been able to establish a selling price for the lease deliverables (i.e., the OCS Console) using VSOE or TPE. The Company determines BESP by considering its overall pricing objectives and market conditions. Significant pricing practices taken into consideration include the Company's discounting practices, the Company's price lists, the Company's go-to-market strategy, historical sales and contract prices. The determination of BESP is made in consultation with, and is approved by, the Company's management.

In any multiple-element arrangement, the Company limits the amount of the arrangement fee allocated to deliverables to the amount that is not contingent on the future delivery of products or future performance obligations and the amount that is not subject to customer-specific return or refund privileges. Because the Company does not require minimum purchase commitments in any of its customer arrangements, the arrangement fee generated by expected future sales of OCS disposable sets is considered contingent for purposes of the allocation of the arrangement fee in each customer agreement.

Other Revenue Recognition Policies

Under all of the Company's customer arrangements that include a customer clinical trial agreement, the Company receives payments from sales to the customer of its OCS products and also makes payments to that customer for reimbursements of clinical trial materials and for specified clinical documentation related to the customer's use of its OCS products. If the clinical trial includes a patient arm that uses existing standard-of-care protocols for organ transplants (and does not use the Company's OCS products), then the Company makes additional payments to that customer to obtain clinical documentation related to existing standard-of-care protocols (i.e., unrelated to its OCS products).

In these cases, the Company has determined that the payments made to the customer for clinical trial materials and its costs incurred to execute specific clinical trial protocols related to its OCS products do not provide the Company with a separately identifiable benefit, and therefore, such payments are recorded as a reduction of revenue from the customer in the Company's consolidated statements of operations. Reductions of revenue related to such payments made to customers for reimbursements are recognized when the Company recognizes the revenue for the sale of its OCS disposable sets. For the fiscal years ended December 31, 2016 and December 30, 2017 and the fiscal nine months ended September 30, 2017 and September 29, 2018 (unaudited), the Company recorded as a reduction of revenue $0.9 million, $0.7 million, $0.6 million and $1.3 million, respectively, of reimbursable clinical trial costs.

In these same cases, the Company has also determined that payments made to the customer to obtain clinical documentation related to existing standard-of-care protocols (i.e., unrelated to its OCS products) do meet the

criteria to be classified as a cost because the Company receives an identifiable benefit separate from the customer's purchase of its OCS products and the consideration paid represents the fair value of the benefit received by the Company. As a result, payments made by the Company to customers for standard-of-care protocols are recorded as research, development and clinical trials expenses. For the fiscal years ended December 31, 2016 and December 30, 2017 and the fiscal nine months ended September 30, 2017 and September 29, 2018 (unaudited), the Company recorded as research, development and clinical trials expenses $0.3 million, $0.2 million, $0.1 million and $0.3 million, respectively, related to payments made to customers at clinical trial sites for documentation related to existing standard-of-care protocols.

Billings to customers for shipping costs and reimbursement of out-of-pocket expenses, including travel, lodging and meals, are recorded as revenue, and the associated costs incurred by the Company for those items are recorded as cost of revenue.

The Company excludes any taxes assessed by a governmental authority that are directly imposed on a revenue-producing transaction (e.g., sales, use and value added taxes) from its revenue and costs.

Distributors

The Company markets and sells its products primarily through its direct sales force, which sells its products to end customers globally. A small portion of the Company's revenue is generated by sales to a limited number of distributors in Europe and Asia-Pacific. When the Company transacts with a distributor, its contractual arrangement is with the distributor and not with the end customer. Whether the Company transacts business with and receives the order from a distributor or directly from an end customer, its revenue recognition policy and resulting pattern of revenue recognition for the order are the same.

In its business with distributors, the Company enters into a distributor agreement under which the distributor places orders to the Company for its products in connection with the distributor's own sales to identified end customers, and the Company confirms the identification of the end customer prior to accepting each order. The Company's distributors do not stock OCS Consoles purchased from the Company and stock only minimal quantities of OCS disposable sets. Under these contractual arrangements, the Company invoices the distributor for the arrangement fee (which reflects a distributor discount relative to typical end customer pricing) and payment to the Company from the distributor is not contingent upon the distributor's collection from the end customer. The Company records revenue based on the amount of the discounted arrangement fee.

When a sale to a distributor includes an OCS Console, the Company performs the training and OCS Console equipment set-up for the end customer. The Company recognizes no revenue from a distributor order that includes an OCS Console until the OCS Console has been delivered and the training and equipment set-up have been completed by the Company.

Deferred Revenue

Deferred revenue consists of amounts that have been invoiced but that have not been recognized as revenue. Deferred revenue that is expected to be recognized as revenue during the succeeding 12 months is recorded as current, and the remaining deferred revenue is recorded as non-current on the consolidated balance sheets.

Research, Development and Clinical Trials Costs

Research, development and clinical trials expenses consist of costs incurred for research activities, product development, hardware and software engineering and clinical trial activities, including salaries and bonuses, stock-based compensation, employee benefits, facilities costs, laboratory supplies, depreciation, testing, regulatory, data management and consulting costs.

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Research, development and clinical trials costs are expensed as incurred. Advance payments for goods or services to be received in the future for use in research, development and clinical trials activities are recorded as prepaid expenses. Such prepaid expenses are recognized as an expense when the related goods have been delivered or the related services have been performed, or when it is no longer expected that the goods will be delivered or the services rendered.

Patent Costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred are classified as general and administrative expenses.

Foreign Currency Translation

The functional currency of each of the Company's foreign subsidiaries is the currency of the local country. Assets and liabilities of the Company's foreign subsidiaries are translated into U.S. dollars using the period-end exchange rates, and income and expense items are translated into U.S. dollars using average exchange rates in effect during each period. The effects of these foreign currency translation adjustments are included in accumulated other comprehensive loss, a separate component of stockholders' equity (deficit).

The Company also incurs transaction gains and losses resulting from intercompany transactions of a short-term nature as well as transactions with customers or vendors denominated in currencies other than the functional currency of the legal entity in which the transaction is recorded. Foreign currency transaction gains (losses) are included in the consolidated statements of operations as a component of other income (expense) and totaled $(0.1) million and $0.3 million for the fiscal years ended December 31, 2016 and December 30, 2017, respectively, and $0.1 million and less than $(0.1) million for the fiscal nine months ended September 30, 2017 and September 29, 2018 (unaudited), respectively.

Stock-Based Compensation

The Company measures stock-based option awards granted to employees and directors based on their fair value on the date of grant using the Black-Scholes option-pricing model. Compensation expense for those awards is recognized over the requisite service period, which is generally the vesting period of the respective award. Generally, the Company issues awards with only service-based vesting conditions and records the expense for these awards using the straight-line method.

For stock-based option awards granted to non-employee consultants, compensation expense is recognized over the period during which services are rendered by such consultants until completed. At the end of each financial reporting period prior to completion of the service, the fair value of these awards is remeasured using the then-current fair value of the Company's common stock and updated assumption inputs in the Black-Scholes option-pricing model.

The Company classifies stock-based compensation expense in its consolidated statements of operations in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

Comprehensive Loss and Accumulated Other Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity (deficit) that result from transactions and economic events other than those with stockholders. The Company's only elements of

other comprehensive loss are foreign currency translation adjustments and unrealized gains (losses) on marketable securities.

Accumulated other comprehensive loss on the consolidated balance sheets consists primarily of foreign currency translation adjustments. Accumulated other comprehensive loss attributable to unrealized losses on marketable securities was not significant.

Net Income (Loss) per Share

The Company follows the two-class method when computing net income (loss) per share, as the Company has issued shares that meet the definition of participating securities. The two-class method determines net income (loss) per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed.

Basic net income (loss) per share attributable to common stockholders is computed by dividing the net income (loss) attributable to common stockholders by the weighted average number of common shares outstanding for the period. Diluted net income (loss) attributable to common stockholders is computed by adjusting net income (loss) attributable to common stockholders to reallocate undistributed earnings based on the potential impact of dilutive securities. Diluted net income (loss) per share attributable to common stockholders is computed by dividing the diluted net income (loss) attributable to common stockholders by the weighted average number of common shares outstanding for the period, including potential dilutive common shares assuming the dilutive effect of common stock equivalents.

The Company's convertible preferred stock contractually entitles the holders of such shares to participate in dividends but does not contractually require the holders of such shares to participate in losses of the Company. Accordingly, in periods in which the Company reports a net loss, such losses are not allocated to such participating securities. In periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive. The Company reported a net loss attributable to common stockholders for the fiscal years ended December 31, 2016 and December 30, 2017 and for the fiscal nine months ended September 30, 2017 and September 29, 2018 (unaudited).

Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in the Company's tax returns. Deferred tax assets and liabilities are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

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The Company accounts for uncertainty in income taxes recognized in the consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the consolidated financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

Recently Adopted Accounting Pronouncements

In March 2016, the Financial Accounting Standards Board ("FASB") issued ASU No. 2016-09, *Compensation—Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting* ("ASU 2016-09"). ASU 2016-09 involves several aspects of the accounting for share-based transactions, including the income tax consequences, classification of awards as either equity or liabilities, an option to recognize gross share compensation expense with actual forfeitures recognized as they occur and certain classifications on the statement of cash flows. Certain of these changes are required to be applied retrospectively, while other changes are required to be applied prospectively. For public entities, this guidance was effective for annual reporting periods beginning after December 15, 2016 and for interim periods within those fiscal years. For nonpublic entities, this guidance was effective for annual periods beginning after December 15, 2017 and for interim periods within those fiscal years. As early adoption was permitted, the Company adopted ASU 2016-09 as of January 1, 2017 and has elected to account for forfeitures as they occur rather than apply an estimated forfeiture rate to stock-based compensation expense. The adoption of this guidance had no impact on the Company's financial position, results of operations or cash flows.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows: Classification of Certain Cash Receipts and Cash Payments* ("ASU 2016-15"), to address diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows. For public entities, this standard was effective for annual periods beginning after December 15, 2017, including interim periods within those fiscal years. For nonpublic entities, the standard is effective for annual periods beginning after December 15, 2018. As early adoption was permitted, the Company adopted ASU 2016-15 as of January 1, 2017. The adoption of this guidance had no impact on the Company's financial position, results of operations or cash flows.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash* ("ASU 2016-18"). ASU 2016-18 requires that the statement of cash flows explain the change during the period in the total of cash, cash equivalents and amounts generally described as restricted cash or restricted cash equivalents. Entities will also be required to reconcile such total to amounts on the balance sheet and disclose the nature of the restrictions. For public entities, this guidance was effective for annual reporting periods beginning after December 15, 2017 and interim periods within those fiscal years. For nonpublic entities, this guidance is effective for annual reporting periods beginning after December 15, 2018 and interim periods within those fiscal years. As early adoption was permitted, the Company adopted this standard retrospectively as of January 1, 2017. Restricted cash is now included as a component of cash, cash equivalents and restricted cash on the Company's consolidated statement of cash flows. Upon the adoption of ASU 2016-18, the amount of cash and cash equivalents previously presented in the consolidated statements of cash flows for the fiscal year ended December 31, 2016 increased by $0.5 million as of beginning and end of the fiscal year to reflect the inclusion of restricted cash in the amount reported for changes in cash, cash equivalents and restricted cash.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting* ("ASU 2017-09"). The amendments in ASU 2017-09 clarify that modification

accounting is required only if the fair value, the vesting conditions, or the classification of the awards (as equity or liability) changes as a result of the changes in terms or conditions. This guidance is effective for all entities for annual reporting periods beginning after December 15, 2017 and interim periods within those fiscal years. As early adoption was permitted, the Company adopted this standard as of January 1, 2017. The adoption of this guidance had no impact on the Company's financial position, results of operations or cash flows.

In March 2018, the FASB issued ASU No. 2018-05, *Income Taxes (Topic 740): Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118* ("ASU 2018-05"). This standard amends ASC 740, *Income Taxes*, to provide guidance on accounting for the tax effects of the Tax Cuts and Jobs Act (the "TCJA") pursuant to Staff Accounting Bulletin No. 118. ASU 2018-05 applies to both public and nonpublic entities. ASU 2018-05 allows a company to record a provisional amount when it does not have the necessary information available, prepared or analyzed in reasonable detail to complete the accounting for certain income tax effects of the TCJA. The Company adopted ASU 2018-05 in the fourth quarter of 2017, and when the Company has been able to make reasonable estimates of the effects related to the TCJA, the Company has recorded provisional amounts. Provisional amounts will be finalized no later than the fourth quarter of 2018, which is one year from when the TCJA was signed into law. The Company is still in the process of analyzing the impact to the Company of the TCJA and its analysis is not yet complete. The impact of the changes in U.S. tax law may be refined as further guidance, interpretations or information becomes available or upon completion by the Company of its evaluation of the impact of the changes in U.S. tax law. The ultimate impact to the Company's consolidated financial statements of the TCJA may differ from the provisional amounts.

Recently Issued Accounting Pronouncements

The Company qualifies as "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 and has elected not to "opt out" of the extended transition related to complying with new or revised accounting standards, which means that when a standard is issued or revised and it has different application dates for public and nonpublic companies, the Company will adopt the new or revised standard at the time nonpublic companies adopt the new or revised standard and will do so until such time that the Company either (i) irrevocably elects to "opt out" of such extended transition period or (ii) no longer qualifies as an emerging growth company.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)* ("ASU 2014-09") and has since issued several additional amendments thereto, collectively referred to herein as ASC 606. ASC 606 outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry specific guidance. The new standards require entities to apportion consideration from contracts to performance obligations on a relative standalone selling price basis, based on a five-step model. Under ASC 606, revenue is recognized when a customer obtains control of a promised good or service and is recognized in an amount that reflects the consideration that the entity expects to receive in exchange for the good or service. In addition, ASC 606 provides guidance on accounting for certain revenue related costs, including costs associated with obtaining and fulfilling a contract. ASC 606 may be applied using either a full retrospective approach, under which all years included in the financial statements will be presented under the revised guidance, or a modified retrospective approach, under which financial statements will be prepared under the revised guidance for the year of adoption, but not for prior years. Under the latter method, entities will recognize a cumulative catch-up adjustment to the opening balance of retained earnings at the effective date for contracts that still require performance by the entity at the date of adoption. For public entities, the guidance was effective for annual periods beginning after December 15, 2017, including interim periods within those fiscal years. For nonpublic entities, the guidance is effective for annual periods beginning after December 15, 2018. The Company will adopt ASC 606 in its fiscal year 2019, which begins on December 30, 2018, in accordance with the nonpublic

company requirements. The Company is currently evaluating the method of adoption and the potential impact that the adoption of ASC 606 will have on its consolidated financial statements.

In January 2016, the FASB issued ASU No. 2016-01, *Financial Instruments—Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities* ("ASU 2016-01"). This new standard amends certain aspects of accounting and disclosure requirements for financial instruments, including the requirement that equity investments with readily determinable fair values are to be measured at fair value with any changes in fair value recognized in a company's earnings. This new standard does not apply to investments accounted for under the equity method of accounting or those investments that result in consolidation of the investee. Equity investments that do not have readily determinable fair values may be measured at fair value or at cost minus impairment adjusted for changes in observable prices. A financial liability that is measured at fair value in accordance with the fair value option is required to be presented separately in other comprehensive income for the portion of the total change in the fair value resulting from change in the instrument-specific credit risk. In addition, a valuation allowance should be evaluated on deferred tax assets related to available-for-sale debt securities in combination with other deferred tax assets. For public entities, this guidance is effective for annual reporting periods beginning after December 15, 2017 and interim periods within those fiscal years. For nonpublic entities, the guidance is effective for annual reporting periods beginning after December 15, 2018 and for interim periods within fiscal years beginning after December 15, 2019. The Company is currently evaluating the impact that the adoption of ASU 2016-01 will have on its consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* ("ASU 2016-02"), which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e., lessees and lessors). The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or less may be accounted for similar to existing guidance for operating leases today. For public entities, the guidance is effective for annual reporting periods beginning after December 15, 2018 and for interim periods within those fiscal years. For nonpublic entities, the guidance is effective for annual reporting periods beginning after December 15, 2019 and for interim periods within fiscal years beginning after December 15, 2020. Early adoption is permitted for all entities. ASU 2016-02 initially required adoption using a modified retrospective approach, under which all years presented in the financial statements would be prepared under the revised guidance. In July 2018, the FASB issued ASU No. 2018-11, *Leases (Topic 842)*, which added an optional transition method under which financial statements may be prepared under the revised guidance for the year of adoption, but not for prior years. Under the latter method, entities will recognize a cumulative catch-up adjustment to the opening balance of retained earnings in the period of adoption. The Company is currently evaluating whether to early adopt ASU 2016-02, the method of adoption of this guidance and the impact that the adoption of ASU 2016-02 will have on its consolidated financial statements.

In July 2017, the FASB issued ASU No. 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815) I. Accounting for Certain Financial Instruments with Down Round Features II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception* ("ASU 2017-11"). Part I applies to entities that issue financial instruments such as warrants, convertible debt or convertible preferred stock that contain down-round features. Part II replaces the indefinite deferral for certain mandatorily redeemable noncontrolling interests and mandatorily redeemable

financial instruments of nonpublic entities contained within ASC Topic 480 with a scope exception and does not impact the accounting for these mandatorily redeemable instruments. For public entities, this guidance is effective for annual periods beginning after December 15, 2018, including interim periods within those fiscal years. For nonpublic entities, this guidance is effective for annual periods beginning after December 15, 2019 and for interim periods within fiscal years beginning after December 15, 2020. Early adoption is permitted for all entities, including adoption in an interim period. If an entity early adopts the amendments in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. The Company is currently evaluating whether to early adopt ASU 2017-11 and evaluating the impact that the adoption of ASU 2017-11 will have on its consolidated financial statements.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation—Stock Compensation (Topic 718), Improvements to Nonemployee Share-Based Payment Accounting* ("ASU 2018-07"). This ASU is intended to simplify aspects of share-based compensation issued to non-employees by making the guidance consistent with the accounting for employee share-based compensation. For public entities, this guidance is effective for annual periods beginning after December 15, 2018, including interim periods within those fiscal years. For nonpublic entities, this guidance is effective for annual periods beginning after December 15, 2019. Early adoption is permitted for all entities as of a period no earlier than the Company's adoption of ASU 2014-09. The Company is currently evaluating the impact that the adoption of ASU 2018-07 will have on its consolidated financial statements.

3. Marketable Securities and Fair Value Measurements

Marketable securities by security type consisted of the following (in thousands):

	December 31, 2016			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury securities (due within one year)	$ 21,554	$ —	$ (2)	$ 21,552
U.S. government agency bonds (due within one year)	16,453	—	(4)	16,449
	$ 38,007	$ —	$ (6)	$ 38,001

	December 30, 2017			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury securities (due within one year)	$ 5,763	$ —	$ (3)	$ 5,760
U.S. government agency bonds (due within one year)	6,971	—	(4)	6,967
	$ 12,734	$ —	$ (7)	$ 12,727

The Company had no marketable securities as of September 29, 2018 (unaudited).

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The following tables present the Company's fair value hierarchy for its assets and liabilities that are measured at fair value on a recurring basis (in thousands):

	Fair Value Measurements at December 31, 2016 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 7,468	$ —	$ —	$ 7,468
Marketable securities:				
U.S. Treasury securities	—	21,552	—	21,552
U.S. government agency bonds	—	16,449	—	16,449
	$ 7,468	$ 38,001	$ —	$ 45,469
Liabilities:				
Preferred stock warrant liability	$ —	$ —	$ 512	$ 512

	Fair Value Measurements at December 30, 2017 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 5,568	$ —	$ —	$ 5,568
U.S. government agency bonds	—	1,497	—	1,497
Marketable securities:				
U.S. Treasury securities	—	5,760	—	5,760
U.S. government agency bonds	—	6,967	—	6,967
	$ 5,568	$ 14,224	$ —	$ 19,792
Liabilities:				
Preferred stock warrant liability	$ —	$ —	$ 353	$ 353

	Fair Value Measurements at September 29, 2018 (unaudited) Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 22,479	$ —	$ —	$ 22,479
	$ 22,479	$ —	$ —	$ 22,479
Liabilities:				
Preferred stock warrant liability	$ —	$ —	$ 776	$ 776

Money market funds were valued by the Company based on quoted market prices, which represent a Level 1 measurement within the fair value hierarchy. U.S. Treasury securities and U.S. government agency bonds were valued by the Company using quoted prices in active markets for similar securities, which represent a Level 2 measurement within the fair value hierarchy. There were no transfers between Level 1, Level 2 and Level 3 during the fiscal years ended December 31, 2016 and December 30, 2017 and the fiscal nine months ended September 30, 2017 and September 29, 2018 (unaudited).

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The preferred stock warrant liability in the table above consisted of the fair value of warrants to purchase Series B, Series D and Series F convertible preferred stock (see Note 9) and was based on significant inputs not observable in the market, which represent a Level 3 measurement within the fair value hierarchy. The Company's valuation of the preferred stock warrants utilized the Black-Scholes option-pricing model, which incorporates assumptions and estimates to value the preferred stock warrants. The Company assesses these assumptions and estimates on a quarterly basis as additional information impacting the assumptions is obtained. Changes in the fair value of the preferred stock warrants are recognized as other income (expense) in the consolidated statements of operations.

The quantitative elements associated with the Company's Level 3 inputs impacting the fair value measurement of the preferred stock warrant liability include the fair value per share of the underlying Series B, Series D and Series F convertible preferred stock, the remaining contractual term of the warrants, risk-free interest rate, expected dividend yield and expected volatility of the price of the underlying preferred stock. The most significant assumption in the Black-Scholes option-pricing model impacting the fair value of the preferred stock warrants is the fair value of the Company's convertible preferred stock as of each remeasurement date. The Company determines the fair value per share of the underlying preferred stock by taking into consideration the most recent sales of its convertible preferred stock, results obtained from third-party valuations and additional factors that the Company deems relevant. As of December 31, 2016, the fair value of each share of Series B, Series D and Series F convertible preferred stock was $0.98 per share, $3.76 per share and $4.99 per share, respectively. As of December 30, 2017, the fair value of each share of Series B, Series D and Series F convertible preferred stock was $0.75 per share, $2.99 per share and $4.83 per share, respectively. As of September 29, 2018 (unaudited), the fair value of each share of Series D and Series F convertible preferred stock was $5.50 per share and $5.32 per share, respectively. The Company historically has been a private company and lacks company-specific historical and implied volatility information of its stock. Therefore, it estimates its expected stock volatility based on the historical volatility of publicly traded peer companies for a term equal to the remaining contractual term of the warrants. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the warrants. The Company has estimated a 0% dividend yield based on the expected dividend yield and the fact that the Company has never paid or declared dividends.

The following table provides a roll-forward of the aggregate fair values of the Company's preferred stock warrants for which fair value is determined by Level 3 inputs (in thousands):

	Preferred Stock Warrant Liability
Fair value at December 26, 2015	$ 325
Issuance of warrants to purchase shares of Series F convertible preferred stock	82
Change in fair value	105
Fair value at December 31, 2016	512
Change in fair value	(159)
Fair value at December 30, 2017	353
Expiration of warrants to purchase shares of Series B convertible preferred stock	—
Change in fair value	423
Fair value at September 29, 2018 (unaudited)	$ 776

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4. Inventory

Inventory consisted of the following (in thousands):

	December 31, 2016	December 30, 2017	September 29, 2018 (unaudited)
Raw materials	$ 2,608	$ 3,127	$ 3,655
Work-in-process	599	720	1,161
Finished goods	3,128	4,124	4,805
	$ 6,335	$ 7,971	$ 9,621

During the fiscal years ended December 31, 2016 and December 30, 2017, the Company made non-cash transfers of OCS Consoles from inventory to property and equipment (OCS Consoles loaned to customers) of $1.2 million and $1.1 million, respectively. During the fiscal nine months ended September 30, 2017 and September 29, 2018 (unaudited), the Company made non-cash transfers of OCS Consoles from inventory to property and equipment (OCS Consoles loaned to customers) of $1.0 million and $1.2 million, respectively.

5. Property and Equipment, Net

Property and equipment, net consisted of the following (in thousands):

	December 31, 2016	December 30, 2017	September 29, 2018 (unaudited)
Manufacturing equipment	$ 1,163	$ 1,201	$ 1,205
OCS Consoles loaned to customers	1,380	2,549	3,688
Computer equipment and software	744	763	839
Laboratory equipment	475	512	514
Office and trade show equipment	173	173	173
Leasehold improvements	1,319	1,319	1,319
Construction-in-progress	202	332	529
	5,456	6,849	8,267
Less: Accumulated depreciation and amortization	(3,733)	(4,390)	(4,925)
	$ 1,723	$ 2,459	$ 3,342

During the fiscal years ended December 31, 2016 and December 30, 2017 and the fiscal nine months ended September 30, 2017 and September 29, 2018 (unaudited), total depreciation and amortization expense was $0.4 million, $0.6 million, $0.5 million and $0.6 million, respectively. Of those amounts, $0.2 million, $0.4 million, $0.3 million and $0.5 million, respectively, was recorded as expense in cost of revenue related to the depreciation of OCS Consoles loaned to customers. The Company retains title to OCS Consoles loaned to customers.

Construction-in-progress recorded as of December 31, 2016, December 30, 2017 and September 29, 2018 (unaudited) was primarily related to the in-process construction of manufacturing equipment and, to a lesser extent, internal-use software under development.

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6. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	December 31, 2016	December 30, 2017	September 29, 2018 (unaudited)
Accrued research, development and clinical trials expenses	$ 1,171	$ 1,394	$ 1,806
Accrued payroll and related expenses	1,162	1,136	2,002
Accrued financing fees (Note 13)	1,466	1,466	1,466
Accrued professional fees	176	258	787
Accrued premium for manufacturing contract (Note 13)	—	—	354
Accrued other	758	756	755
	$ 4,733	$ 5,010	$ 7,170

7. Long-Term Debt

As of December 31, 2016, December 30, 2017 and September 29, 2018 (unaudited), long-term debt consisted of the following (in thousands):

	December 31, 2016	December 30, 2017	September 29, 2018 (unaudited)
Principal amount of long-term debt	$ 8,500	$ 8,500	$ 35,000
Less: Current portion of long-term debt	—	(1,805)	—
Long-term debt, net of current portion	8,500	6,695	35,000
Debt discount, net of accretion	(193)	(100)	(1,485)
Accrued end-of-term payments	100	252	49
Long-term debt, net of discount and current portion	$ 8,407	$ 6,847	$ 33,564

Hercules Loan and Security Agreement

The Company had a loan agreement, entered into in 2015, (the "2015 Loan Agreement") with Hercules Technology Growth Capital, Inc. ("Hercules"). The 2015 Loan Agreement provided for borrowings of $8.5 million under a term loan, all of which was borrowed by the Company prior to 2016. Borrowings under the 2015 Loan Agreement bore interest at an annual rate equal to the greater of (i) 9.55% plus *The Wall Street Journal* prime rate minus 4.25% or (ii) 9.55%. Borrowings under the 2015 Loan Agreement were repayable in monthly interest-only payments through September 2016 and in equal monthly payments of principal and accrued interest from October 2016 until the maturity date in March 2019. The Company was also required to make an end-of-term payment of $0.1 million upon the earlier of the payment of all obligations under the 2015 Loan Agreement or the maturity date in March 2019.

In August 2016, the Company entered into an amendment to the 2015 Loan Agreement (the "Amended Loan Agreement") to extend the interest-only period to December 2017, to extend the maturity date to February 2020 and to add an additional end-of-term payment of $0.4 million, payable upon the earlier of the payment of all obligations under the Amended Loan Agreement or the maturity date in February 2020. The amendment to the 2015 Loan Agreement was accounted for as a debt modification, rather than a debt extinguishment, based on a comparison of the present value of the cash flows under the terms of the debt immediately before and after the

amendment, which resulted in a change of less than 10%. As a result, issuance costs paid to the lender of $0.1 million in connection with the amendment were recorded as a reduction of the carrying amount of the debt. Unamortized debt issuance costs as of the date of the amendment were amortized to interest expense using the effective interest method over the revised repayment term. Issuance costs paid to third parties were recorded as expense and were not significant.

As of December 31, 2016 and December 30, 2017, the interest rate applicable to borrowings under the Amended Loan Agreement was 9.55% and 9.80%, respectively. During the fiscal years ended December 31, 2016 and December 30, 2017, the weighted average effective interest rate on outstanding borrowings under the Amended Loan Agreement was approximately 13.1% and 13.1%, respectively.

In August 2016, in connection with entering into the Amended Loan Agreement, the Company issued to Hercules a warrant to purchase (i) 34,068 shares of Series F convertible preferred stock, at an exercise price of $4.99 per share, or (ii) if there is a subsequent preferred stock financing of at least $10.0 million and the price per share of preferred stock in such financing is lower than $4.99, that number of shares of series of stock offered in such financing equal to $0.2 million divided by the price per share in such financing, at an exercise price per share equal to the price per share in such financing (see Note 9). In each case, such exercise prices are subject to adjustment upon specified dilutive issuances. The warrant was immediately exercisable upon issuance and expires on the later of (i) August 4, 2023 or (ii) the fifth anniversary of the effective date of the Company's registration statement for its completed initial public offering (see Note 9). The fair value of the warrant on the issuance date of $0.1 million was recorded as a debt discount and as a component of the preferred stock warrant liability.

In June 2018, the Company repaid all amounts due under the Amended Loan Agreement, including $6.7 million of principal repayments, and the Amended Loan Agreement was terminated. Upon prepayment of the outstanding amounts, the Company recorded a loss on extinguishment of debt of $0.3 million, which was classified as other expense in the consolidated statement of operations.

In accordance with the applicable accounting standards, a short-term debt obligation should be excluded from current liabilities if the entity has both the intent and ability to refinance the obligation on a long-term basis. The intent and ability can be demonstrated by the issuance of a long-term obligation to refinance the short-term obligation on a long-term basis after the date of an entity's balance sheet but before that balance sheet is issued. Accordingly, as of December 30, 2017, the Company reclassified to long-term debt the $1.9 million aggregate principal amount payable within 12 months that had not been paid prior to the June 2018 repayment of all borrowings under the Amended Loan Agreement because the Company refinanced its obligations under the Amended Loan Agreement with long-term borrowings under a credit agreement with OrbiMed Royalty Opportunities II, L.P.

As part of the original 2015 Loan Agreement, the Company granted to Hercules the right, in its discretion, to participate in any subsequent preferred stock financing resulting in aggregate proceeds to the Company of at least $10.0 million in an amount of up to $1.0 million on the same terms, conditions and pricing afforded to others participating in such subsequent financing. As of December 30, 2017 and September 29, 2018 (unaudited), Hercules' right to participate in any subsequent financing remained unexercised.

OrbiMed Credit Agreement

In June 2018, the Company entered into a credit agreement (the "Credit Agreement") with OrbiMed Royalty Opportunities II, L.P. ("OrbiMed") pursuant to which OrbiMed made certain term loans available to the Company. The Credit Agreement provides for aggregate maximum borrowings of up to $65.0 million, consisting

of (i) $35.0 million upon entering into the Credit Agreement, which was borrowed by the Company in June 2018, and (ii) potential additional borrowings of up to $30.0 million that may become available upon the Company's achievement of specified revenue thresholds and a regulatory milestone by determinable dates. As of September 29, 2018 (unaudited), the Company had not yet met the conditions for additional borrowings.

Borrowings under the Credit Agreement bear interest at an annual rate equal to the London Interbank Offered Rate ("LIBOR"), subject to a minimum of 1.0% and a maximum of 4.0%, plus 8.5% (the "Applicable Margin"), subject in the aggregate to a maximum interest rate of 11.5%. In addition, borrowings under the Credit Agreement bear paid-in-kind ("PIK") interest at an annual rate equal to the amount by which LIBOR plus the Applicable Margin exceeds 11.5%, but not to exceed 12.5%. The PIK interest is added to the principal amount of the borrowings outstanding at the end of each quarter until the maturity date of the Credit Agreement in June 2023. Borrowings under the Credit Agreement are repayable in quarterly interest-only payments until the maturity date, at which time all principal and accrued interest is due and payable. At its option, the Company may prepay outstanding borrowings under the Credit Agreement, subject to a prepayment premium of 9.0% of the principal amount of any prepayment within the first three years, which percentage decreases annually until it reaches zero at the end of three years. The Company is also required to make a final payment in an amount equal to 3.0% of the principal amount of any prepayment or repayment. The final payment is being accreted to interest expense over the term of the Credit Agreement using the effective interest method.

In connection with entering into the Credit Agreement, the Company paid OrbiMed an upfront fee of $0.9 million and paid other costs to OrbiMed and third parties of $0.7 million, both of which were recorded by the Company as a debt discount. The debt discount is reflected as a reduction of the carrying value of long-term debt on the Company's consolidated balance sheet and is being accreted to interest expense over the term of the Credit Agreement using the effective interest method.

All obligations under the Credit Agreement are guaranteed by the Company and each of its material subsidiaries. All obligations of the Company and each guarantor are secured by substantially all of the Company's and each guarantor's assets, including their intellectual property, subject to certain exceptions, including a perfected security interest in substantially all tangible and intangible assets of the Company and each guarantor. Under the Credit Agreement, the Company has agreed to certain affirmative and negative covenants to which it will remain subject until maturity. The negative covenants include maintaining a minimum liquidity amount of $3.0 million and restrictions on the Company's activities, including limitations on dispositions, mergers or acquisitions; encumbering its intellectual property; incurring indebtedness or liens; paying dividends; making certain investments; and engaging in certain other business transactions. The obligations under the Credit Agreement are subject to acceleration upon the occurrence of specified events of default, including payment default, change in control, bankruptcy, insolvency, certain defaults under other material debt, certain events with respect to governmental approvals (if such events could cause a material adverse change in the Company's business) and a material adverse change in the Company's business, operations or other financial condition.

Upon the occurrence of an event of default and until such event of default is no longer continuing, the Applicable Margin will increase by 4.0% per annum. If an event of default (other than certain events of bankruptcy or insolvency) occurs and is continuing, OrbiMed may declare all or any portion of the outstanding principal amount of the borrowings plus accrued and unpaid interest to be due and payable. Upon the occurrence of certain events of bankruptcy or insolvency, all of the outstanding principal amount of the borrowings plus accrued and unpaid interest will automatically become due and payable. In addition, the Company may be required to prepay outstanding borrowings, subject to certain exceptions, with portions of net cash proceeds of certain asset sales and certain casualty and condemnation events.

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The Company assessed all terms and features of the Credit Agreement in order to identify any potential embedded features that would require bifurcation. As part of this analysis, the Company assessed the economic characteristics and risks of the debt. The Company determined that all features of the Credit Agreement are either clearly and closely associated with a debt host or have a *de minimis* fair value and, as such, do not require separate accounting as a derivative liability.

As of September 29, 2018 (unaudited), the interest rate applicable to borrowings under the Credit Agreement was 10.875%. During the fiscal nine months ended September 29, 2018 (unaudited), the weighted average effective interest rate on outstanding borrowings under the Credit Agreement was approximately 12.6%.

8. Convertible Preferred Stock

The Company has issued Series A-1 convertible preferred stock (the "Series A-1 Preferred Stock"), Series B convertible preferred stock (the "Series B Preferred Stock"), Series B-1 convertible preferred stock (the "Series B-1 Preferred Stock"), Series C convertible preferred stock (the "Series C Preferred Stock"), Series D convertible preferred stock (the "Series D Preferred Stock"), Series E convertible preferred stock (the "Series E Preferred Stock") and Series F convertible preferred stock (the "Series F Preferred Stock"). The Series A-1 Preferred Stock, Series B Preferred Stock, Series B-1 Preferred Stock, Series C Preferred Stock, Series D Preferred Stock, Series E Preferred Stock and Series F Preferred Stock are collectively referred to as the "Preferred Stock". The Series A-1 Preferred Stock, Series B Preferred Stock, Series B-1 Preferred Stock and Series C Preferred Stock are collectively referred to as the "Junior Preferred Stock", a subset of the Preferred Stock.

In May and June 2016, the Company issued and sold 12,771,490 shares of Series F Preferred Stock to new and existing investors at a price of $4.99 per share for gross proceeds of $63.7 million. The Company incurred issuance costs in connection with this transaction of $0.1 million.

Upon issuance of each class of Preferred Stock, the Company assessed the embedded conversion and liquidation features of the securities and determined that such features did not require the Company to separately account for these features. The Company also concluded that no beneficial conversion feature existed on the issuance date of each class of Preferred Stock.

As of December 31, 2016, December 30, 2017 and September 29, 2018 (unaudited), Preferred Stock consisted of the following (in thousands, except share amounts):

	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A-1 Preferred Stock	13,332	13,332	$ 3,333	$ 33	3,440
Series B Preferred Stock	3,771,020	3,624,650	10,691	12,382	1,001,356
Series B-1 Preferred Stock	2,560,245	2,560,245	8,746	8,746	707,301
Series C Preferred Stock	6,198,057	6,198,057	14,970	15,495	6,198,057
Series D Preferred Stock	14,740,000	14,565,000	34,868	72,825	14,565,000
Series E Preferred Stock	6,562,232	6,562,232	29,865	29,966	6,562,232
Series F Preferred Stock	16,931,168	16,880,624	84,046	84,234	16,880,624
	50,776,054	50,404,140	$ 186,519	$ 223,681	45,918,010

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The holders of Preferred Stock have the following rights and preferences:

Voting

The holders of the Preferred Stock are entitled to vote, together with the holders of common stock as a single class, on all matters submitted to stockholders for a vote. Each holder of Preferred Stock is entitled to the number of votes equal to the number of shares of common stock into which each share of Preferred Stock is convertible as of the record date for determining stockholders entitled to vote on such matter.

The holders of Series E Preferred Stock, voting exclusively and as a separate class, are entitled to elect one director of the Company, and the holders of Series D Preferred Stock, voting exclusively and as a separate class, are entitled to elect two directors of the Company. The holders of Preferred Stock, voting exclusively and as a separate class, are entitled to elect two directors of the Company.

Conversion

Each share of Preferred Stock is convertible into shares of common stock at the option of the holder at any time after the date of issuance. Each share of Preferred Stock will be automatically converted into shares of common stock, at the applicable conversion ratio then in effect, upon either (i) the closing of a firm commitment public offering with at least $30.0 million of gross proceeds to the Company and at a price of at least $9.98 per share, subject to appropriate adjustment in the event of any stock split, stock dividend, combination or other similar recapitalization, or (ii) the vote or written consent of the holders of at least 55% of the then-outstanding shares of Preferred Stock. Additionally, in the event a holder of Preferred Stock does not participate in a transaction that involves the issuance or sale of additional shares of common stock at a price per share that would result in a reduction to the Series F Preferred Stock conversion price (a “Qualified Financing”), then all shares of Preferred Stock held by such holder will automatically convert into shares of common stock at the applicable conversion ratio then in effect, unless the holders of at least 55% of the then-outstanding shares of Preferred Stock, elect that the transaction does not qualify as a Qualified Financing.

The conversion ratio of each series of Preferred Stock is determined by dividing the Original Issue Price of each series by the Conversion Price of each series. The Original Issue Price per share is $2.50 for Series A-1 Preferred Stock, $3.416 for Series B Preferred Stock, $3.416 for Series B-1 Preferred Stock, $2.50 for Series C Preferred Stock, $2.50 for Series D Preferred Stock, $4.5664 for Series E Preferred Stock and $4.99 for Series F Preferred Stock. The Conversion Price per share is $9.68 for Series A-1 Preferred Stock, $12.365 for Series B Preferred Stock, $12.365 for Series B-1 Preferred Stock, $2.50 for Series C Preferred Stock, $2.50 for Series D Preferred Stock, $4.5664 for Series E Preferred Stock and $4.99 for Series F Preferred Stock, each subject to appropriate adjustment in the event of any stock split, stock dividend, combination or other similar recapitalization and other adjustments as set forth in the Company’s certificate of incorporation, as amended and restated.

Dividends

The holders of the Series B Preferred Stock, Series B-1 Preferred Stock, Series C Preferred Stock, Series D Preferred Stock, Series E Preferred Stock and Series F Preferred Stock shall be entitled to receive, when, as and if declared by the board of directors, noncumulative cash dividends at the rate of 8% per annum of the respective Original Issue Price on each outstanding share of that series of Preferred Stock. The dividends on the Series F Preferred Stock are payable in preference and priority to any payment of any dividends on Series E Preferred Stock, Series D Preferred Stock, Junior Preferred Stock and common stock. The dividends on Series E Preferred

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Stock are payable in preference and priority to any payment of any dividend on Series D Preferred Stock, Junior Preferred Stock and common stock. The dividends on Series D Preferred Stock are payable in preference and priority to any payment of any dividend on Junior Preferred Stock and common stock. The dividends on Series C Preferred Stock are payable in preference and priority to any payment of any dividend on Series B-1 Preferred Stock, Series B Preferred Stock, Series A-1 Preferred Stock and common stock. The dividends on Series B-1 Preferred Stock are payable in preference and priority to any payment of any dividend on Series B Preferred Stock, Series A-1 Preferred Stock and common stock. The dividends on Series B Preferred Stock are payable in preference and priority to any payment of any dividend on Series A-1 Preferred Stock and common stock.

Subject to the provisions above, with respect to the declaration, payment and setting aside of dividends on the Series A-1 Preferred Stock or common stock, (i) the holders of Series F Preferred Stock, Series E Preferred Stock, Series D Preferred Stock, Series C Preferred Stock, Series B-1 Preferred Stock and Series B Preferred Stock shall be entitled to participate with the Series A-1 Preferred Stock and common stock and receive, *pari passu*, before any dividends shall be declared, paid or set aside for the Series A-1 Preferred Stock or the common stock, the same dividends as are proposed to be distributed to the holders of Series A-1 Preferred Stock or the common stock and (ii) the holders of Series A-1 Preferred Stock shall be entitled to participate with the common stock and receive, before any dividends shall be declared, paid or set aside for the common stock, the same dividends as are proposed to be distributed to the holders of common stock. Each share of Preferred Stock shall be treated as being equal to the number of shares of common stock into which such share could then be converted.

Through December 30, 2017 and September 29, 2018 (unaudited), no dividends have been declared on any series or class of shares.

Liquidation

In the event of any voluntary or involuntary liquidation, dissolution or winding-up of the Company or Deemed Liquidation Event (as described below), the holders of Preferred Stock then outstanding will be entitled to receive, in preference to any distribution to the holders of common stock, an amount per share equal to the Original Issue Price per share of each respective series of Preferred Stock (except for Series D Preferred Stock, which shall be entitled to an amount equal to two times the Series D Original Issue Price) plus any dividends declared but unpaid thereon. In the event that the assets available for distribution to the stockholders are insufficient to pay the holders of Preferred Stock the full amount to which they are entitled, then the holders of Series F Preferred Stock will be paid in full, prior to payments to the holders of Series E Preferred Stock, Series D Preferred Stock and Junior Preferred Stock. The holders of Series E Preferred Stock will be paid in full, prior to payments to the holders of Series D Preferred Stock and Junior Preferred Stock. The holders of Series D Preferred Stock will be paid in full, prior to payments to the holders of Junior Preferred Stock. The holders of Series C Preferred Stock will be paid in full, prior to payments to the holders of Series B-1 Preferred Stock, Series B Preferred Stock, and Series A-1 Preferred Stock. The holders of Series B-1 Preferred Stock will be paid in full, prior to payments to the holders of Series B Preferred Stock and Series A-1 Preferred Stock. The holders of Series B Preferred Stock will be paid in full, prior to payments to the holders of Series A-1 Preferred Stock. After payment of all preferential amounts to the holders of Preferred Stock, the remaining assets available for distribution to the Company's stockholders shall be distributed among the holders of Series D Preferred Stock and common stock, pro rata based on the number of shares held by each holder, treating for this purpose all such securities as if they had been converted to common stock immediately prior to such dissolution, liquidation, winding up of the Company or Deemed Liquidation Event. If the aggregate amount per share that the holders of Series D Preferred Stock are entitled to receive exceeds $7.50 per share (subject to adjustment in the event of a stock split, stock dividend, combination, reclassification or similar event affecting the Series D Preferred Stock),

then each holder of Series D Preferred Stock will be entitled to receive a variable amount per share based upon a specified formula contained in the Company's certificate of incorporation, as amended and restated.

Unless the holders of at least 55% of the then-outstanding shares of Preferred Stock, voting together as a single class on an as-converted basis, elect otherwise, a Deemed Liquidation Event shall include a merger or consolidation (other than one in which the stockholders of the Company own a majority by voting power of the outstanding shares of the surviving or acquiring corporation) or a sale, lease, transfer, exclusive license or other disposition of all or substantially all the assets of the Company.

9. Warrants to Purchase Preferred Stock

In connection with its debt agreements and amendments to such agreements, the Company issued to Hercules warrants to purchase shares of Series B Preferred Stock, Series D Preferred Stock and Series F Preferred Stock. In August 2016, in connection with entering into the Amended Loan Agreement (see Note 7), the Company issued to Hercules a warrant to purchase (i) 34,068 shares of Series F Preferred Stock, at an exercise price of $4.99 per share, or (ii) if there is subsequent preferred stock financing of at least $10.0 million and the price per share of preferred stock in such financing is lower than $4.99, that number of shares of series of stock offered in such financing equal to $0.2 million divided by the price per share in such financing, at an exercise price per share equal to the price per share in such financing. In each case, such exercise prices are subject to adjustment upon specified dilutive issuances. The warrant was immediately exercisable upon issuance and expires on the later of (i) August 4, 2023 or (ii) the fifth anniversary of the effective date of the Company's registration statement for its completed initial public offering. The fair value of the warrant on the issuance date of $0.1 million was recorded as a debt discount and as a component of the preferred stock warrant liability.

The Company classifies all of its preferred stock warrants as a liability on its consolidated balance sheet because the warrants are freestanding financial instruments that may require the Company to transfer assets upon exercise. The liability associated with each of these warrants was initially recorded at fair value upon the issuance date of each warrant and is subsequently remeasured to fair value at each reporting date. Fair value of these warrants was determined using the Black-Scholes option-pricing model (see Note 3), and the resulting change in fair value of the warrant liability was recorded in other income (expense) in the Company's consolidated statements of operations (see Note 3). Changes in the fair value of each warrant comprising the preferred stock warrant liability will continue to be recognized until each respective warrant is exercised, expires or qualifies for equity classification.

During the fiscal nine months ended September 29, 2018 (unaudited), outstanding warrants to purchase 146,370 shares of Series B Preferred Stock expired unexercised. As of December 30, 2017 and at the time of expiration, the Company determined the fair value of such warrants was $0.

As of each balance sheet date, the Company's outstanding preferred stock warrants consisted of the following (in thousands, except share and per share amounts):

	December 31, 2016				
Issuance Date	Contractual Term (in Years)	Series of Preferred Stock	Number of Preferred Shares Issuable under Warrant	Exercise Price	Warrant Fair Value
May 15, 2008	10	Series B	146,370	$3.416	$ 1
November 7, 2012	10	Series D	175,000	$2.50	378
September 11, 2015	10(1)	Series F(2)	16,476	$4.99	52
August 4, 2016	7(1)	Series F(2)	34,068	$4.99	81
			371,914		$ 512

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December 30, 2017					
Issuance Date	Contractual Term (in Years)	Series of Preferred Stock	Number of Preferred Shares Issuable under Warrant	Exercise Price	Warrant Fair Value
May 15, 2008	10	Series B	146,370	$3.416	$ —
November 7, 2012	10	Series D	175,000	$2.50	243
September 11, 2015	10(1)	Series F(2)	16,476	$4.99	40
August 4, 2016	7(1)	Series F(2)	34,068	$4.99	70
			371,914		$ 353

September 29, 2018 (unaudited)					
Issuance Date	Contractual Term (in Years)	Series of Preferred Stock	Number of Preferred Shares Issuable under Warrant	Exercise Price	Warrant Fair Value
November 7, 2012	10	Series D	175,000	$2.50	$ 638
September 11, 2015	10(1)	Series F(2)	16,476	$4.99	49
August 4, 2016	7(1)	Series F(2)	34,068	$4.99	89
			225,544		$ 776

(1) Upon the closing of an initial underwritten public offering of the Company's common stock, the warrants will expire on the fifth anniversary of the effective date of the Company's registration statement for its initial public offering, rather than expiring at the end of the contractual term.

(2) If there is a subsequent preferred stock financing of at least $10.0 million and the price per share of preferred stock in such financing is lower than $4.99, the warrants will be exercisable, at an exercise price per share equal to the price per share in such financing, for the number of shares of series of stock offered in such financing equal to $0.1 million divided by the price per share in such financing (with respect to the preferred stock warrants issued in September 2015) and equal to $0.2 million divided by the price per share in such financing (with respect to the preferred stock warrants issued in August 2016).

10. Common Stock

Each share of common stock is entitled to one vote on all matters submitted to a vote of the Company's stockholders. The holders of common stock, voting exclusively and as a separate class, are entitled to elect two directors of the Company. The holders of common stock are entitled to receive dividends, if any, as may be declared by the board of directors, subject to the preferential dividend rights of the holders of all Preferred Stock, as described above. Through December 30, 2017 and September 29, 2018 (unaudited), no dividends had been declared or paid.

11. Stock-Based Compensation

2014 Stock Incentive Plan

The Company's 2014 Stock Incentive Plan (the "2014 Plan") provides for the Company to sell or issue incentive stock options or nonqualified stock options, stock appreciation rights, restricted stock, restricted stock units and other stock-based awards to employees, directors and non-employee consultants of the Company. The 2014 Plan is administered by the board of directors or, at the discretion of the board of directors, by a committee of the board of directors. The exercise prices, vesting and other restrictions are determined at the discretion of the board of directors, or its committee if so delegated.

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Stock options granted under the 2014 Plan with service-based vesting conditions typically vest over three or four years and expire after ten years. The total number of shares of common stock that may be issued under the 2014 Plan was 7,419,876 as of December 30, 2017 and September 29, 2018 (unaudited), of which 830,298 shares and 571,860 shares remained available for future issuance as of December 30, 2017 and September 29, 2018 (unaudited), respectively. Shares that are expired, terminated, surrendered or canceled without having been fully exercised will be available for future grant under the 2014 Plan. Additionally, shares that are expired, terminated, surrendered or canceled without having been fully exercised under the previously outstanding 2004 Stock Incentive Plan will be available for future grant under the 2014 Plan.

The exercise price for stock options granted is not less than the fair value of common shares as determined by the board of directors as of the date of grant. The Company's board of directors values the Company's common stock, taking into consideration its most recently available valuation of common stock performed by third parties as well as additional factors which may have changed since the date of the most recent contemporaneous valuation through the date of grant.

Stock Option Valuation

The fair value of stock option grants is estimated using the Black-Scholes option-pricing model. The Company historically has been a private company and lacks company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. For options with service-based vesting conditions, the expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

The following table presents, on a weighted average basis, the assumptions used in the Black-Scholes option-pricing model to determine the grant-date fair value of stock options granted to employees and directors:

	Fiscal Years Ended		Fiscal Nine Months Ended	
	December 31, 2016	December 30, 2017	September 30, 2017	September 29, 2018
			(unaudited)	
Risk-free interest rate	1.69%	1.89%	1.89%	2.70%
Expected term (in years)	5.97	6.08	6.08	6.08
Expected volatility	46%	45%	45%	50%
Expected dividend yield	0%	0%	0%	0%

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The following table summarizes the Company's option activity since December 31, 2016:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2016	4,433,873	$ 0.25		
Granted	1,427,959	0.63		
Exercised	(15,755)	0.19		
Forfeited	(497,341)	0.32		
Outstanding as of December 30, 2017	5,348,736	$ 0.35	6.40	$ 1,433
Granted	310,000	0.92		
Exercised	(220,881)	0.20		
Forfeited	(51,562)	0.63		
Outstanding as of September 29, 2018 (unaudited)	5,386,293	$ 0.39	5.81	$ 2,849
Vested and expected to vest as of December 30, 2017	5,348,736	$ 0.35		
Vested and expected to vest as of September 29, 2018 (unaudited)	5,386,293	$ 0.39		
Options exercisable as of December 30, 2017	3,790,376	$ 0.26		
Options exercisable as of September 29, 2018 (unaudited)	3,998,935	$ 0.29		

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock. The aggregate intrinsic value of stock options exercised during the fiscal years ended December 31, 2016 and December 30, 2017 was $0.1 million and less than $0.1 million, respectively. The aggregate intrinsic value of stock options exercised during the fiscal nine months ended September 30, 2017 and September 29, 2018 (unaudited) was less than $0.1 million and $0.2 million, respectively.

The weighted average grant-date fair value of stock options granted during the fiscal years ended December 31, 2016 and December 30, 2017 was $0.26 per share and $0.20 per share, respectively. The weighted average grant-date fair value of stock options granted during the fiscal nine months ended September 30, 2017 and September 29, 2018 (unaudited) was $0.20 per share and $0.47 per share, respectively.

The Company has not granted to employees any stock-based awards with performance-based vesting conditions.

TRANSMEDICS, INC.

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Stock-Based Compensation

The Company recorded stock-based compensation expense in the following expense categories of its consolidated statements of operations (in thousands):

	Fiscal Year Ended		Fiscal Nine Months Ended	
	December 31, 2016	December 30, 2017	September 30, 2017	September 29, 2018
			(unaudited)	
Cost of revenue	$ 2	$ 3	$ 2	$ 4
Research, development and clinical trials expenses	13	17	12	28
Selling, general and administrative expenses	30	50	33	60
	$ 45	$ 70	$ 47	$ 92

As of December 30, 2017, total unrecognized compensation cost related to unvested employee and director stock-based awards was $0.6 million, which is expected to be recognized over a weighted average period of 3.0 years. As of September 29, 2018 (unaudited), total unrecognized compensation cost related to unvested employee and director stock-based awards was $0.5 million, which is expected to be recognized over a weighted average period of 2.4 years.

As of December 30, 2017, there were no outstanding unvested service-based stock options held by non-employees. As of September 29, 2018 (unaudited), there were outstanding unvested service-based stock options held by non-employees for the purchase of 22,292 shares of common stock. Amounts expensed during the remaining vesting periods of the stock options held by non-employees will be determined based on the fair value of the awards at time of their vesting.

12. Income Taxes

2017 U.S. Tax Reform

On December 22, 2017, the TCJA was signed into United States law. The TCJA includes a number of changes to existing tax law, including, among other things, a permanent reduction in the federal corporate income tax rate from a top marginal tax rate of 35% to a flat rate of 21%, effective as of January 1, 2018, as well as limitation of the deduction for net operating losses to 80% of annual taxable income and elimination of net operating loss carrybacks, in each case, for losses arising in taxable years beginning after December 31, 2017 (though any such net operating losses may be carried forward indefinitely). The TCJA also transitions international taxation from a worldwide system to a modified territorial system and includes base erosion prevention measures on non-U.S. earnings. These changes are effective January 1, 2018. The TCJA also includes a one-time mandatory deemed repatriation tax on accumulated foreign subsidiaries' previously untaxed foreign earnings, referred to as the Transition Toll Tax.

The FASB issued ASU 2018-05 to address the application of GAAP in situations when a registrant does not have the necessary information available, prepared or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the TCJA. The Company is still in the process of analyzing the impact to the Company of the TCJA and its analysis is not yet complete. Where the Company has been able to make reasonable estimates of the effects related to the TCJA, the Company has recorded provisional amounts.

In connection with the initial analysis of the impact of the TCJA, the Company remeasured its deferred tax assets based on the rates at which they are expected to reverse in the future, which is generally 21% for federal

tax purposes. The remeasurement of the Company's deferred tax assets was offset by a change in the valuation allowance. As a result, no income tax expense or benefit was recognized as of the enactment date of the TCJA. All of the Company's recorded income tax benefits and provisions related to the TCJA are provisional. The provisional amounts recorded by the Company are based on guidance, interpretations and other information available as of October 19, 2018. The impact of the changes in U.S. tax law may be refined as further guidance, interpretations or information becomes available or upon completion by the Company of its evaluation of the impact of the changes in U.S. tax law. Provisional amounts will be finalized no later than the fourth quarter of 2018, which is one year from when the TCJA was signed into law. The ultimate impact to the Company's consolidated financial statements of the TCJA may differ from the provisional amounts. During the fiscal nine months ended September 29, 2018 (unaudited), the Company did not make any adjustments to the provisional amounts recorded as a result of the TCJA.

Income Taxes

During the fiscal years ended December 31, 2016 and December 30, 2017 and the fiscal nine months ended September 30, 2017 and September 29, 2018 (unaudited), the Company recorded no income tax benefits for the net operating losses incurred or for the research and development tax credits generated in each year in the United States, due to its uncertainty of realizing a benefit from those items. The Company generated income in the Netherlands for the fiscal year ended December 30, 2017 and the fiscal nine months ended September 29, 2018 (unaudited) and, accordingly, recorded a foreign income tax provision of less than $0.1 million for each of the fiscal year ended December 30, 2017 and the fiscal nine months ended September 30, 2017 and September 29, 2018 (unaudited).

Income (loss) before income taxes consisted of the following (in thousands):

	Fiscal Year Ended		Fiscal Nine Months Ended	
	December 31, 2016	December 30, 2017	September 30, 2017	September 29, 2018
			(unaudited)	
United States	$ (24,124)	$ (20,952)	$ (16,286)	(16,266)
Foreign	59	161	139	168
	$ (24,065)	$ (20,791)	$ (16,147)	$ (16,098)

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate is as follows:

	Fiscal Year Ended	
	December 31, 2016	December 30, 2017
Federal statutory income tax rate	(34.0)%	(34.0)%
State taxes, net of federal benefit	(5.1)	(5.2)
Federal and state research and development tax credits	(2.5)	(4.1)
Remeasurement of deferred taxes due to the Tax Cuts and Jobs Act	—	156.1
Nondeductible items	0.5	1.5
Other	0.8	0.1
Change in deferred tax asset valuation allowance	40.3	(114.2)
Effective income tax rate	0.0%	0.2%

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Net deferred tax assets consisted of the following (in thousands):

	December 31, 2016	December 30, 2017
Deferred tax assets:		
Net operating loss carryforwards	$ 69,022	$ 54,577
Capitalized research and development expense	23,174	13,387
Research and development tax credit carryforwards	7,749	9,119
Accrued expenses	1,487	1,002
Stock-based compensation expense	368	258
Deferred rent	506	292
Other	80	15
Total deferred tax assets	102,386	78,650
Valuation allowance	(102,386)	(78,650)
Net deferred tax assets	$ —	$ —

As of December 30, 2017, the Company had U.S. federal and state net operating loss carryforwards of $215.2 million and $148.5 million, respectively, which may be available to offset future taxable income and begin to expire in 2018 and 2030, respectively. As of December 30, 2017, the Company also had U.S. federal and state research and development tax credit carryforwards of $6.0 million and $4.0 million, respectively, which may be available to offset future tax liabilities and begin to expire in 2020 and 2024, respectively. During the fiscal nine months ended September 29, 2018 (unaudited), gross deferred tax assets, before valuation allowance, increased by approximately $4.3 million due to the operating loss incurred by the Company during that period.

Utilization of the U.S. federal and state net operating loss carryforwards and research and development tax credit carryforwards may be subject to a substantial annual limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, and corresponding provisions of state law, due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income or tax liabilities. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain stockholders or public groups in the stock of a corporation by more than 50% over a three-year period. The Company has not conducted a study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception due to the significant complexity and cost associated with such a study. If the Company has experienced a change of control, as defined by Section 382, at any time since inception, utilization of the net operating loss carryforwards or research and development tax credit carryforwards would be subject to an annual limitation under Section 382, which is determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the net operating loss carryforwards or research and development tax credit carryforwards before utilization. Further, until a study is completed by the Company and any limitation is known, no amounts are being presented as an uncertain tax position.

The Company has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets. Management has considered the Company's history of cumulative net losses incurred since inception and has concluded that it is more likely than not that the Company will not realize the benefits of the deferred tax assets. Accordingly, a full valuation allowance has been established against the net deferred tax assets as of December 31, 2016, December 30, 2017 and September 29, 2018 (unaudited). Management reevaluates the positive and negative evidence at each reporting period.

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Changes in the valuation allowance for deferred tax assets during the fiscal years ended December 31, 2016 and December 30, 2017 related primarily to the increase in net operating loss carryforwards and research and development tax credit carryforwards in 2016 and 2017, partially offset in 2017 by a decrease in deferred tax assets resulting from the decreased federal corporate tax rate impact of the TCJA, and were as follows (in thousands):

	December 31, 2016	December 30, 2017
Valuation allowance as of beginning of year	$ (92,676)	$ (102,386)
Decreases recorded as benefit to income tax provision	—	32,463
Increases recorded to income tax provision	(9,710)	(8,727)
Valuation allowance as of end of year	$ (102,386)	$ (78,650)

As of December 31, 2016 and December 30, 2017 and September 29, 2018 (unaudited), the Company had not recorded any amounts for unrecognized tax benefits. The Company's policy is to record interest and penalties related to income taxes as part of its income tax provision. As of December 31, 2016 and December 30, 2017 and September 29, 2018 (unaudited), the Company had no accrued interest or penalties related to uncertain tax positions and no amounts had been recognized in the Company's consolidated statements of operations. The Company files income tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. There are currently no pending tax examinations. The Company is open to future tax examination under statute from 2015 to the present; however, carryforward attributes that were generated prior to December 28, 2014 may still be adjusted upon examination by federal, state or local tax authorities if they either have been or will be used in a future period.

13. Commitments and Contingencies

Operating Leases

The Company leases its office, laboratory and manufacturing space under two noncancelable operating leases that expire in December 2021. The lease agreements include payment escalations, rent holidays and other lease incentives, which are accrued or deferred as appropriate such that rent expense for each lease is recognized on a straight-line basis over the respective lease terms, recording deferred rent for rent expense incurred but not yet paid (see Note 2). Rent expense for the fiscal years ended December 31, 2016 and December 30, 2017 was $1.2 million and $1.2 million, respectively. Rent expense for the fiscal nine months ended September 30, 2017 and September 29, 2018 (unaudited) was $0.9 million and $0.9 million, respectively.

Future minimum lease payments under operating leases as of December 30, 2017 are as follows (in thousands):

Fiscal Year Ending:	
December 29, 2018	$ 1,530
December 28, 2019	1,549
December 26, 2020	1,570
December 25, 2021	1,589
	$ 6,238

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License Agreement with the Department of Veterans Affairs

In 2002, the Company entered into a license agreement with the Department of Veterans Affairs (the "VA"), under which the Company was granted an exclusive, worldwide license under specified patents to make, use, sell and import certain technology used in the Company's products and a non-exclusive, worldwide license to make, use, sell and import solutions for use in or with those products. The rights under the license agreement continue until the expiration of the last to expire of the licensed patents. The majority of the licensed U.S. patents expired in 2017, and the foreign patents expired in September 2018. However, the Company has requested a patent term extension for one U.S. patent covered by the VA license agreement, U.S. Patent No. 6,100,082. The Company has been granted an interim patent term extension for this patent. As of October 19, 2018, the issuance date of the consolidated financial statements as of December 30, 2017 and for the fiscal year then ended, and as of December 12, 2018, the issuance date of the interim consolidated financial statements as of September 29, 2018 and for the fiscal nine months then ended, the Company had not received final approval of the patent extension beyond the interim patent term extension already granted. The maximum extension granted would be through May 2022; however, the length of the patent term extension will be determined by the United States Patent and Trademark Office. The license includes the right to grant sublicenses, subject to approval by the VA and other restrictions, and is subject to the U.S. government's right to practice the licensed patents on its own behalf without payment of a royalty and obligation to grant certain sublicenses as necessary to fulfill public health, welfare and safety needs. The license agreement also requires the Company to make its products covered by the licensed patents available to the public on reasonable terms and to provide the U.S. government such products at the lowest price.

As consideration for the licenses granted by the VA, the Company is obligated to pay tiered royalties ranging from a low single-digit to a mid single-digit percentage on net sales of each product covered by a licensed patent (subject to a minimum aggregate royalty payment of less than $0.1 million per year during each of the first five years after the first commercial sale, after which no minimum is required). Royalties will be paid by the Company on a licensed product-by-licensed product and country-by-country basis, beginning on the first commercial sale of such licensed product in such country until expiration of the last valid patent claim covering such licensed product in such country. The Company is also responsible for all costs related to the amendment, prosecution and maintenance of the licensed patent rights.

The Company paid the VA royalties of $0.1 million during each of the fiscal years ended December 31, 2016 and December 30, 2017. The Company accrued VA royalties of $0.2 million as of September 29, 2018 (unaudited), which were paid by the Company in October 2018 (unaudited).

The VA license agreement can be terminated by the Company or the VA only if the other party fails to cure its material breach within a specified period after receiving notice of such breach.

Minimum Purchase Commitments

The Company entered into an agreement with Fresenius Kabi Austria GmbH ("Fresenius") under which Fresenius develops, manufactures and supplies the Company with its OCS Lung Solution used in connection with its OCS Perfusion Sets. In accordance with the agreement, as amended, the Company is obligated to purchase minimum quantities annually through 2018. If the Company does not meet the minimum annual purchase requirements, it is required to pay a premium calculated as the minimum committed order quantity less the actual ordered quantity during the respective year, multiplied by the applicable price as specified in the agreement.

The Company capitalizes any estimated premium it expects to pay at the end of the year as an adjustment to its cost of the OCS Lung Solution (i.e., inventory) purchased during each year. Inventory cost in each interim

period includes an appropriate portion of the annual estimated premium by the use of accruals. During the fiscal years ended December 31, 2016 and December 30, 2017, the Company incurred premiums of $0.6 million and $1.1 million, respectively, which the Company recorded in accounts payable at December 31, 2016 and December 30, 2017, respectively. During the fiscal nine months ended September 29, 2018 (unaudited), the Company capitalized as an adjustment to its cost of the OCS Lung Solution an estimated premium of $0.4 million for a proportion of the annual estimated premium for 2018, calculated as the difference between the minimum order quantity and its actual and estimated purchases for fiscal 2018, and recorded that same $0.4 million amount in accrued expenses (see Note 6) at September 29, 2018 (unaudited).

As of December 30, 2017, the Company's future minimum purchase commitment, which represents the amount the Company would pay as a premium if it placed no orders in 2018, was $1.4 million. As of September 29, 2018 (unaudited), the Company's future minimum purchase commitment, which represents the amount the Company would pay as a premium if it placed no further orders after September 29, 2018, was $1.3 million.

Accrued Financing Fees

In periods prior to 2016, the Company incurred financing fees of $1.5 million for amounts due to its former financial advisors related to the issuance of its Series B Preferred Stock and Series D Preferred Stock. These financing fees are contingently payable in cash only upon an IPO or certain alternative transactions, including a sale of the Company. The Company recorded an accrual of $1.5 million as of December 31, 2016, December 30, 2017 and September 29, 2018 (unaudited) related to such contingently payable fees (see Note 6).

401(k) Savings Plan

The Company has a defined-contribution savings plan under Section 401(k) of the Internal Revenue Code. This plan covers substantially all employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. Company contributions to the plan may be made at the discretion of the board of directors. As of December 31, 2016, December 30, 2017 and September 29, 2018 (unaudited), the Company had not made any contributions to the plan.

Indemnification Agreements

In the ordinary course of business, the Company has agreed to defend and indemnify its customers against third-party claims asserting infringement of certain intellectual property rights, which may include patents, copyrights, trademarks or trade secrets. The Company's exposure under these indemnification provisions is generally limited to the total amount paid by the end-customer under the agreement. However, certain agreements include indemnification provisions that could potentially expose the Company to losses in excess of the amount received under the agreement. In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or services as directors or officers.

The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not currently aware of any indemnification claims and had not accrued any liabilities related to such obligations in its consolidated financial statements as of December 31, 2016, December 30, 2017 or September 29, 2018 (unaudited).

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Legal Proceedings

The Company is not currently party to any material legal proceedings. At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company expense as incurred the costs related to such legal proceedings.

Inspection of Manufacturing Facilities by Regulatory Agencies

The Company is subject to periodic inspection of its manufacturing facilities by regulatory agencies, both in the United States and abroad. Any adverse regulatory action, depending on its magnitude, may restrict the Company from manufacturing, marketing or selling its products and could have a material adverse effect on its business, financial condition or results of operations. In July 2018 (unaudited), the Company was inspected by European regulatory authorities, which resulted in observations. The Company has implemented corrective and preventive actions to address these observations, but the matters will not be officially closed out until the next inspection. As of December 31, 2016, December 30, 2017 and September 29, 2018 (unaudited), the Company was not aware of any regulatory action that could have a material impact on its consolidated financial statements.

14. Net Loss per Share and Unaudited Pro Forma Net Loss per Share

Net Loss per Share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows (in thousands, except share and per share amounts):

	Fiscal Year Ended		Fiscal Nine Months Ended	
	December 31, 2016	December 30, 2017	September 30, 2017	September 29, 2018
			(unaudited)	
Numerator:				
Net loss attributable to common stockholders	$ (24,065)	$ (20,823)	$ (16,175)	$ (16,121)
Denominator:				
Weighted average common shares outstanding, basic and diluted	4,502,099	4,647,495	4,646,570	4,714,298
Net loss per share attributable to common stockholders, basic and diluted	$ (5.35)	$ (4.48)	$ (3.48)	$ (3.42)

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The Company's potential dilutive securities have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	Fiscal Year Ended		Fiscal Nine Months Ended	
	December 31, 2016	December 30, 2017	September 30, 2017	September 29, 2018
			(unaudited)	
Convertible preferred stock (as converted to common stock)	45,918,010	45,918,010	45,918,010	45,918,010
Warrants to purchase convertible preferred stock (as converted to common stock)	265,981	265,981	265,981	225,544
Options to purchase common stock	4,433,873	5,348,736	5,356,757	5,386,293
	50,617,864	51,532,727	51,540,748	51,529,847

Unaudited Pro Forma Net Loss per Share

Unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the fiscal year ended December 30, 2017 and the fiscal nine months ended September 29, 2018 have been prepared to give effect to adjustments arising from the Corporate Reorganization (see Note 1). The unaudited pro forma net loss attributable to common stockholders used in the calculation of unaudited pro forma basic and diluted net loss per share attributable to common stockholders does not include the change in the fair value of the preferred stock warrant liability because the calculation gives effect to the Corporate Reorganization, including the conversion of all warrants to purchase shares of convertible preferred stock of the Company into warrants to purchase shares of common stock of TransMedics Group, as if the Corporate Reorganization had occurred on the later of January 1, 2017 or the issuance date of the preferred stock warrants.

Unaudited pro forma basic and diluted weighted average common shares outstanding used in the calculation of unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the fiscal year ended December 30, 2017 and the fiscal nine months ended September 29, 2018 have been prepared to give effect to the Corporate Reorganization, including the conversion of all outstanding shares of convertible preferred stock of the Company into shares of common stock of TransMedics Group and the conversion of all outstanding shares of common stock of the Company into an aggregate of shares of common stock of TransMedics Group, as if the Corporate Reorganization had occurred on the later of January 1, 2017 or the issuance date of the convertible preferred stock or common stock.

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Unaudited pro forma basic and diluted net loss per share attributable to common stockholders was calculated as follows (in thousands, except share and per share amounts):

	Fiscal Year Ended December 30, 2017	Fiscal Nine Months Ended September 29, 2018
		(unaudited)
Numerator:		
Net loss attributable to common stockholders	$ (20,823)	$ (16,121)
Change in fair value of convertible preferred stock warrant liability	(159)	423
Pro forma net loss attributable to common stockholders	$ (20,982)	$ (15,698)
Denominator:		
Weighted average common shares outstanding, basic and diluted	4,647,495	4,714,298
Pro forma adjustment to weighted average common shares outstanding to reflect conversion of common stock upon the Corporate Reorganization	( )	( )
Pro forma adjustment to reflect conversion of convertible preferred stock upon the Corporate Reorganization		
Pro forma weighted average common stock outstanding, basic and diluted		
Pro forma net loss per share attributable to common stockholders, basic and diluted	$	$

15. Segment Reporting and Geographic Data

The Company has determined that it operates in one segment (see Note 2).

Net revenue by OCS product is summarized as follows (in thousands):

	Fiscal Year Ended		Fiscal Nine Months Ended	
	December 31, 2016	December 30, 2017	September 30, 2017	September 29, 2018
			(unaudited)	
Net revenue by OCS product:				
OCS Lung net revenue	$ 1,934	$ 789	$ 523	$ 3,146
OCS Heart net revenue	3,598	5,761	4,060	4,860
OCS Liver net revenue	677	1,135	996	1,467
Total net revenue	$ 6,209	$ 7,685	$ 5,579	$ 9,473

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Financial data by geographical area is summarized as follows (in thousands):

	Fiscal Year Ended		Fiscal Nine Months Ended	
	December 31, 2016	December 30, 2017	September 30, 2017	September 29, 2018
			(unaudited)	
Net revenue by country(1):				
United States	$ 3,468	$ 2,744	1,892	$ 4,391
United Kingdom	1,352	2,354	1,617	2,049
Germany	*	*	*	1,098
Australia	*	*	*	987
Kazakhstan	*	*	562	*
All other countries	1,389	2,587	1,508	948
Total net revenue	$ 6,209	$ 7,685	$ 5,579	$ 9,473

* Less than 10% of total

	December 31, 2016	December 30, 2017	September 29, 2018
			(unaudited)
Long-lived assets by country(2):			
United States	$ 1,476	$ 1,649	$ 2,356
All other countries	247	810	986
Total long-lived assets	$ 1,723	$ 2,459	$ 3,342

(1) Net revenue by country is categorized based on the location of the end customer.

(2) The Company's only long-lived assets consist of property and equipment, net of depreciation, which are categorized based on their location of domicile.

16. Significant Customer Concentrations

Significant customers are those that accounted for 10% or more of the Company's net revenue or accounts receivable, as set forth in the following tables for the periods presented:

	Net Revenue			
	Fiscal Year Ended		Fiscal Nine Months Ended	
	December 31, 2016	December 30, 2017	September 30, 2017	September 29, 2018
			(unaudited)	
Company A	12%	16%	18%	11%
Company B	*	*	10%	*
Company C	14%	*	*	*
Company D	11%	*	*	*

* Less than 10% of total

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Net revenue derived from Company E through Company J accounted for less than 10% of the Company's net revenue in each of the periods presented.

	Accounts Receivable		
	December 31, 2016	December 30, 2017	September 29, 2018 (unaudited)
Company A	*	*	*
Company B	*	*	*
Company C	13%	14%	13%
Company D	17%	*	*
Company E	*	23%	*
Company F	16%	*	*
Company G	16%	14%	*
Company H	*	14%	*
Company I	10%	*	*
Company J	*	*	13%

* Less than 10% of total

17. Related Party Transactions

Employment of Dr. Amira Hassanein

Dr. Amira Hassanein, who serves as Product Director for the Company's OCS Lung program, is the sister of Dr. Waleed Hassanein, the Company's President, Chief Executive Officer and a member of the Company's board of directors. The Company paid Dr. Amira Hassanein $0.2 million, $0.2 million and $0.2 million in total compensation in the fiscal years ended December 31, 2016 and December 30, 2017 and the fiscal nine months ended September 29, 2018 (unaudited), respectively, for her services as an employee.

18. Subsequent Events

For its consolidated financial statements as of December 30, 2017 and for the fiscal year then ended, the Company evaluated subsequent events through October 19, 2018, the date on which those financial statements were issued.

OrbiMed Credit Agreement

In June 2018, the Company entered into the Credit Agreement with OrbiMed (see Note 7) pursuant to which OrbiMed made certain term loans available to the Company. The Credit Agreement provides for aggregate maximum borrowings of up to $65.0 million, consisting of (i) $35.0 million upon entering into the Credit Agreement, which was borrowed by the Company in June 2018, and (ii) potential additional borrowings of up to $30.0 million that may become available upon the Company's achievement of specified revenue thresholds and a regulatory milestone by determinable dates. Borrowings under the Credit Agreement are repayable in quarterly interest-only payments until the maturity date in June 2023, at which time all principal and accrued interest is due and payable (see Note 7).

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Repayment of Borrowings under Hercules Amended Loan Agreement

In June 2018, the Company repaid all amounts due under the Amended Loan Agreement, including $6.7 million of principal repayments, and the Amended Loan Agreement was terminated. Upon prepayment of the outstanding amounts, the Company recorded a loss on extinguishment of debt of $0.3 million, which was classified as other expense in the consolidated statement of operations (see Note 7).

19. Subsequent Events (Unaudited)

For its interim consolidated financial statements as of September 29, 2018 and for the fiscal nine months then ended, the Company evaluated subsequent events through December 12, 2018, the date on which those financial statements were issued.

Prospectus

Morgan Stanley
J.P. Morgan
Cowen
Canaccord Genuity

, 2018

Until , 2018 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth the estimated expenses payable by us in connection with the sale and distribution of the securities registered hereby, other than underwriting discounts and commissions. All amounts are estimates, except the SEC registration fee and the Financial Industry Regulatory Authority, or FINRA, filing fee.

	Amount
SEC registration fee	$ *
FINRA filing fee	15,500
Nasdaq Global Market listing fee	*
Legal fees and expenses	*
Accountants' fees and expenses	*
Printing and engraving expenses	*
Transfer agent and registrar fees and expenses	*
Miscellaneous expenses	*
Total	$ *

* To be completed by amendment.

Item 14. Indemnification of Directors and Officers.

Section 2.02 of the Massachusetts Business Corporation Act, or the MBCA, under which the registrant is governed, provides that the articles of organization of a corporation may contain a provision eliminating or limiting the personal liability of a director to the corporation for monetary damages for breach of a fiduciary duty as a director notwithstanding any provision of law imposing such liability; provided, however, that such provision shall not eliminate or limit the liability of a director (1) for any breach of the director's duty of loyalty to the corporation or its shareholders, (2) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (3) for improper distributions under Sections 6.40 of the MBCA or (4) for any transaction from which the director derived an improper personal benefit. Article VI.C of the registrant's restated articles of organization provides that a director shall not be liable to the registrant or its shareholders for damages for any breach of fiduciary duty, except to the extent that the elimination or limitations of liability is not permitted under law.

Section 8.51 of the MBCA provides that a corporation may indemnify a director who is a party to a proceeding because he or she is a director against liability incurred in the proceeding if he or she conducted himself or herself in good faith and he or she reasonably believed that his or her conduct was in the best interests of the corporation or that his or her conduct was at least not opposed to the best interests of the corporation, and, in the case of any criminal proceeding, he or she had no reasonable cause to believe his or her conduct was unlawful. Section 8.52 of the MBCA requires corporations to indemnify any director who was wholly successful in the defense of any proceeding to which he or she was a party because he or she was a director of the corporation against reasonable expenses incurred by him or her in connection with the proceeding.

Section 8.53 of the MBCA provides that, before the final disposition of a proceeding, a corporation may advance funds to pay for or reimburse the reasonable expenses incurred by a director who is party to such proceeding because he or she is a director if he or she delivers to the corporation (a) a written affirmation of his or her good faith belief that he or she has met the relevant standard of good faith described in Section 8.51 of the MBCA or that the proceeding involves conduct for which liability has been eliminated pursuant to Section 2.02 of the MBCA and (b) a written undertaking with an unlimited general obligation of the director to repay any funds advanced if he or she is not entitled to mandatory indemnification under Section 8.52 and it is ultimately determined, under Section 8.54 or Section 8.55 that he or she does not meet the relevant standard of conduct described in Section 8.51.

Section 8.56 of the MBCA provides that a corporation may indemnify and advance expenses to an officer of the corporation who is a party to a proceeding because he or she is an officer of the corporation to the same extent as a director, and, if he or she is an officer but not a director, to such further extent as may be provided by the articles of organization, the bylaws, a resolution of the board of directors or contract, except for liability arising out of acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law. Section 8.56 also provides that an officer of the corporation who is not a director is entitled to mandatory indemnification under Section 8.52, and that the officer may apply to a court for indemnification or an advance for expenses, in each case to the same extent to which a director may be entitled to indemnification or advance under those provisions.

Article VI of the registrant's amended and restated bylaws provide that the registrant will indemnify, and advance funds to and reimburse expenses of, its directors and its officers that have been appointed by the board of directors to the fullest extent permitted by law, and may indemnify, and advance funds to and reimburse expenses of, such other officers and employees as determined by the board of directors, in each case including those circumstances in which indemnification would otherwise be discretionary. We intend to enter into indemnification agreements with our directors and officers. These agreements will provide broader indemnity rights than those provided under the MBCA and our articles of organization. The indemnification agreements are not intended to deny or otherwise limit third-party or derivative suits against us or our directors or officers, but to the extent a director or officer were entitled to indemnity or contribution under the indemnification agreement, the financial burden of a third-party suit would be borne by us, and we would not benefit from derivative recoveries against the director or officer. Such recoveries would accrue to our benefit but would be offset by our obligations to the director or officer under the indemnification agreement.

The underwriting agreement provides that the underwriters are obligated, under certain circumstances, to indemnify our directors, officers and controlling persons against certain liabilities, including liabilities under the Securities Act. Reference is made to the form of underwriting agreement filed as Exhibit 1.1 hereto.

Section 8.57 of the MBCA also contains provisions authorizing a corporation to obtain insurance on behalf of any director or officer of the corporation against liabilities asserted against or incurred by him or her in that capacity or arising from his or her status as an officer or officer, whether or not the corporation would have the power to indemnify against such liabilities. We maintain directors' and officers' liability insurance for the benefit of our directors and officers.

Item 15. Recent Sales of Unregistered Securities.

The Registrant is a recently formed Massachusetts corporation formed for the purpose of this offering and has not conducted any activities other than in connection with its formation and the preparation for this offering.

The following list sets forth information regarding all unregistered securities sold by us since December 1, 2015. No underwriters were involved in the sales and the certificates representing the securities sold and issued contain legends restricting transfer of the securities without registration under the Securities Act or an applicable exemption from registration. The issuances of the securities in the transactions described below were issued without registration in reliance on the exemptions afforded by Section 4(a)(2) of the Securities Act and Rules 506 and 701 promulgated thereunder. The below share numbers do not reflect the Corporate Reorganization.

1. In May 2016, we issued and sold 10,266,480 shares of Series F preferred stock at a purchase price of $4.99 per share or aggregate gross consideration of $51.2 million.
2. In June 2016, we sold an additional 2,505,010 shares of Series F preferred stock at a purchase price of $4.99 per share or aggregate gross consideration of $12.5 million.
3. In August 2016, in connection with entering into an amendment to a loan agreement with Hercules Technology Growth Capital, Inc., we issued to Hercules Technology Growth Capital, Inc. a warrant to purchase (A) 16,476 shares of Series F preferred stock, at an exercise price of $4.99 per share, or (B) if

there is subsequent preferred stock financing of at least $10.0 million and the price per share of preferred stock in such financing is lower than $4.99, that number of shares of series of stock offered in such financing equal to $82,219 divided by the price per share in such financing, at an exercise price per share equal to the price per share in such financing. In each case, such exercise prices are subject to adjustment upon specified dilutive issuances. No consideration was received for such warrants.

4. Since December 1, 2015, we have issued options to purchase an aggregate of 2,626,959 shares of common stock with exercise prices ranging from $0.20 to $2.47 per share. Since December 1, 2015, 468,616 shares of our common stock have been issued upon the exercise of stock options pursuant to the 2004 Plan and the 2014 Plan.

Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits.

Some of the agreements included as exhibits to the registration statement of which this prospectus forms a part contain representations and warranties by the parties to the applicable agreement. These representations and warranties were made solely for the benefit of the other parties to the applicable agreement and (1) were not intended to be treated as categorical statements of fact, but rather as a way of allocating the risk to one of the parties if those statements prove to be inaccurate; (2) may have been qualified in such agreement by disclosures that were made to the other party in connection with the negotiation of the applicable agreement; (3) may apply contract standards of "materiality" that are different from "materiality" under the applicable securities laws; and (4) were made only as of the date of the applicable agreement or such other date or dates as may be specified in the agreement.

The Registrant acknowledges that, notwithstanding the inclusion of the foregoing cautionary statements, it is responsible for considering whether additional specific disclosures of material information regarding contractual provisions are required to make the statements in the registration statement of which this prospectus forms a part not misleading.

Exhibit	Description
1.1*	Form of Underwriting Agreement
2.1*	Form of Agreement and Plan of Merger and Reorganization
3.1	Articles of Organization of the Registrant
3.2**	Bylaws of the Registrant
3.3*	Form of Restated Articles of Organization of the Registrant (to be effective upon the closing of this offering)
3.4*	Form of Amended and Restated Bylaws of the Registrant (to be effective upon the closing of this offering)
4.1*	Specimen stock certificate evidencing shares of common stock
4.2**	Warrant Agreement to Purchase Preferred Stock, dated as of November 7, 2012, between the Registrant and Hercules Technology Growth Capital, Inc.
4.3**	Warrant Agreement to Purchase Preferred Stock, dated as of September 11, 2015, between the Registrant and Hercules Technology Growth Capital, Inc.
4.4**	Warrant Agreement to Purchase Preferred Stock, dated as of August 4, 2016, between the Registrant and Hercules Technology Growth Capital, Inc.
5.1*	Opinion of Ropes & Gray LLP

Exhibit	Description
10.1*	Form of Ninth Amended and Restated Investors' Rights Agreement
10.2*	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers
10.3#**	Amended and Restated 2004 Stock Incentive Plan
10.4#**	Form of Incentive Stock Option Agreement under 2004 Stock Incentive Plan
10.5#**	Amended and Restated 2014 Stock Incentive Plan
10.6#**	Form of Incentive Stock Option Agreement under 2014 Stock Incentive Plan
10.7#**	Form of Non-Qualified Stock Option Agreement under 2014 Stock Incentive Plan
10.8**	Lease Agreement, dated as of June 25, 2004, between the Registrant and 200 Minuteman Limited Partnership
10.9**	First Amendment to Lease, dated as of September 28, 2004, between the Registrant and 200 Minuteman Limited Partnership
10.10**	Second Amendment to Lease, dated as of November 29, 2005, between the Registrant and 200 Minuteman Limited Partnership
10.11**	Third Amendment to Lease, dated as of June 12, 2006, between the Registrant and 200 Minuteman Limited Partnership
10.12**	Fourth Amendment to Lease, dated as of February 1, 2007, between the Registrant and 200 Minuteman Limited Partnership
10.13**	Fifth Amendment to Lease, dated as of April 30, 2010, between the Registrant and 200 Minuteman Limited Partnership
10.14**	Lease Agreement, dated as of June 25, 2004, between the Registrant and 30 Minuteman Limited Partnership
10.15**	Second Amendment to Lease, dated as of November 29, 2005, between the Registrant and 30 Minuteman Limited Partnership
10.16**	Third Amendment to Lease, dated as of April 30, 2010, between the Registrant and 30 Minuteman Limited Partnership
10.17**	Credit Agreement, dated as of June 22, 2018, by and between the Registrant and OrbiMed Royalty Opportunities II, L.P.
10.18**	Pledge and Security Agreement, dated as of June 22, 2018, by and between the Registrant and OrbiMed Royalty Opportunities II, L.P.
10.19**	Guarantee, dated as of June 22, 2018, made by TransMedics B.V. in favor of OrbiMed Royalty Opportunities II, L.P.
10.20†**	License Agreement dated as of August 27, 2002 by and between the Registrant and The Department of Veterans Affairs
10.21†	Development and Supply Agreement dated as of May 24, 2005 by and between the Registrant and Fresenius Kabi AB

Exhibit	Description
10.22†	Contract Manufacturing Agreement dated as of April 1, 2015 by and between the Registrant and Fresenius Kabi Austria GmbH
21.1*	List of Subsidiaries of the Registrant
23.1*	Consent of PricewaterhouseCoopers LLP, independent registered public accounting firm
23.2*	Consent of Ropes & Gray LLP (included in Exhibit 5.1)
24.1*	Powers of Attorney (included on signature page)

* To be filed by amendment.
† Confidential treatment requested as to certain portions, which portions have been filed separately with the Securities and Exchange Commission.
# Indicates a management contract or compensatory plan, contract or arrangement.
** Previously submitted.

(b) Financial Statement Schedules.

No financial statement schedules have been submitted because they are not required or are not applicable or because the information required is included in the financial statements or the notes thereto.

Item 17. Undertakings.

The undersigned registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, or the Securities Act, may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person of the registrant in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of the registration statement of which this prospectus forms a part in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of the registration statement of which this prospectus forms a part as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act, the registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the Town of Andover, Commonwealth of Massachusetts, on this day of , 2018.

TRANSMEDICS GROUP, INC.

By: _____
Waleed H. Hassanein
President and Chief Executive Officer

POWER OF ATTORNEY

Each individual whose signature appears below constitutes and appoints Waleed H. Hassanein and Stephen Gordon, and each of them, his or her true and lawful attorney-in-fact and agent, acting alone, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any or all amendments to this Registration Statement, including post-effective amendments and registration statements filed pursuant to Rule 462(b) and otherwise, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the U.S. Securities and Exchange Commission, granting unto said attorney-in-fact full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as such person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities held on the dates indicated.

Signature	Title	Date
Waleed H. Hassanein	President, Chief Executive Officer and Director (Principal Executive Officer)	
Stephen Gordon	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	
James R. Tobin	Director, Chairman of the Board of Directors	
Edward M. Basile	Director	
James Gilbert	Director	
Thomas J. Gunderson	Director	
Edwin M. Kania, Jr.	Director	

Exhibit 3.1

The Commonwealth of Massachusetts
William Francis Galvin
Secretary of the Commonwealth
One Ashburton Place, Boston, Massachusetts 02108-1512

Restated Articles of Organization
(General Laws Chapter 156D, Section 10.07; 950 CMR 113.35)

(1) Exact name of corporation: TransMedics Group, Inc.

(2) Registered office address: 84 State Street, Boston, MA 02109
(number, street, city or town, state, zip code)

(3) Date adopted: November 26, 2018
(month, day, year)

(4) Approved by:

(check appropriate box)

☐ the directors without shareholder approval and shareholder approval was not required;

OR

☒ the board of directors and the shareholders in the manner required by G.L. Chapter 156D and the corporation's articles of organization.

(5) The following information is required to be included in the articles of organization pursuant to G.L. Chapter 156D, Section 2.02 except that the supplemental information provided for in Article VIII is not required:

ARTICLE I

The exact name of the corporation is:

TransMedics Group, Inc.

ARTICLE II

Unless the articles of organization otherwise provide, all corporations formed pursuant to G.L. Chapter 156D have the purpose of engaging in any lawful business. Please specify if you want a more limited purpose:

To engage in any lawful activity permitted of a corporation governed by the Massachusetts Business Corporation Act or any successor thereto.

ARTICLE III

State the total number of shares and par value, if any, of each class of stock that the corporation is authorized to issue. All corporations must authorize stock. If only one class or series is authorized, it is not necessary to specify any particular designation.

Without Par Value		With Par Value	
Common	1,000		

ARTICLE IV

Prior to the issuance of shares of any class or series, the articles of organization must set forth the preferences, limitations and relative rights of that class or series. The articles may also limit the type or specify the minimum amount of consideration for which shares of any class or series may be issued. Please set forth the preferences, limitations and relative rights of each class or series and, if desired, the required type and minimum amount of consideration to be received.

ARTICLE V

The restrictions, if any, imposed by the articles of organization upon the transfer of shares of any class or series of stock are:

N/A

ARTICLE VI

Other lawful provisions, and if there are no such provisions, this article may be left blank.

1. The Board of Directors may make, amend, or repeal the bylaws in whole or in part, except with respect to any provision thereof which by law or these Articles of Organization requires action by the shareholders. To the extent permitted by law, the bylaws, including a provision adopted solely through action of the Board of Directors, may provide for a different quorum or voting requirement than is provided for in Chapter 156D of the Massachusetts General Laws or any successor statute.

2. A director shall not be liable to the Corporation or its shareholders for damages for any breach of fiduciary duty, except to the extent that the elimination or limitations of liability is not permitted under law. No amendment or repeal of this provision shall deprive a director of the benefits hereof with respect to any act or omission occurring prior to such amendment or repeal.

3. Unless the Board of Directors of the Corporation consents in writing to the selection of an alternative forum, a state or federal court located within the Commonwealth of Massachusetts shall be the sole and exclusive forum for (a) any derivative action or proceeding brought on behalf of the Corporation, (b) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of the Corporation to the Corporation or the Corporation's shareholders, (c) any action asserting a claim arising pursuant to any provision of the Massachusetts Business Corporation Act, or (d) any action asserting a claim governed by the internal affairs doctrine, in all cases subject to the court's having personal jurisdiction over the indispensable parties named as defendants. Any person or entity purchasing or otherwise acquiring any interest in shares of capital stock of the Corporation shall be deemed to have notice of and consented to this Article VI.

ARTICLE VII

The effective date of organization of the corporation is the date and time the articles were received for filing if the articles are not rejected within the time prescribed by law. If a later effective date is desired, specify such date, which may not be later than the 90th day after the articles are received for filing:

N/A

It is hereby certified that these restated articles of organization consolidate all amendments into a single document. If a new amendment authorizes an exchange, or effects a reclassification or cancellation, of issued shares, provisions for implementing that action are set forth in these restated articles unless contained in the text of the amendment.

Specify the number(s) of the article(s) being amended: Article VI.3

Signed by: /s/ Waleed Hassanein, M.D.

(signature of authorized individual)

☐ Chairman of the board of directors,

☒ President,

☐ Other officer,

☐ Court-appointed fiduciary,

on this 26th day of November , 2018 ..

COMMONWEALTH OF MASSACHUSETTS
William Francis Galvin
Secretary of the Commonwealth
One Ashburton Place, Boston, Massachusetts 02108-1512

Restated Articles of Organization
(General Laws Chapter 156D, Section 10.07; 950 CMR 113.35)

I hereby certify that upon examination of these restated articles of organization, duly submitted to me, it appears that the provisions of the General Laws relative to the organization of corporations have been complied with, and I hereby approve said articles; and the filing fee in the amount of $_____ having been paid, said articles are deemed to have been filed with me this _____ day of _____, 20_____ , at _____a.m./p.m.
time

Effective date: _____
(must be within 90 days of date submitted)

WILLIAM FRANCIS GALVIN
Secretary of the Commonwealth

_____
Examiner

_____
Name approval

Filing fee: Minimum filing fee $200, plus $100 per article amended, stock increases $100 per 100,000 shares, plus $100 for each additional 100,000 shares or any fraction thereof.

_____
C

TO BE FILLED IN BY CORPORATION
Contact Information

_____
M

Waleed Hassanein, M.D.

TransMedics Group, Inc.

200 Minuteman Road, Andover, MA 01810

Telephone: (978) 552-0900

Email: _____

Upon filing, a copy of this filing will be available at www.sec.state.ma.us/cor. If the document is rejected, a copy of the rejection sheet and rejected document will be available in the rejected queue.

Exhibit 10.21

THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [***] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

DEVELOPMENT AND SUPPLY AGREEMENT

THIS AGREEMENT is made this 24th day of May 2005, (the "Effective Date") by and between **FRESENIUS KABI AB**, a company formed under the laws of Sweden ("FRESENIUS") and **TransMedics Inc.**, a corporation formed under the laws of Delaware, USA ("TRANSMEDICS"). Each of FRESENIUS and TRANSMEDICS are a "Party", and together they are the "Parties". References to FRESENIUS and TRANSMEDICS, or collectively to the Parties, shall include their respective Affiliates.

WITNESSETH:

WHEREAS, FRESENIUS researches, develops and manufactures chemical solutions for sale worldwide;

WHEREAS, TRANSMEDICS is engaged in the development, manufacture and sale of medical device products, including without limitation, a Portable Organ Preservation System ("POPS") that is intended to utilize the Products (as defined below) and desires FRESENIUS to develop and manufacture the Products for TRANSMEDICS in accordance with the specifications provided by TRANSMEDICS; and

WHEREAS, FRESENIUS and TRANSMEDICS hereby agree upon the terms and conditions under which i) FRESENIUS is willing to perform the Preliminary Activities (as defined below) and ii) FRESENIUS will toll manufacture and supply the Products for commercial sale by TRANSMEDICS;

NOW, THEREFORE, in consideration of the mutual covenants and agreements contained herein, and upon the terms and subject to the conditions set forth below, the Parties hereby agree as follows:

ARTICLE 1

DEFINITIONS

For the purpose of this Agreement, the terms set forth in this Article shall have the following meanings stated below. The singular form of the terms shall thereby include the plural form thereof:

1.1 "Affiliate" means, with respect to any person or Entity (as hereinafter defined), any other person or Entity that controls, is controlled by or is under common control with the specified person or Entity. As used in this definition, the term "control" means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of an Entity, whether through ownership of voting securities, by contract or otherwise.

1.2 "Approval" means TRANSMEDICS' approval of Development Deliverables in accordance with the procedures set forth in Section 3.6.2 "Approves", "Approve", "Approved" and the like shall have their correlative meanings.

1.3 "Batch" means the quantity of units of the Products produced from a single homogeneous mix.

1.4 "Business Day" means any day other than a Saturday, a Sunday or a day on which either of the Parties is closed generally.

1.5 "cGMP" means the current good manufacturing practices as they relate to that part of quality assurance which ensures that medicinal products are consistently produced and controlled to the quality standards appropriate to their intended use in each jurisdiction in which Regulatory Approval has been obtained, including without limitation, the principles and guidelines specified in Chapter II of European Commission Directive 91/356/EEC, and the regulations set forth in Title 21 of the U.S. Code of Federal Regulations, Parts 210-211, 820 and Subchapter C (Drugs), Quality System Regulations and the requirements there under imposed by the FDA. In case of conflict with respect to the laws in such jurisdictions, the laws with the strictest interpretation shall control.

1.6 "Calendar Year" means a period from January 1 to December 31.

1.7 "Confidential Information" means, subject to the exceptions of Article 12, ideas, inventions, discoveries, improvements, concepts, formulas, practices, procedures, processes, methods, knowledge, know-how, trade secrets, skill, experience, documents, apparatus, results, clinical and regulatory strategies, test data, including biological, chemical, biochemical, pharmacological, toxicological, metabolic and clinical test data, analytical, stability and quality control data, manufacturing data and descriptions, patent and legal data, market data, financial data or descriptions, devices, assays, chemical formulations, specifications, compositions of matter, standard operating procedures, protocols relating to the research scale, pilot scale and commercial synthesis of physical, chemical and biological materials and compounds and products, product samples and other samples, physical, chemical and biological materials and compounds, and the like, whether or not patentable.

1.8 "Development Deliverable" means any document, report, prototype or Product to be delivered by FRESENIUS to TRANSMEDICS within the framework of the Preliminary Activities as specified in the Project Plan annexed hereto as Exhibit A.

1.9 "Device Master File" means all documentation necessary for TRANSMEDICS' submission of a master file on the Products for 510K approval by the FDA and any equivalent Regulatory Agencies in other nations.

1.10 "Entity" means any corporation, association, partnership (general or limited), joint venture, trust, estate, limited liability partnership or other legal entity or organization.

1.11 "FDA" means the United States Food and Drug Administration, and any successor agency thereto.

1.12 "Facility" means FRESENIUS' sterile manufacturing facility at its premises at Rapsgatan 7, 754 50 Uppsala, Sweden or such other physical facilities that are agreed in writing by the Parties.

1.13 "Improvements" means improvements or modifications to the Products.

1.14 "Initial Feasibility Study" means the study and preparation work undertaken by FRESENIUS for TRANSMEDICS pursuant to and under the Letter of Intent.

1.15 "Label", "Labeled", OR "Labeling" shall mean all labels and other written, printed or graphic matter placed upon (i) the Products or any container or wrapper utilized with the Products, and/or (ii) any written material accompanying the Products, including, without limitation, package inserts.

1.16 "Letter of Intent" means that Letter of Intent between the Parties dated July 7, 2004, as amended.

1.17 "Liaison" means a representative chosen by a Party to communicate with the other Party regarding the Preliminary Activities.

1.18 "Manufacturing Process" means any and all methods, techniques, processes, procedures and quality control necessary or relevant for manufacture of the Products, as contained, in general terms, in Exhibit B as the same may be amended from time to time in writing by mutual agreement of the Parties.

1.19 "Material" means all ingredients, materials, compounds, components and constituent parts included in Product or expended in the manufacture of Product. Material shall not include equipment or general plant or manufacturing supplies used in connection with manufacture of the Product. All Material is described and set forth in the Material Specifications.

1.20 "Material Specifications" means the description of the Material, including requirements, tolerances, shelf life, specifications, suppliers and safety data, that are set forth in Exhibit D.

1.21 "New Equipment" means all equipment currently not possessed by FRESENIUS but required to manufacture the Products.

1.22 "POPS Field" means the study and/or practice of preservation, evaluation, resuscitation, transplantation or ex vivo perfusion of human or human compatible tissue and/or organs, including without limitation the production of devices and systems therefore and components thereof, used in the production of the Products.

1.23 "Preliminary Activities" means those research and development activities set forth in the Project Plan annexed hereto as Exhibit A, which have been or are to be performed by FRESENIUS in order to develop the Products and to supply TRANSMEDICS with the Development Deliverables and may be amended from time to time by the mutual written agreement of the Parties.

1.24 "Production Standards" shall have the meaning set forth in Section 4.1.2.

1.25 "Project Plan" means the overview and description of Preliminary Activities agreed upon between the Parties and to be undertaken by FRESENIUS in order to develop the Products and provide TRANSMEDICS with the Development Deliverables. The Project Plan is set forth on Exhibit A and may be amended from time to time by the mutual written consent of the Parties.

1.26 "Purchase Order" means a written document issued by TRANSMEDICS specifying certain commercial conditions for the purchase of the Products, including but not limited to quantities, delivery instructions and delivery times.

1.27 "Products" means the finished dosage form of TransMedics' priming and maintenance solutions produced by FRESENIUS in accordance with the Product Specifications and Production Standards.

1.28 "Product Specifications" means the specifications, formulas, and compositions for the Products set forth in Exhibit D as the same may be amended from time to time in writing by the parties.

1.29 "Quality Agreement" means the document that specifies the quality standard and procedures between TRANSMEDICS and FRESENIUS for Products manufactured by FRESENIUS, a copy of which is annexed hereto as Exhibit C.

1.30 "Qualified Person" means a person who is registered and named as a Qualified Person as defined under the provisions of European Commission Directive 75/319/EEC.

1.31 "Regulatory Agency" means, with respect to any particular jurisdiction in which Regulatory Approval has been obtained, the federal, provincial or state regulatory agency, department, bureau or other governmental authority, body, commission, agency or other instrumentality of such jurisdiction, with the primary responsibility for the evaluation or approval of pharmaceutical products before the Products can be tested, manufactured, marketed, promoted, imported, transported exported, stored, distributed or sold in such jurisdiction, including such governmental bodies that have jurisdiction over the pricing of such pharmaceutical product. The term "Regulatory Agency" includes the FDA.

1.32 "Regulatory Approval" means any approval, product license, registration or authorization of any Regulatory Agency, sufficient for the manufacture, use, storage, import, export, transport and sale of the Products in the applicable jurisdiction.

1.33 "Research & Development Phase" means the period during the term of this Agreement beginning on the Effective Date and ending with the commencement of the Clinical Testing Phase, as described in Section 3.2.

1.34 "Subcontractors" shall have the meaning set forth in Section 3.4.1.

1.35 "Supply Phase" means the period during the term of this Agreement beginning with the completion of the Preliminary Activities and TRANSMEDICS' Approval of all Development Deliverables, whichever is later, and ending with the termination of this Agreement.

1.36 "Testing Period" means six (6) weeks for a Product and five (5) business days for documents.

1.37 "Testing Specifications" means the testing procedures and specifications with respect to the receipt of the Materials, as set forth in Exhibit E as the same may be amended by the Parties from time to time.

1.38 "TRANSMEDICS Know-How" means all Confidential Information, owned or otherwise controlled by TRANSMEDICS at any time during the term of this Agreement relating to the POPS system or any component thereof PROVIDED that this Confidential Information has been disclosed by TRANSMEDICS to FRESENIUS. For the avoidance of doubt, TRANSMEDICS Know-How includes, without limitation, the Specifications, Manufacturing Process (as of the date hereof), provided that any TransMedics Know-How as to Manufacturing Process must be reduced into writing and designated as confidential, and the formulation for the Products. Any such TRANSMEDICS Know-how shall be subject to the limitations of Article 12.1.

ARTICLE 2

SCOPE AND LICENSE

2.1 Development. Pursuant to the terms of this Agreement, TRANSMEDICS hereby commissions FRESENIUS to perform the Preliminary Activities described in more detail in Article 3 and the Appendices referred to in Article 3. In the course of such Preliminary Activities, FRESENIUS shall evaluate a composition for the Products as determined by TRANSMEDICS for overall feasibility, mainly with regards of manufacture of the Products. The Parties foresee that these Preliminary Activities may lead to amendments and modifications of the composition. As described in more detail hereinbelow, TRANSMEDICS shall own all rights to the Products and shall be responsible for final Approval of the Development Deliverables.

2.2 Appointment. Pursuant to the terms of this Agreement, and subject to TRANSMEDICS' Approval of the Development Deliverables TRANSMEDICS hereby appoints FRESENIUS as its contract manufacturer for the Products for as long as FRESENIUS fulfills its obligations under this Agreement.

2.3 Acceptance. FRESENIUS hereby accepts such appointment and agrees to manufacture the Products as requested by TRANSMEDICS in accordance with the terms of this Agreement. FRESENIUS shall provide the Products in a cost-effective manner so as to minimize any charges that might otherwise be made to TRANSMEDICS. In performing its obligations under this Agreement, FRESENIUS shall use its best efforts and act in good faith to avoid incurring costs it would not incur in similar circumstances for itself or any third party.

2.4 License Grant. TRANSMEDICS hereby grants to FRESENIUS a non-exclusive royalty- free right and license under TRANSMEDICS Know-How, without right to grant sublicenses, to manufacture the Products solely for TRANSMEDICS in accordance with the Products Specifications and the terms and conditions of this Agreement. FRESENIUS is authorized to use

the TRANSMEDICS Know-How solely for the purpose of performing its obligations under this Agreement.

2.5 No Other Rights. FRESENIUS acknowledges that, except as expressly provided in this Agreement, FRESENIUS shall not, by virtue of this Agreement, at any time have any right, title, license or interest in or to the TRANSMEDICS Know-How or to any other intellectual property rights relating to the Products which are owned by or licensed to TRANSMEDICS or to which TRANSMEDICS is otherwise entitled.

ARTICLE 3

PRELIMINARY ACTIVITIES

3.1 Preliminary Activities.

3.1.1 FRESENIUS shall use commercially reasonable efforts in performing the Preliminary Activities in accordance with the provisions of this Agreement and in completing the Preliminary Activities within the time frame set forth in Exhibit A.

3.1.2 In order to facilitate execution of the Preliminary Activities, TRANSMEDICS shall supply FRESENIUS with the TRANSMEDICS Know-How.

3.2 Development Phase. FRESENIUS shall perform the work packages described in the Project Plan; FRESENIUS shall develop a report to document the results of such work (the "Research & Development Report").

3.2.1 Clinical Batches. Following TRANSMEDICS acceptance of the Research & Development Report, if FRESENIUS and TRANSMEDICS so agree, FRESENIUS shall produce one or more Clinical Batches of the Products. FRESENIUS will manufacture batches according to its typical batch size ([***] units) only. TRANSMEDICS shall inform FRESENIUS of the number of Batches required 90 days before delivery.

3.2.2 Stability Testing. FRESENIUS shall start a Stability Testing Program using three suitable batches to assess the long-term stability of the Products, as described in the Project Plan of Exhibit A.

3.3 Cooperation.

3.3.1 FRESENIUS and TRANSMEDICS shall each designate a Liaison with the other Party during the Preliminary Activities. Each Party shall have the right to change its Liaison upon written notice to the other Party. All communications of a technical nature shall be directed to the other Party's Liaison or his or her designee. FRESENIUS shall inform the TRANSMEDICS Liaison of all material internal discussions, meetings and correspondence (including e-mail) relating to the Preliminary Activities.

3.3.2 At the request of TRANSMEDICS, the Parties shall hold regularly scheduled, meetings relating to the status of the Preliminary Activities by telephone or, if requested by TRANSMEDICS, in person.

3.3.3 FRESENIUS will deliver written reports as specified in the Project Plan to TRANSMEDICS regarding the status of the Preliminary Activities, including progress on the Development Deliverables, test results, and significant achievements or risks, in reasonable detail.

3.3.4 FRESENIUS will immediately notify TRANSMEDICS of any circumstances or conditions that could lead to increased costs or delays in delivery of Development Deliverables or to the inability to develop Products that meet the Product Specifications. Such notification shall not relieve FRESENIUS of its liability under this Agreement.

3.4 Subcontractors.

3.4.1 FRESENIUS shall not engage or use any contractor, subcontractor or consultant to perform work hereunder without TRANSMEDICS' prior written approval, which may not be unreasonably withheld. Contractors, subcontractors and consultants hereunder shall be termed "Subcontractors." This clause notwithstanding, FRESENIUS may engage a Subcontractor to perform administrative work.

3.4.2 FRESENIUS shall be responsible and liable for all actions and omissions of Subcontractors in their performance of contractual services and/or Deliverables subcontracted, and shall ensure that all Subcontractors execute written agreements imposing restrictions as to the protection of TRANSMEDICS' Confidential Information at least as stringent as those imposed hereby, and irrevocably releasing TRANSMEDICS from any liability to such Subcontractors. To allow for further transfer or license to TRANSMEDICS, FRESENIUS shall submit any and all Subcontractors to obligations allowing for the automatic transfer or license of all inventions and results (whether protectable or not) conceived in rendering any subcontracted Deliverables or part thereof. Engagement of any Sub-Contractor shall not release FRESENIUS of any and all of its obligations hereunder. TRANSMEDICS shall have no obligation or liability to any Subcontractor, and FRESENIUS shall be solely responsible for all payments to the Subcontractors.

3.5 Records and Device Master File.

3.5.1 FRESENIUS shall maintain records in sufficient detail and in good scientific manner as will properly reflect all work done and results achieved in the performance of the Preliminary Activities and as described in more detail in the Project Plan (the "Documentation").

3.5.2 FRESENIUS shall furnish to TRANSMEDICS the Documentation.

3.5.3 FRESENIUS shall prepare, maintain and share with TRANSMEDICS the records described in the Project Plan and related to the development of the Products in such form as required for the Device Master File as needed for TRANSMEDICS' submission for such Regulatory Approvals as TRANSMEDICS may elect, and shall update such records during the Development Phase, no less than monthly, with such documentation as appropriate or as instructed by TRANSMEDICS. FRESENIUS shall maintain a copy of all records needed for the portion of the Device Master File which relates to the Products. These records shall include, but not be limited to, a description of experimental plans for the work carried out, handling and archiving of raw data as well as technical reports. TRANSMEDICS shall own a Device Master File and any registration with the regulatory agencies for the Products where the Products are determined to be medicinal products.

3.6 Testing and Approval of Development Deliverables.

3.6.1 FRESENIUS shall provide the Development Deliverables to TRANSMEDICS at the location(s) designated by TRANSMEDICS no later than the times set forth in the Project Plan. Each Development Deliverable shall be accompanied by all relevant documentation, notes, diagrams, bills of materials, diagnostic reports and other information necessary for TRANSMEDICS to understand the design, fabrication and quality assurance aspects of the Development Deliverable, all to the extent customary in the trade.

3.6.2 TRANSMEDICS shall review and test each Development Deliverable to determine whether it conforms with the Product Specifications where such Development Deliverable is a Batch of Product, or where such Development Deliverable pertains to documentation, with the parameters of section 3.5 hereinabove. If TRANSMEDICS fails to review, test and notify FRESENIUS of any deficiencies in such Development Deliverables within the Testing Period, such Development Deliverables shall be deemed accepted. FRESENIUS shall not be deemed to have satisfied its obligation to provide a Development Deliverable until TRANSMEDICS has issued a written Approval of such Development Deliverable. TRANSMEDICS may only withhold its Approval to Development Deliverables if such Development Deliverables fail to meet the Product Specifications in the case of a Product, or are not suited for submission to Regulatory Agencies in the case of documents. With such Approval, the Development Deliverables shall be deemed fully accepted in that TRANSMEDICS shall be fully responsible for any defects of the Development Deliverables and no further obligations or liability with respect to the Approved Deliverables shall arise for FRESENIUS. The Parties agree and acknowledge that TRANSMEDICS' Approval under this Section shall only extend to the approved Deliverables.

3.6.3 If TRANSMEDICS determines that a Development Deliverable does not conform with the Product Specifications, TRANSMEDICS shall provide FRESENIUS with a written notification specifying the nonconformities that have been identified by TRANSMEDICS (the "Rejection Notice"). FRESENIUS shall have ten (10) business days from the date of receipt of the Rejection Notice to analyze any deficiency specified in the Rejection Notice and give TRANSMEDICS a timeline for redelivery of the Deliverable. If TRANSMEDICS so chooses, FRESENIUS shall deliver a corrected Development Deliverable at FRESENIUS' expense and as soon as practicable. Following such redelivery, TRANSMEDICS shall be given a further re-testing period, equivalent in length to the applicable Testing Period. If TRANSMEDICS rejects the redelivered Development Deliverable, TRANSMEDICS, as its sole remedies, shall be entitled to have FRESENIUS redeliver the Deliverable or terminate this Agreement without penalty. If FRESENIUS does not agree with TRANSMEDICS that a Development Deliverable fails to conform with the Product Specifications, the Parties agree to meet and work out a mutually acceptable solution.

3.7 New Equipment.

3.7.1 It is not expected that New Equipment will be needed for FRESENIUS to perform its obligations under this Agreement. However, if New Equipment is in fact needed, FRESENIUS and TRANSMEDICS agree to negotiate in good faith a separate agreement covering the purchase of such New Equipment.

3.8 Delay or Failure in Completion of Preliminary Activities.

3.8.1 FRESENIUS shall use its commercial reasonable efforts to complete the Preliminary Activities in accordance with the schedule set forth on Exhibit A. To the extent that the Preliminary Activities are not completed by the date set forth in the Project Plan, the Parties agree to meet and discuss in good faith strategies for completing the Preliminary Activities as quickly as possible.

3.8.2 To the extent that either Party shall determine in good faith that substantial technical difficulties prevent FRESENIUS from completing the Preliminary Activities, the Parties agree to meet to discuss and examine the situation. If no commercially reasonable solution can be found within sixty (60) days of such meeting, either Party may terminate this Agreement with immediate effect.

3.8.3 TRANSMEDICS shall have the right to terminate this Agreement upon not less than ten (10) days prior written notice to FRESENIUS given at any time prior to the commencement of the Supply Phase if TRANSMEDICS determines, in its sole discretion, that the Product is not commercially viable.

3.8.4 In the event of early termination pursuant to this Section 3.8, in addition to the provisions surviving under Section 13.3.5:

(a) TRANSMEDICS shall pay to FRESENIUS (on a time and materials basis at the labor rates specified in Exhibit F) the documented and reasonable costs that FRESENIUS has incurred exclusively in connection with the Preliminary Activities in accordance with the Project Plan prior to notification of termination and which costs cannot be reversed, mitigated or recovered by FRESENIUS using commercially reasonable efforts; and

(b) FRESENIUS shall deliver to TRANSMEDICS all plans, designs, analyses, test results, solutions, components, models, Materials, prototypes and other works-in-progress that have been developed by or for FRESENIUS during the course of the Preliminary Activities; and

(c) All other rights and obligations of the Parties under this Agreement shall terminate.

3.9 Remuneration for Preliminary Activities.

3.9.1 TRANSMEDICS shall compensate FRESENIUS for its costs and expenses directly related to its performance of the Preliminary Activities which estimated costs and expenses are set forth on Exhibit F. FRESENIUS shall use its best efforts to complete the Preliminary Activities within said estimates set forth in Exhibit F, however, TRANSMEDICS understands and agrees that Exhibit F merely contains estimates.

3.9.2 At the end of each calendar month, FRESENIUS shall provide TRANSMEDICS with a detailed accounting of the actual number of hours its personnel spent on performing the Preliminary Activities, including a breakdown of the activities performed and the out-of-pocket expenses incurred during the month that are directly related to the Preliminary Activities, including copies of third party invoices.

3.9.3 FRESENIUS shall invoice TRANSMEDICS for work performed during a calendar month no earlier than the end of such calendar month. TRANSMEDICS shall pay such invoices within 30 days from the invoice date. Payments shall be payable in SEK.

ARTICLE 4

MANUFACTURE AND SUPPLY

4.1 Manufacture of the Product.

4.1.1 During the Supply Phase, FRESENIUS shall manufacture and supply to TRANSMEDICS the quantities of Products ordered by TRANSMEDICS from time to time pursuant to Section 5.3.

4.1.2 The Products manufactured shall conform to cGMP, the Quality Agreement, all applicable laws, and the Product Specifications (as may apply from time to time, collectively, the "Production Standards").

4.2 Materials.

4.2.1 FRESENIUS shall be responsible for purchasing all Materials (including the cost of import duties of such Materials, to the extent applicable), as well as for furnishing all labor, supervision, equipment, facilities and services to manufacture the Products in accordance with the Production Standard

4.2.2 Subject to compliance with any higher standards required under this Agreement, FRESENIUS shall inspect, sample, identify and store the Materials in accordance with FRESENIUS' standard operating procedures and shall test and release Materials in accordance with the Testing Specifications.

4.3 Storage and Handling.

4.3.1 FRESENIUS shall handle and store the Materials in accordance with the Material Specifications so as to avoid any risk of damage thereto or with FRESENIUS' own ingredients or supplies or with those held by FRESENIUS for third parties.

4.3.2 FRESENIUS shall handle and store the Products in accordance with the Product Specifications so as to avoid any risk of damage thereto or confusion with other products held by FRESENIUS for itself or third parties.

4.4 Control Samples. FRESENIUS shall maintain control samples of the Materials in accordance with the provisions set forth in the Quality Agreement. The records pertaining to the testing of the Materials shall be maintained by FRESENIUS in accordance with its internal record retention policies and cGMP. FRESENIUS shall make such records available to TRANSMEDICS during normal business hours, upon prior written request.

4.5 Stability Testing. FRESENIUS shall be responsible for maintaining a routine stability testing program for the Products as set forth in the Quality Agreement. TRANSMEDICS shall

reimburse FRESENIUS for costs related to the execution of the routine stability testing program at a rate set forth on Exhibit G.

4.6 Changes in Specifications.

4.6.1 TRANSMEDICS shall have the right to make other changes to the Product Specifications, the Material Specifications, and the Testing Specifications (collectively, the "Specifications") at any time. Any increase in costs for the manufacture of the Products by FRESENIUS as a result of such changes in the Specifications as well as any FRESENIUS internal and out-of-pocket cost to implement said changes by FRESENIUS shall be borne by TRANSMEDICS. FRESENIUS shall advise TRANSMEDICS of such cost prior to implementation of the changes to the Specifications requested by TRANSMEDICS and FRESENIUS shall not commence to implement any such changes or incur any costs until TRANSMEDICS has given its written authorization to do so. The Parties shall further agree on a reasonable time schedule for the implementation of said changes.

4.6.2 TRANSMEDICS shall reimburse FRESENIUS for the reasonable costs related to new labels, package inserts or packaging materials or changes to existing labels, package inserts, or packaging materials that are requested by TRANSMEDICS.

4.6.3 TRANSMEDICS shall reimburse FRESENIUS for direct costs of inventories and for costs of destruction thereof, of manufacturing materials, including printed materials, which become obsolete due to changes in Specifications made at the request of TRANSMEDICS.

4.6.4 FRESENIUS may make changes to the Manufacturing Process only with the prior written consent of TRANSMEDICS. Any increased costs resulting from any changes to the Manufacturing Process arising from a request from FRESENIUS shall be borne by FRESENIUS. Unless subject to section 14.1, any benefit arising from a request by FRESENIUS shall be to the benefit of FRESENIUS.

4.6.5 The Parties shall cooperate to determine an appropriate qualification protocol for all changes to Product Specifications.

4.6.6 The Parties shall determine an appropriate inventory level of pre-change Products in order to cover on-going requirements during the qualification process.

4.7 Notification of Problems. TRANSMEDICS shall notify FRESENIUS of any problems of which TRANSMEDICS becomes aware associated with the Products, or FRESENIUS' Manufacturing Process, packaging or testing procedures within 48 hours of TRANSMEDICS' knowledge of such problems. FRESENIUS shall notify TRANSMEDICS of any problems encountered by FRESENIUS in manufacturing or testing the Products within 48 hours of FRESENIUS' knowledge of such problems if FRESENIUS has reason to assume that such problems will affect the agreed upon delivery schedule or quality, safety or compliance of the Products.

4.8 Compliance with Laws.

4.8.1 FRESENIUS shall observe and comply with all applicable laws and regulations in Sweden in respect of the manufacture of the Products in Sweden. FRESENIUS, at its own expense, shall maintain all regulatory files, government permits and licenses required for manufacture of the Products in Sweden including, but not limited to, health, safety and environmental permits for the conduct of the activities and procedures that FRESENIUS undertakes pursuant to this Agreement. In no event shall FRESENIUS be required to maintain its Facility or manufacture the Products in a manner that violates the said applicable laws and regulations of Sweden.

4.9 Record Retention. FRESENIUS shall retain records pertaining to the Products in accordance with the provisions set forth in the Quality Agreement. TRANSMEDICS shall have the right to review such records upon reasonable notice during the term of this Agreement and for three years following termination or expiration of this Agreement.

4.10 Change in Manufacturing Site. FRESENIUS will manufacture the Products only at the Facility. FRESENIUS may not change the site of manufacture or testing operations without the prior written consent of TRANSMEDICS, which will not be unreasonably withheld, and receipt of all requisite regulatory approvals and provided that FRESENIUS' ability to supply the Products will not be adversely affected. Cost resulting from the change of manufacturing site, including additional costs related to the manufacture of the Products, shall be borne solely by FRESENIUS. The premises and equipment used to manufacture the Products will be maintained according to current regulatory requirements, cGMP guidelines and as otherwise agreed to by the parties.

4.11 Right of First Refusal. If FRESENIUS desires to sell, lease, surrender, license or otherwise transfer, either directly or indirectly, the assets described in Exhibit I (the "Offered Items") to any third party, FRESENIUS will first give TRANSMEDICS the opportunity to acquire the Offered Items on terms equivalent to those offered to the third party (the "Proposed Terms"). TRANSMEDICS shall have thirty (30) days in which to accept the Proposed Terms in writing. If TRANSMEDICS does not accept the Proposed Terms within thirty (30) days, then FRESENIUS shall be entitled to enter into an agreement with such third party on the Proposed Terms. If the Parties agree that this Agreement shall be transferred to the acquirer of the Offered Items, FRESENIUS shall require that any third party acquirer of the Offered Items be bound by all relevant provisions of this Agreement relating to the Offered Items, including, without limitation, this Section 4.11.

ARTICLE 5

FORECASTS AND PURCHASE ORDERS

5.1 Forecast. As soon as practicable after the commencement of the Supply Phase and thereafter, at least [***] prior to the first day of each January, April, July and October during the Supply Phase, TRANSMEDICS shall submit to FRESENIUS a good faith, estimated rolling forecast of the quantity of Products TRANSMEDICS expects to order for production on a monthly basis during the next [***] (a "Forecast"). TRANSMEDICS agrees that (i) the Forecast for the first [***] reflected therein shall be considered a "firm" Forecast and TRANSMEDICS shall place

Purchase Orders for all Product forecasted therein during the month indicated by the Forecast, and (ii) the Forecast for the fourth, fifth and sixth months shall be "semi-firm", and TRANSMEDICS shall place Purchase Orders for between [***]% and [***]% of the Product forecast therein during the month indicated by the Forecast. The Forecast for the seventh through [***] of the Forecast shall be non-binding.

5.2 Manufacturing and Production Capacity.

5.2.1 For the semi-binding and the non-binding portion of the Forecast, FRESENIUS shall allocate sufficient manufacturing capacity, components and parts, for manufacture of the Products in sufficient quantity to exceed TRANSMEDICS' then current Forecast amounts by at least [***]%. For the binding portion of the Forecast, FRESENIUS shall use best efforts to manufacture quantities of Products to exceed TRANSMEDICS' then current Forecast amounts by [***]%. FRESENIUS shall manufacture all of the Products ordered by TRANSMEDICS in compliance the with Production Standards.

5.2.2 At any time during the Supply Phase, if TRANSMEDICS so chooses, FRESENIUS shall, at TRANSMEDICS' expense, fully qualify a second manufacturing plant for the Products that is at least 250 miles geographically distant from its initial manufacturing plant. Alternatively, with TRANSMEDICS' prior written consent, FRESENIUS may qualify, at TRANSMEDICS' expense, a reputable third party manufacturer with a physically distinct manufacturing facility to produce the Products. TRANSMEDICS shall be entitled to visit and inspect all proposed production facilities for the Products.

5.3 Purchase Orders.

5.3.1 Not less than 45 days before the beginning of a calendar month TRANSMEDICS shall submit its Purchase Orders setting forth the quantities, delivery dates and shipping instructions with respect to each shipment for said calendar month. FRESENIUS understands that the Purchase Orders may not reflect FRESENIUS' typical batch size for an extended period after commencement of commercial production. TRANSMEDICS agrees to have the Purchase Orders reflecting FRESENIUS' typical batch size as soon as commercially viable, taking both TRANSMEDICS' and FRESENIUS' commercial interest into consideration and in particular the shelf life of the Product and potential storage of ordered to manufactured Product.

5.3.2 In the event that the quantity of Products for delivery in any calendar quarter reflected in the binding portion of the Forecast is more than [***]% above the quantity of the Products reflected in the latest Semi-Firm Forecast for said calendar quarter FRESENIUS shall use all reasonable commercial efforts, but shall not be obligated, to deliver during such calendar quarter the quantity of the Products ordered by TRANSMEDICS beyond such threshold amount. For purposes of clarity, FRESENIUS shall be obligated to provide the quantity of Products ordered by TRANSMEDICS up to [***]% over its Semi-Firm Forecast, so long as TRANSMEDICS has submitted Purchase Orders in accordance with Section 5.3.1.

5.4 Acceptance of Purchase Orders. Unless FRESENIUS informs TRANSMEDICS otherwise in writing within 10 Business Days of its receipt of a Purchase Order, the Purchase Order shall be deemed accepted by FRESENIUS. The only grounds upon which FRESENIUS may reject a

Purchase Order shall be that the Purchase Order: (i) sets forth a delivery schedule that is inconsistent with Sections 5.1 and 6.1, or (ii) if TRANSMEDICS has not paid three consecutive invoices. Should the requested delivery date set forth on a Purchase Order not be reasonably achievable by FRESENIUS, FRESENIUS will inform TRANSMEDICS thereof within 5 Business Days following receipt of the Purchase Order and at the same time will propose an alternative ship date, the acceptance thereof not to be unreasonably withheld by TRANSMEDICS. A request by FRESENIUS to change the ship date shall not be deemed to be a rejection of a Purchase Order.

5.4.1 In addition to the foregoing, TRANSMEDICS shall be entitled to cancel, without penalty, any order for the Products if such order has not been delivered within two (2) weeks of the scheduled delivery date. FRESENIUS shall refund TRANSMEDICS all amounts paid by TRANSMEDICS in respect of such canceled orders.

5.5 Shipment Quantity Deviation. FRESENIUS is entitled to deviate plus or minus [***]% from the quantity of Products set forth on the Purchase Order. If FRESENIUS has a reasonable belief that it anticipates a deviation beyond the [***]% threshold referred in the foregoing sentence, FRESENIUS will advise TRANSMEDICS within three (3) Business Days of the basis upon which such reasonable belief is formulated. FRESENIUS is entitled, at its own risk and discretion, to produce the Products according to the Forecast and hold such Products as safety stock, provided that the Products, at the time of delivery to TRANSMEDICS shall have a shelf-life of no less than [***]% of the shelf life set forth in the Product Specifications based on the assumption that the shelf-life of the Products is set at two years. If the determined shelf-life is materially less than 2 years, the Parties shall agree on a reasonably shortened rest of the shelf-life to be unexpired at the time of delivery of the Products.

5.6 Conflicts. In the event that the terms of this Agreement conflict with the terms of a Purchase Order, unless otherwise mutually agreed in writing by the Parties, the terms of this Agreement shall prevail.

ARTICLE 6

DELIVERY AND INVOICE

6.1 Delivery.

6.1.1 All Products shall be handled, packaged, labeled and shipped by FRESENIUS according to the Product Specifications and any reasonable instructions from TRANSMEDICS, and shall be accompanied by an appropriate certificate of analysis. FRESENIUS shall provide TRANSMEDICS by fax with a copy of the certificate of analysis and the part of the batch documentation required for release of the product. In the first year of commercial supply, FRESENIUS shall provide TRANSMEDICS with appropriate samples of each batch to be delivered by air mail. All Products shall be appropriately labeled with traceable batch numbers and date of manufacture. FRESENIUS shall mark the Products and packaging with the country of origin as required, and provide a certificate of origin and any other documents required for customs purposes. FRESENIUS shall deliver each shipment, FCA (as defined in Incoterms 2000 or latest revisions thereof), FRESENIUS' Facility, to TRANSMEDICS or TRANSMEDICS' designee. At the request of TRANSMEDICS, FRESENIUS will give assistance in arranging

transport of the Products in which case FRESENIUS shall follow the instructions of TRANSMEDICS.

6.1.2 All freight and insurance costs in respect of the Products shall be borne by TRANSMEDICS. Title, risk of loss, delay or damage in transit shall be with TRANSMEDICS from and after delivery to TRANSMEDICS' designated carrier.

6.2 Invoice.

6.2.1 Subject to Section 6.2.2, FRESENIUS shall invoice TRANSMEDICS no earlier than the time of delivery of the Products for the applicable Purchase Price and for prepaid cost of transport for the Products then shipped. Each such invoice shall state the quantity of the Products contained in the shipment in question.

6.2.2 TRANSMEDICS or its designee shall have the right to confirm the quantity of the Products contained in any shipment. In the event the quantity of the Products shipped is greater or less than the quantity reflected in FRESENIUS' invoice for such delivery, then within 60 days after TRANSMEDICS or its designee' s receipt of such shipment, TRANSMEDICS may notify FRESENIUS of such overage or shortage, and, unless FRESENIUS disputes such notice, the amount of such invoice shall be corrected by FRESENIUS through issuing an additional invoice or a credit note, as the case may be, to reflect the actual quantity of the Products contained in such shipment.

6.2.3 TRANSMEDICS shall have the right to withhold payment of the portion of any invoice that is in dispute under 6.2.2 until such dispute has been resolved.

ARTICLE 7

PURCHASE PRICE

7.1 The "Purchase Price" for the Products is as set forth on Exhibit H.

7.2 Purchase Price Adjustment. The Purchase Price shall be increased each [***] effective on [***] beginning with the [***] year of the Supply Phase by the lower of (i) [***]% or (ii) the percentual increase in the index level specified in the **Net Price Index (1980=100) published by Statistics Sweden** for the 12 months period ending on October 31 of the preceding calendar year compared with the index level specified in said production index as of October 31 of the second preceding calendar year. For the avoidance of doubt, the Purchase Price effective on January 1 shall apply on all Products delivered on or after such January 1. If the index described above ceases to be published, then the Parties agree to substitute, without the necessity of any further action by the Parties, the index designated by the Swedish government as the successor index to the discontinued one, or if no successor is designated, the successor index agreed to by Parties (such agreement not to be unreasonably withheld or delayed), or if the Parties are unable to agree, the index designated by FRESENIUS' independent certified accountant.

7.3 Other Purchase Price Adjustments. In addition to the annual Purchase Price adjustment referred to in Section 7.2 above, the Purchase Prices may also be adjusted (either up or down) upon the mutual consent of the Parties upon the occurrence of one of the following events:

7.3.1 Changes in Specifications are required by TRANSMEDICS or an applicable Regulatory Agency;

7.3.2 Changes to the Manufacturing Process or equipment are required by TRANSMEDICS or an applicable Regulatory Agency;

7.3.3 Changes to the control or monitoring procedures are required by TRANSMEDICS or an applicable Regulatory Agency; or

7.3.4 Sales quantities are significantly above or below the projected quantities as set forth in the forecasts pursuant to Section 5.1.

7.4 Taxes. Any and all taxes imposed upon or with respect to or measured by the sale or delivery by FRESENIUS to TRANSMEDICS of the Products in accordance with TRANSMEDICS' instructions (other than taxes levied upon FRESENIUS' gross or net income) shall be on TRANSMEDICS' account.

ARTICLE 8

PAYMENT

8.1 Payment Due Date. TRANSMEDICS shall make payment on invoices (including value added tax, if any, due thereon) by wire transfer in SEK no later than 30 days from the date the invoice is received unless the invoice needs to be corrected per Section 6.5.2, in which case TRANSMEDICS shall make payment no later than 30 days from the date a corrected invoice is received.

8.2 No Set-Offs. All payments shall be made without deduction, set off or counterclaim unless TRANSMEDICS and FRESENIUS otherwise expressly agree in this Agreement (e.g., Section 6.2.3.) or otherwise in writing.

8.3 Conflicts. No terms contained in any invoice shall be construed to amend or modify the terms of this Agreement and, in the event of any conflict; this Agreement shall prevail unless otherwise expressly agreed in writing by TRANSMEDICS and FRESENIUS.

8.4 Late Fee. If any sum payable under this Agreement is not paid on the due date for payment, the Party in default shall pay interest on such sum at an annual rate equal to the three (3) months LIBOR plus three percent (3%) per annum as published by Bloomberg Financial Services or any other bank reference source mutually agreed upon by the Parties or, if less, the maximum rate permitted by law from the due date until payment (whether before or after judgment), such interest to accrue on a daily basis provided that this right shall not prejudice any other right or remedy in respect of any such sum.

ARTICLE 9

ACCEPTANCE OR REJECTION OF THE PRODUCTS

9.1 Protocol for Receipt or Rejection of Products. Other than for Hidden Defects as described in Section 9.4, TRANSMEDICS shall have thirty (30) days after delivery of any Batch of Products pursuant to Section 6.1.1 to reject such Batch. TRANSMEDICS may reject a Batch of Products, or a portion thereof, for the (i) failure of such Batch to meet the Production Standards; or (ii) failure of such Batch to meet FRESENIUS' warranties set forth herein. Failure of TRANSMEDICS to reject a Batch of the Products in the manner set forth above within thirty (30) days after delivery of such Batch shall constitute acceptance thereof.

9.2 Partial Acceptance. If only a portion of a Batch should be rejected, the Parties shall cooperate and endeavor to allow the sale of that portion of the Batch that can be sold in compliance with all applicable laws, rules and regulations, and the portion so allowed, if any, will be considered as purchased and delivered as required under this Agreement.

9.3 Rejection of Product.

9.3.1 Should TRANSMEDICS rightfully reject any Batch of Product, or part thereof, pursuant to Section 9.1 and FRESENIUS agrees that such rejection is justified, FRESENIUS shall not charge TRANSMEDICS for such Batch and shall reimburse TRANSMEDICS for all shipping costs incurred by TRANSMEDICS. FRESENIUS shall have no further liability to TRANSMEDICS in respect of such Batch except that FRESENIUS shall have the obligation to replace the rejected Batch. The Parties shall agree how to destroy any such rejected Batch. Costs related to the disposal, destruction and/or return of such Batch shall be borne by FRESENIUS.

9.3.2 Should TRANSMEDICS reject any Batch, or part thereof, pursuant to Section 9.1 and FRESENIUS and TRANSMEDICS, after good faith negotiation, fail to agree that such rejection is justified, the Parties shall mutually agree on an independent third party to evaluate all documentation relating to such Batch of Products and other relevant information developed by both Parties relating thereto to ascertain whether the rejection is justified. If the third party determines that TRANSMEDICS' rejection is justified, FRESENIUS shall pay for the costs of the independent third party's review, all shipping costs incurred by TRANSMEDICS, all costs related to the disposal, destruction and/or return of such Batch and FRESENIUS shall have no further liability to TRANSMEDICS in respect of such Batch, except to replace such Batch at no cost to TRANSMEDICS. If the third party determines that TRANSMEDICS' rejection is not justified, TRANSMEDICS shall pay for the costs of the independent third party's review, and TRANSMEDICS shall pay FRESENIUS for such Batch, and FRESENIUS shall have no further liability to TRANSMEDICS.

9.4 Hidden Defects. If it is found that a Batch of Products has not been manufactured in accordance with the Product Specifications, cGMP and/or FRESENIUS' warranties hereunder, which could not reasonably be found by diligent and adequate inspection by TRANSMEDICS (a "Hidden Defect"), TRANSMEDICS shall notify FRESENIUS within thirty (30) days of the discovery of such Hidden Defect but in any case within 12 months from the delivery of said Batch

of Products. Such Batch of Products (or relevant portion thereof) shall be treated as rejected pursuant to Section 9.1 above.

ARTICLE 10

AUDITS AND INSPECTIONS

10.1 Audits. TRANSMEDICS may audit the Facility, (i) on an annual basis, (ii) during any FDA Application Integrity Policy investigation or action that is specific to TRANSMEDICS' POPS product or the Product, (iii) during any inspection by a Regulatory Agency that involves the POPS product or the Product, (iv) in the event of a Batch-related rejection or investigation as contemplated in Article 9, (v) in the event FRESENIUS shall receive a "Warning Letter" from the FDA relating to the manufacture, packaging or Labeling of the Products by FRESENIUS or otherwise affecting the Products or similar notification from a Regulatory Agency, auditing FRESENIUS' operation, and (vi) in accordance with the procedures set forth in the Quality Agreement to ensure that the principles of cGMP and the provisions of this Agreement are followed in connection with the production of the Products. FRESENIUS will rectify any deficiencies noted during the course of an audit. If TRANSMEDICS requests FRESENIUS to implement changes over and above cGMP, and if FRESENIUS agrees to implement such changes, the costs therefore will be borne by TRANSMEDICS.

10.2 Correspondence. FRESENIUS shall provide to TRANSMEDICS copies of all correspondence from applicable Regulatory Agencies relating to the Product, and all inspection reports issued by such Regulatory Agencies during the term of this Agreement to the extent they relate to the manufacture of the Products as such reports and correspondence become available. FRESENIUS agrees to notify TRANSMEDICS promptly of any governmental inspection activity or actions relating to general cGMP compliance or to any of Products, or to any process, equipment or facilities used to manufacture any Product.

ARTICLE 11

INDEMNIFICATION AND INSURANCE

11.1 Indemnification by TRANSMEDICS. TRANSMEDICS shall defend, indemnify and hold harmless FRESENIUS, its officers, agents and employees from any third party loss, claim, action, damage, expense or liability, including reasonable defense costs and attorneys' fees ("Claim") arising out of or related to:

11.1.1 the alleged infringement of a third party's intellectual property rights relating to the use of TRANSMEDICS Know-How in accordance with the terms of this Agreement or TRANSMEDIC's other instruction;

11.1.2 TRANSMEDICS' negligence, willful or reckless acts or omissions with respect to the distribution, marketing and/or sale of the Products; and

11.1.3 personal injury to consumers relating to the Products, other than injury due to FRESENIUS' negligence, willful or reckless acts or omissions, FRESENIUS' breach of this

Agreement or applicable law or FRESENIUS' failure to manufacture, Label or package the Products in accordance with the Product Specifications.

11.2 Indemnification by FRESENIUS. FRESENIUS shall defend, indemnify and hold harmless TRANSMEDICS its officers, agents and employees from any Claim arising out of or related to:

11.2.1 FRESENIUS' negligence, willful or reckless acts or omissions, with respect to the manufacture, Labeling or packaging of the Products, including any personal injury to consumers relating to the Products arising as a result thereof; or

11.2.2 FRESENIUS' breach of this Agreement or applicable law or failure to manufacture the Products in accordance with the Production Standards; and

11.2.3 infringement of a third party's intellectual property rights relating to the Products as a result of FRESENIUS' use of a manufacturing process for the manufacture of the Products hereunder to the extent such process does not involve TRANSMEDICS Know-How or any formulation or composition of the Products that is not a direct result of the written instructions of TRANSMEDICS or the direct compliance with the Product Specification.

11.3 Procedure. In the event either FRESENIUS or TRANSMEDICS seeks indemnification under this Article 11 from the other, it shall inform such other Party of a Claim as soon as reasonably practicable after it receives notice of the Claim, shall permit the indemnifying party to assume direction and control of the defense of the Claim (including the right to settle the claim solely for monetary consideration), and shall reasonably cooperate as requested by and at the expense of, the indemnifying party in the defense of the Claim. In addition, either Party may be represented by its own counsel at its own expense.

11.4 Limitation on Liability. EXCEPT AS OTHERWISE STATED HEREIN, NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY AMOUNTS REPRESENTING ITS LOSS OF PROFITS, LOSS OF BUSINESS, LOSS OF GOODWILL, LOSS OF ECONOMIC OPPORTUNITY, OR INDIRECT, SPECIAL, EXEMPLARY, CONSEQUENTIAL OR PUNITIVE DAMAGES, ARISING FROM THE PERFORMANCE OR NONPERFORMANCE OF THIS AGREEMENT OR ANY ACTS OR OMISSIONS ASSOCIATED THEREWITH OR RELATED TO THE USE OF ANY ITEMS OR SERVICES FURNISHED HEREUNDER, WHETHER THE BASIS OF THE LIABILITY IS BREACH OF CONTRACT, TORT (INCLUDING NEGLIGENCE AND STRICT LIABILITY, STATUTES OR ANY OTHER LEGAL THEORY).

11.5 Insurance. TRANSMEDICS and FRESENIUS shall each maintain throughout the term of this Agreement commercial liability insurance covering product liability and other consumer injuries arising from the sale of the Products in an amount of at least US$1,000,000 per occurrence and US$3,000,000 in the aggregate. At the request of either Party, the other Party shall provide documentation sufficient to show proof of coverage.

ARTICLE 12

CONFIDENTIALITY

12.1 Defined. With respect to all Confidential Information furnished by one Party to the other Party pursuant to this Agreement, the Party receiving such Confidential Information (the "Receiving Party") shall maintain the confidential and proprietary status of such Confidential Information, keep such Confidential Information and each part thereof within its possession or under its control, use all reasonable efforts to prevent the disclosure of any Confidential Information to any other person, and use all reasonable efforts to ensure that such Confidential Information is used only for those purposes specifically authorized by this Agreement. These mutual obligations of confidentiality shall not apply to any information to the extent that such information is:

12.1.1 independently developed by the Receiving Party outside the scope and not in violation of this Agreement by employees not having access to the other Party's Confidential Information as reasonably demonstrated by the Receiving Party's written records;

12.1.2 in the public domain at the time of its receipt or thereafter becomes part of the public domain through no fault of the Receiving Party;

12.1.3 received without an obligation of confidentiality from a third party having the right to disclose such information and who is not disclosing such information on behalf of the disclosing Party;

12.1.4 released, in writing, by the disclosing Party from the restrictions of this Article 12;

12.1.5 required by law, statute, rule or court order to be disclosed (but only to the extent such disclosure is required), provided that the Receiving Party shall immediately provide notice of such requirement and use reasonable efforts to obtain confidential treatment of any such disclosure, consult with the other Party and permit the other Party to participate in seeking an appropriate protective order.

12.2 Permitted Disclosure. Notwithstanding the other provisions of this Article 12, each Party may disclose Confidential Information of the other Party to any governmental authority, including any Regulatory Agency to comply with law or the request of such authority or Regulatory Agency, or, to the extent necessary, to any Subcontractor authorized by TRANSMEDICS performing work in connection with this Agreement, provided such Subcontractor agrees to keep such Confidential Information confidential in accordance with terms no less restrictive than those set forth herein.

12.3 Remedies. The Parties hereby acknowledge and agree that in the event of any breach of this Agreement by the other Party, including, without limitation, the actual or threatened disclosure of a disclosing Party's Confidential Information without the express prior written consent of the disclosing Party, the disclosing Party will suffer an irreparable injury, such that no remedy at law will afford it adequate protection against, or appropriate compensation for, such injury. Accordingly, each Party hereby agrees that the other Party shall be entitled to specific performance of a Receiving Party's obligations under this Agreement, as well as such further injunctive relief

as may be granted by a court of competent jurisdiction without the necessity of posting an injunction bond.

12.4 Survival. This Article shall survive the termination or expiration of this Agreement for a period of 5 years.

ARTICLE 13

TERM AND TERMINATION

13.1 Term; Extension. Subject to the provisions of Section 13.2, this Agreement shall be effective from the Effective Date and shall continue to be in force for a period of five (5) years from the first delivery during the Supply Phase. Thereafter, the term shall be automatically renewed for one year renewal periods unless terminated by either Party by giving at least 12 months prior written notice to the other Party.

13.2 Early Termination. Notwithstanding the Section 13.1 above, this Agreement may be terminated as follows:

13.2.1 By either Party forthwith upon written notice to the other Party if the other Party is in material breach of this Agreement, and a cure of such breach has not occurred during a period of one hundred twenty (120) days following receipt of written notice thereof by the non-breaching Party;

13.2.2 By either Party upon sixty (60) days written notice following the discussion period provided in this Section 13.2.2, if TRANSMEDICS fails to obtain Regulatory Approval from Regulatory Authorities for the marketing of the Products in either the United States or Europe by December 31st 2006 provided that TRANSMEDICS shall have the right for 60 days following such date to discuss and FRESENIUS agrees to consider in good faith an extension of such date upon terms and conditions mutually acceptable to the Parties;

13.2.3 By either Party forthwith upon written notice to the other Party if the other Party filed or has filed against it a petition under any bankruptcy law or similar law generally affecting creditors' rights, which is not dismissed within 90 days of filing, or goes into liquidation or has a receiver, liquidator, administrator, or administrative receiver appointed over substantially all of its property or assets or anything analogous to this occurs in any jurisdiction; and

13.2.4 In accordance with Sections 3.6.3 and 3.8 hereinabove.

13.3 Effects of Termination.

13.3.1 On termination of this Agreement under Section 13.2, each Party shall be obligated during the applicable termination notice period to perform all of its obligations under this Agreement. FRESENIUS shall fill the Purchase Orders already placed by TRANSMEDICS and accepted by FRESENIUS and TRANSMEDICS shall pay for the Products properly delivered under such Purchase Orders.

13.3.2 If this Agreement is terminated by FRESENIUS as a result of TRANSMEDICS material breach, TRANSMEDICS shall reimburse FRESENIUS for the costs of Materials in FRESENIUS' stock or on non-cancelable order on the date the Agreement terminates, up to six months supply of the most recent Forecast. FRESENIUS shall deliver such Materials to TRANSMEDICS for its own use or sale. Any such reimbursement shall be dependent on (i) FRESENIUS applying reasonable efforts to built off stock or cancel orders for Materials during the notice of termination period, (ii) FRESENIUS not being able to reasonably use the Materials for other products. Said reimbursement shall be invoiced by FRESENIUS to TRANSMEDICS within 30 days following the date on which the Agreement terminates or expires. The payment term of such invoice shall be net 30 days.

13.3.3 Termination, expiration, cancellation, or abandonment of this Agreement through any means and for any reasons shall not relieve the Parties of any obligation accruing prior thereto and shall be without prejudice to the rights and remedies of either Party with respect to any antecedent breach of any of the provisions of this Agreement.

13.3.4 Upon termination of this Agreement pursuant to Section 3.8, the provisions of Section 3.8.4 shall apply.

13.3.5 In addition, expiration or early termination of this Agreement shall not relieve either Party of its obligations incurred prior to such expiration or early termination. The following provisions shall survive expiration or early termination of this Agreement: Article 1 (Definitions); Section 8.4 (Late Fee), Article 11 (Indemnity and Insurance); Article 12 (Confidentiality); Article 13 (Term and Termination); Section 14.2(ii) (License of Process Improvements to Transmedics); Section 14.3 (Ownership of Joint Improvements); Section 18.1 (No Rights in Trademarks or Logos); Section 20.5 (Governing Law); and Section 20.6 (Dispute Resolution).

ARTICLE 14

MUTUAL BENEFIT AND OWNERSHIP OF TECHNOLOGY

14.1 Mutual Benefit. The Parties have the intention to establish a mutually beneficial relationship and therefore agree to implement a program aimed at manufacturing the Products more cost-effectively, for example by increasing the process yield or by reducing the cost of material. The Parties shall meet from time to time to define potential improvements, to set targets, and to discuss timelines for implementation of improvements. The purchase of Materials from alternative suppliers may be part of such discussion. Should such efforts lead to a cost reduction of the manufacturing of the Products, then FRESENIUS and TRANSMEDICS shall benefit from the net benefit of such cost reduction equally.

14.2 Improvements. Each Party shall solely own, and shall alone have the right to apply for patents and inventor's certificates within and outside the United States on any Improvement which is conceived solely by such Party's employees or consultants; provided, however, that (i) all Product Improvements shall be the sole property of TRANSMEDICS and FRESENIUS hereby irrevocably assigns and transfers to TRANSMEDICS all right, title and interest in and to all Product Improvements as they are made; and (ii) FRESENIUS hereby grants to TRANSMEDICS

solely in the POPS Field a perpetual, irrevocable, royalty-free license under any rights it may have in the Process Improvements to make and have made the Products.

14.3 Joint Improvements. Improvements jointly made by employees or consultants of TRANSMEDICS and FRESENIUS ("Joint Inventions") shall be jointly owned by TRANSMEDICS and FRESENIUS. For the avoidance of doubt, Product Improvements shall be the sole property of TRANSMEDICS and shall therefore not be deemed Joint Inventions. The Parties agree to share equally all profits or royalties derived from third-party licenses granted on such Joint Inventions which are not Product Improvements and are not licenses granted by TRANSMEDICS to have the Product made for TRANSMEDICS. Where appropriate, the Parties may engage outside counsel agreeable to both Parties (the costs of which shall be borne equally by the Parties) to represent them jointly in the prosecution of patent applications and the maintenance of patents with respect to Joint Inventions.

14.4 Cooperation in Patent Matters. Upon request, TRANSMEDICS and FRESENIUS shall each provide the other with reasonable assistance in obtaining patents and, if necessary, enforcing patent rights relating to Joint Inventions. In the event that either party wishes to seek patent protection with respect to any Joint Invention, it shall notify the other Party hereto. To that end, each Party agrees to assist the other in executing, verifying and delivering such documents and performance of such acts as may be reasonably requested by the other Party in applying for, obtaining, perfecting, evidencing, sustaining or enforcing the other Party's rights in Joint Inventions. If both Parties wish to seek patent protection with respect to such Joint Inventions, the Parties shall agree which Party shall be responsible for conducting such activities with respect to a particular Joint Inventions. The Party conducting such activities shall keep the other Party fully informed as to the status of such patent matters, including, without limitation, by providing the other Party the opportunity, at the other Party's expense, to review and comment on any proposed filing in any patent office relating to the Joint Inventions with sufficient time for such other Party to reasonably review and comment. The Parties will share equally all expenses and fees incurred by the Party responsible for the activities associated with the filing, prosecution, issuance and maintenance of any patent application and resulting patent for a Joint Invention. Any review costs incurred by the Party not responsible for the filing, prosecution, issuance and maintenance of any patent application and resulting patent shall be borne by such Party. Each Party shall (and shall ensure that its employees and contractors shall) work in every proper way to vest in both Parties good and marketable title to the Joint Inventions and assure both Parties' rights in and to the information and data with respect to the Joint Inventions and the execution of all applications, specifications, oaths and all other instruments of consent, assurance, powers of attorney and other instruments as may be reasonably requested by the Party responsible for pursuing patent protection in order to apply for and obtain such rights, title and interest in and to the Joint Inventions and otherwise in order to carry out the purpose and intent of this Agreement.

14.5 Patent Prosecution by a Single Party. If only one Party wishes to seek patent protection with respect to such Joint Inventions in a country ("Prosecution Party"), it may file, prosecute and maintain patent applications and patents with respect thereto in both Parties' name, at its own expense. In any such case, the Party declining to participate in such activities ("Non-Participating Party") shall not be entitled to exploit or grant any third party a license under its interest in the applicable Joint Inventions until it has reimbursed the Prosecution Party for fifty percent (50%) of the prosecution, filing and maintenance costs incurred for the applicable Joint Inventions and

continues to share equally in future prosecution, filing and maintenance costs for the applicable Joint Inventions. The Non-Participating Party shall (and shall ensure that its employees and contractors shall) assist the Prosecution Party or its designee at the Prosecution Party's expense, but without additional compensation to the Non-Participating Party, in every proper way to vest in both Parties good and marketable title to the Joint Inventions and assure the Prosecution Party's rights in and to the information and data with respect to the Joint Inventions and the execution of all applications, specifications, oaths and all other instruments of consent, assurance, powers of attorney and other instruments as may be reasonably requested by the Prosecution Party in order to apply for and obtain such rights, title and interest in and to the Joint Inventions and otherwise in order to carry out the purpose and intent of this Agreement.

14.6 Enforcement of Rights in Joint Inventions.

14.6.1 In the event that either Party becomes aware of any actual or threatened infringement, misappropriation, or other unauthorized use ("Infringement") of any patents or other intellectual property rights arising from the Joint Inventions ("Joint Rights"), such Party shall promptly notify the other Party, and the Parties shall confer in good faith regarding the most appropriate actions to be taken with respect to such Infringement. Both Parties shall use reasonable efforts to cooperate with each other to terminate such Infringement without litigation.

14.6.2 If one Party brings an enforcement action relating to the Joint Rights (the "Initiating Party"), the other Party (the "Non-Initiating Party") shall have the right to participate in such action as a co-plaintiff. In any event, each Party hereby agrees to cooperate reasonably in any such effort, and the Parties shall reasonably cooperate to address new facts or circumstances that come to light during the course of any action relating to the Joint Rights which may affect the need for the Non-Initiating Party to participate in such action. The Initiating Party may not settle any action brought under this Section 14.6.2, or take any other action in the course thereof, that adversely affects the Non-Initiating Party's interest in the Joint Rights without the written consent of the Non-Initiating Party, such consent not to be unreasonably withheld, conditioned, or delayed.

14.6.3 If both Parties participate in the action to enforce the Joint Rights (by joining as plaintiffs), the expenses and costs of any such action and any damages or monetary award shall be shared equally. Unless otherwise agreed, if only one Party brings the action to enforce the Joint Rights, the costs and expenses shall be borne solely by the Initiating Party and any damages or monetary award shall belong solely to the Initiating Party.

ARTICLE 15

RELATIONSHIP OF THE PARTIES

It is not the intent of the Parties to form any partnership or joint venture with each other. Each Party shall, in relation to its obligations hereunder, act as an independent contractor, and nothing in this Agreement shall be construed to give the other Party the power or authority to act for, bind, or commit the other Party in any way whatsoever.

ARTICLE 16

FORCE MAJEURE

16.1 Notice.

16.1.1 If the performance by a Party of any obligation under this Agreement other than the payment of money, is prevented, delayed or impaired by Force Majeure, such Party shall be excused from performance so long as such situation continues to prevent delay or impair performance, provided the Party claiming such excuse shall have promptly notified the other Party of the existence, nature, and potential duration of such cause and shall at all times use its reasonable efforts consistent with its normal business practices to resume a complete performance.

16.1.2 The affected Party will advise the other Party from time to time as to the progress in remedying the situation and as to the time when the affected Party reasonably expects to resume its obligations and shall notify the others as to the expiration of any Force Majeure as soon as the affected Party knows the date thereof.

16.2 Defined. "Force Majeure" shall mean an event beyond the reasonable control of a Party including, but not limited to, acts of God; acts, regulations, or laws of any government; war; civil commotion; strike, lockout or industrial dispute, whether or not relating to that Party's work force, destruction of manufacture facilities or materials by fire, flood, earthquake, explosion or storm; epidemic and failure of public utilities or common carriers.

16.3 Remedy. If a Force Majeure event occurs, and if FRESENIUS shall be unable to supply the Products for commercial use in such quantities as TRANSMEDICS shall have ordered and in compliance with the delivery periods set forth in this Agreement and the Force Majeure is an event which hinders prevents or delays FRESENIUS from performing its responsibilities under this Agreement, FRESENIUS and TRANSMEDICS will consult with each other to determine what measures to take to solve the supply problem. Notwithstanding the foregoing, TRANSMEDICS will be excused from all obligations under any outstanding Forecast or Purchase Order as to which TRANSMEDICS has reason to believe FRESENIUS will not be able to fulfill within the times set forth therein.

ARTICLE 17

REPRESENTATIONS AND WARRANTIES

17.1 Of Both Parties. Each Party warrants and represents as of the Effective Date that such Party: (i) is authorized to enter into this Agreement; (ii) is aware of no legal, contractual or other restriction, limitation or condition that might affect adversely its ability to perform hereunder, provided that FRESENIUS does not warrant the absence of infringement of a third party's intellectual property rights related to the use of the TRANSMEDICS Know-How; and (iii) is in good standing under the laws of each jurisdiction in which it is incorporated or engages in business activities.

17.2 Of FRESENIUS. FRESENIUS warrants and represents that as of the Effective Date and at all times during the term of this Agreement that:

17.2.1 FRESENIUS has received all approvals required by all applicable Regulatory Agencies for the operation of the Facility as a cGMP manufacturing facility and necessary to operate the Facility in compliance with all applicable local laws, rules and regulations in Sweden.

17.2.2 All quantities of the Products supplied hereunder (i) shall meet the Product Specifications, (ii) shall be manufactured in accordance with Production Standards, and (iii) shall not be adulterated, misbranded or otherwise in violation of the U.S. Federal Food, Drug, and Cosmetic Act, and its foreign equivalents, as such laws exist at the time of shipment of such Product;

17.2.3 FRESENIUS' manufacture of the Products shall adhere to all applicable governmental laws, rules and regulations relating to the manufacture of the Products in the United States and Europe;

17.2.4 All Products delivered to TRANSMEDICS shall be free and clear of any liens and/or encumbrances by any third party;

17.2.5 To the best of FRESENIUS' knowledge, the manufacturing processes used to manufacture of the Products hereunder to the extent such process does not involve TRANSMEDICS Know-How does not infringe on any third party's intellectual property rights.

17.2.6 Limitation on Warranty. EXCEPT AS EXPRESSLY STATED HEREIN, FRESENIUS AND TRANSMEDICS DISCLAIM ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR ANY PURPOSE.

ARTICLE 18

TRADEMARKS AND LABELING

18.1 No Rights in Trademarks or Logos.

18.1.1 Other than for Labeling of the Products purchased by TRANSMEDICS, nothing in this Agreement gives FRESENIUS the right to use any TRANSMEDICS trademark, logo, trade name or design (a "Mark") and FRESENIUS does not obtain any right, title or interest in any TRANSMEDICS Mark by virtue of this Agreement or the performance of services hereunder.

18.1.2 Nothing in this Agreement gives TRANSMEDICS the right to use any FRESENIUS Mark and TRANSMEDICS does not obtain any right, title or interest in any FRESENIUS Mark by virtue of this Agreement or the performance of obligations hereunder.

18.2 Labels. FRESENIUS shall supply all Labels for the Products and be responsible for insuring that all Labeling used in connection therewith shall conform to TRANSMEDICS' written instructions. TRANSMEDICS agrees to provide Label copy and final written approval on all final Labeling and shall be responsible for ensuring the accuracy of all information contained on all

artwork for Labels, Labeling and advertising and promotional material for the Products and for the compliance of all such Labels, Labeling and advertising and promotional material with all applicable laws and Regulatory Approvals. Should TRANSMEDICS desire or be required to make any change in any such Label or Labeling, TRANSMEDICS shall be responsible for the updating of all artwork and text associated with such change and providing such changes to FRESENIUS. FRESENIUS shall make all necessary arrangements for such changed Labels or Labeling to be printed and shall provide to TRANSMEDICS printer's proofs for TRANSMEDICS' review and written approval. TRANSMEDICS shall promptly either provide FRESENIUS with any necessary corrections thereto or notify FRESENIUS in writing of its approval of such proofs. FRESENIUS shall maintain, for audit, a record of all changes and the corresponding TRANSMEDICS approval records. FRESENIUS shall be responsible for insuring that all incoming Labeling is compliant to the approved printer's proofs.

ARTICLE 19

REGULATORY COMPLIANCE/COMPLAINTS

19.1 Marketing Approval. TRANSMEDICS shall be solely responsible for completing and maintaining all marketing applications required by the regulatory authorities in order to allow the marketing and sale of the Products including but not limited to, all changes to the regulatory filings and dossiers as a result of a change in manufacturing site or modifications to the production process that were approved by TRANSMEDICS prior to implementation.

19.2 Product Complaints and Adverse Event Reporting.

19.2.1 In the event TRANSMEDICS receives a manufacturing or Labeling complaint regarding the Products, TRANSMEDICS shall promptly notify FRESENIUS in writing of such complaint.

19.2.2 FRESENIUS shall notify TRANSMEDICS within twenty-four (24) hours of receipt of any product complaint or report of any adverse reaction FRESENIUS receives from any third party. FRESENIUS shall provide TRANSMEDICS with such assistance, which is reasonably expected of contract manufacturers in responding to such complaints.

19.2.3 TRANSMEDICS shall be responsible for the reporting of, and for responding to, such complaints, in compliance with all applicable laws and regulations governing such complaints.

19.2.4 At the request of FRESENIUS, TRANSMEDICS shall ship samples of any Products, which are the subject of a complaint, to FRESENIUS, if available to allow FRESENIUS to analyze the validity of a complaint.

19.2.5 TRANSMEDICS shall be solely responsible for responding to third parties regarding complaints. FRESENIUS shall investigate all Product quality complaints it receives from TRANSMEDICS and related to the manufacturing or Labeling of the Products, and shall provide TRANSMEDICS with a written report within ten (10) days after receipt of the complaint sample, if such is requested by TRANSMEDICS. FRESENIUS shall use its best efforts to respond to, analyze and correct any situation giving rise to any such complaint, and shall immediately

correct any error, deficiency or regulatory non-compliance in the Facility or otherwise affecting FRESENIUS' manufacture, storage, Labeling or shipment of the Product.

ARTICLE 20

MISCELLANEOUS

20.1 Entire Agreement.

20.1.1 This Agreement together with all Exhibits, including, without limitation, the Quality Agreement, constitutes the entire agreement between the Parties hereto relating to the subject matter hereof and no modification, change or amendment to this Agreement shall be binding upon TRANSMEDICS or FRESENIUS except in writing of subsequent date signed by an authorized officer or representative of each of the Parties hereto.

20.1.2 Each Party acknowledges that in entering into this Agreement it is not relying upon any representation, warranty, promise or assurance made or given by the other Party, whether or not in writing, at any time prior to the execution of this Agreement, which is not set out expressly in this Agreement. provided that this shall not exclude any liability which either Party would otherwise have to the other in respect of any statements made fraudulently by that Party prior to the date of this Agreement. In the event of any conflict between this Agreement and the terms of the Quality Agreement, unless such terms pertain the quality standards of the Products, the terms of this Agreement shall prevail.

20.2 Non-Disclosure of Terms. The Parties agree that the terms of this Agreement constitute Confidential Information, and neither shall publish or disclose the terms or the existence of this Agreement unless with the written consent of the other Party.

20.3 Assignment.

20.3.1 Neither Party may assign its rights or obligations under this Agreement without the prior written consent of the other Party, which consent shall not be withheld or delayed unreasonably; provided, however, that (a) either Party may assign this Agreement, in whole but not in part, without such consent, to one of its Affiliates or, subject to Section 4.11, to an assignee who acquires all or substantially all of such Party's business, business division relevant to the Products, the Product line the Products or in the event of such Party's merger or consolidation or similar transaction; and (b) the assigning Party shall promptly notify the non-assigning Party of any such assignment. Any permitted assignee shall assume all obligations of its assignor under this Agreement. No assignment shall relieve any Party of responsibility for the performance of any obligation hereunder.

20.3.2 This Agreement shall be binding upon and inure to the benefit of each of the Parties and its successors and permitted assigns.

20.4 Compliance with Law. Except as otherwise stated above, in performing this Agreement, each Party shall comply with all applicable treaties, laws and regulations and shall not be required to perform or omit to perform any act required or permitted under this Agreement if such performance or omission would violate the provisions of any such treaty, law or regulation.

20.5 Governing Law. This Agreement and the legal relations between the Parties hereunder shall be construed, interpreted and governed by the laws of England and Wales. For purposes of this Agreement, the U.N. Convention on Contracts for the International Sale of Goods shall not apply.

20.6 Dispute Resolution. Any dispute, controversy or claim arising out of or in connection with this Agreement, including any question regarding its formation, existence, validity, enforceability, performance, interpretation, breach or termination, shall be finally resolved under the Rules of Arbitration of the International Chamber of Commerce by one arbitrator appointed in accordance with said rules. The place of arbitration shall be London, England. The language of the arbitration shall be English.

20.7 Notices.

20.7.1 All notices hereunder shall be in writing and shall be: (a) delivered personally; (b) mailed by registered or certified mail, postage prepaid; (c) sent by overnight courier; or (d) sent by facsimile or express mail to the following addresses of the respective Parties:

If to TRANSMEDICS:

TransMedics Inc, Attn. Waleed Hassanein, 200 Minuteman Road, Suite 302, Andover, MA 01810, USA. Tel. +1978552 0900, Fax. +1 978 685 9562

With a copy to:

Wilmer Cutler Pickering Hale and Dorr LLP, Attn. David E. Redlick, Esq., 60 State St., Boston, MA, 02109, USA. Tel. +1 617 526 6434, Fax +1 617 526 5000

If to FRESENIUS:

Fresenius Kabi AB, Att. Magnus Kolsmyr, Rapsgatan 7, 754 50 Uppsala, Sweden. Tel. +46 18 64 4000, Fax: +46 18 64 49 03.

With a copy to:

Fresenius AG, Att. General Counsel, Else-Kröner-Straße 1, 61352 Bad Homburg v. d. H., Germany, Tel.: + 49 (0) 6172 6080, Fax:+ 49 (0) 6172 608 2251.

20.7.2 Notice shall be effective: (a) upon receipt if personally delivered; (b) on the fifth (5th) Business Day following the date of mailing if sent by registered or certified mail; (c) on the third (3rd) Business Day following the date of delivery to the express mail service or the overnight couriers if sent by express mail, and (d) on the first Business Day following the date of transmission sent by facsimile. A Party may change its address listed above by sending notice to the other Party.

20.8 Severability. If any provision of this Agreement for any reason shall be held invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other term or provision hereof, and this Agreement shall be interpreted and construed as if such term or provision, to the extent the same shall have been held to be invalid, illegal or unenforceable, had never been contained herein.

20.9 Interpretation. When a reference is made in this Agreement to Articles or Exhibits, such references shall be to an Article or Exhibit to this Agreement unless otherwise indicated. The words “include,” “includes” and “including” when used herein shall be deemed in each case to be followed by the words “without limitation.” The table of contents and headings if any, contained in this Agreement have been inserted for convenience of reference only and shall not be relied upon in construing this Agreement. Use of any gender herein to refer to any person shall be deemed to comprehend masculine, feminine and neuter unless the context clearly requires otherwise.

20.10 Waiver. No waiver or modification of any of the terms of this Agreement shall be valid unless in writing and signed by authorized representatives of both Parties. Failure by either Party to enforce any of its rights under this Agreement shall not be construed as a waiver of such rights nor shall a waiver by either Party in one or more instances be construed as constituting a continuing waiver or as a waiver in other instances.

20.11 Counterparts. This Agreement may be executed in two (2) original counterparts, each of which shall be deemed an original, but both of which together shall constitute one and the same instrument.

20.12 Joint Work Product. This Agreement is the joint product of TRANSMEDICS and FRESENIUS, and each provision hereof has been subject to the mutual consultation, negotiation and agreement of the Parties and their respective legal counsel and advisers and any rule of construction that a document shall be interpreted or construed against the drafting Party shall not be applicable.

IN WITNESS WHEREOF, each Party has caused this Supply Agreement to be executed by its duly authorized officer on the date written below.

TRANSMEDICS, INC.		**FRESENIUS -KABI AB**	
By:	/s/ Waleed H. Hassanein	By:	/s/ Christoph Funke
Name:	Waleed H. Hassanein	Name:	Christoph Funke
Title:	President & CEO	Title:	Managing Director

Exhibit A - Project Plan

Table of Contents

Exhibit A - Project Plan

1. INTRODUCTION

TransMedics, Inc. has elected to utilize Fresenius Kabi as a contract manufacturer for solutions associated with TransMedics' Portable Organ Preservation System. The intended use of the system is to support and maintain a donated organ in a near-normal physiological state during transportation for eventual transplantation into a recipient patient.

Fresenius Kabi will assist in a Development Phase and a Supply Phase for the manufacture of priming and maintenance solutions. During the Development Phase Fresenius Kabi will develop a process to manufacture and analyze the solutions according to specifications approved by TransMedics, Inc. Upon authorization by TransMedics, Inc., Fresenius Kabi will proceed with manufacture and analysis of stability and clinical batches. The target shelf life of the solutions will be two years. During the Supply Phase, Fresenius Kabi will manufacture and supply solutions to TransMedics, Inc. in quantities ordered by TransMedics, Inc. During the Development and initial Production Phases Fresenius Kabi may conduct manufacturing activities in the Pilot Plant. Based upon future requirements, the production process may be transferred to the Large-Scale Plant.

2. SCOPE

The project scope includes the following:

- Development of a suitable system for production of priming and maintenance solutions.
- Methods set-up for analysis of raw materials to United States Pharmacopeia (USP) and European Pharmacopeia (EP) Standards, where applicable. The USP Standard will be utilized whenever both standards are available for a particular raw material.
- Analysis of raw materials.
- Method validation and analysis of the finished product(s) for stability programs and product release according to specifications approved by TransMedics, Inc.
- Assure that all systems are in place to assure that production equipment is suitable and validated to ensure compliance with cGMPs. Although TransMedics, Inc. intends to register the products as a Medical Device, all efforts that are undertaken for development of the solutions should fulfill the requirements for a finished pharmaceutical product.

Exhibit A - Project Plan

3. OBJECTIVE

In utilizing Fresenius Kabi in the Development and Supply Phases, specific objectives include but are not limited to:

- Validate analytical methods for analysis of finished product under stability programs and product release.
- Manufacture batches for a formal stability program in March 2005.
- Initiate the formal stability program in March 2005.
- Manufacture a batch to be used in clinical trials in March/April 2005.
- Launch the product in Europe during second half of 2005.
- Launch the product in USA during 2006.

4. ORGANIZATION

The TransMedics, Inc. Project Team includes:
[***]
[***]
[***]

The Fresenius Kabi Project Team includes:
[***]
[***]
[***]
[***]
[***]
[***]
[***]
[***]

5. TIME SCHEDULE

A detailed time plan will be generated by Fresenius Kabi for tracking goals and achievements. TransMedics, Inc. will be provided with a copy of the time plan. Regular updates will be provided by Fresenius Kabi on milestone achievements and any required alteration to the milestone schedule.

The important milestones are:

- Feasibility batch manufacture Dec 2004
- Pre-clinical batch/stability batch manufacture March 2005
- Clinical Trial batch release April 2005*
- Commercial production start August 2005*

The achievements marked * require authorization by authorized representatives of TransMedics, Inc. and Fresenius Kabi prior to initiation. The parties hereby acknowledge that some of the work contemplated herein has already been completed or is in progress. The table attached as Appendix I to this Exhibit A shows the work already completed or in progress, along with accountings for the number of hours worked for each part of the Development phase, the number of hours for which TransMedics has been invoiced, and the number of hours for which TransMedics has already paid, as of the date of Appendix I.

6. EXECUTION

The project activities are:

- Purchasing of raw materials and bags
- Optimization and validation of equipment prior to stability batches
- Set up of methods for analysis of raw materials
- Qualification/Validation of raw material methods
- Set up and validation/qualification of finished product analytical methods
- Validation of microbiological methods
- Preparing documentation for batch records
- Manufacturing of batch for pre-clinical testing
- Manufacturing of batches for stability testing
- Set up of stability testing program including multiple temperature conditions, light stability and transport stability
- Compiling of documentation for registration purposes according to specifications from TransMedics, Inc.
- Manufacturing of batch for clinical testing
- Commercial manufacturing

7. PROJECT DELIVERABLES

The deliverables to be supplied to TransMedics, Inc. include documents describing preliminary project activities conducted by Fresenius Kabi for laboratory trials, production records for all manufactured batches, and analytical records for feasibility, stability, clinical and supply batches.

Further, TransMedics, Inc. will be provided with deliverables to support it's registration efforts and project monitoring.

The documents include:

- Method Validation Reports for non USP methods
- Interim Stability Study reports for relevant sampling time-points. The reports will include data from real-time stability studies, accelerated stability studies, light stability studies and transport stability studies, as appropriate. Priming solution data and maintenance solution data will be reported separately. Analytical data from each time point will be included in each report. A final report will be issued upon completion of the study.
- From each sampled time point analytical data will be submitted as soon as the data is available.
- Device Master File documents include but may not be limited to:
    - Personnel responsible for QC Testing
    - Raw Materials descriptions including manufacturers, specifications and analytical methods
    - Finished Product descriptions including components, manufacturers, method of manufacture and packaging, specifications, analytical methods, and stability of individual solutions as well as mixed solutions
    - Packaging Material descriptions including integrity descriptions, material specifications, manufacturing methods, and material specifications and test methods
    - Letter of authorization
    - Method validation reports of raw materials, finished product, and packaging materials
    - Environmental assessments
    - Validation of sterilization cycle
- Transfer documents for specifying one chamber bag, two chamber bag, ports, overpouches, manufacturing process, general inspection and bag integrity report
- Risk analysis
- Validation plan and report
- Box specifications

TransMedics, Inc. may require product throughout the Development and Supply phases in order to conduct internal trials using the Priming and Maintenance solutions. Batches shall be produced so that the stability study program can be executed as if the product were a pharmaceutical.

All documentary deliverables will be provided by Fresenius to TransMedics in English.

8. REFERENCES

Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General, 21 CFR, Part 210.

Current Good Manufacturing Practice for Finished Pharmaceuticals, 21 CFR, Part 211.

9. DISTRIBUTION LIST

This document is an appendix to the supply contract and an updated copy shall be included in the copy held by each party.

Exhibit B

Manufacturing process

1. PRODUCTION CONDITIONS

Manufacturing is carried out according to the European Union Pharmaceutical Legislation for Good Manufacturing Practices and the US Code of Federal Regulations, 21 CFR parts 210 and 211.

The manufacturing process is carried out by means of sanitized equipment and under clean conditions. To prevent oxidation the preparation and filling process is carried out under supply of nitrogen. Equipment cleaning is verified prior to each production campaign. Batch records and Fill records are prepared prior to each production campaign and are completed throughout the production process.

[***]

Exhibit B
Manufacturing process

2 SOLUTION PRODUCTION

Priming solution

A. [***]
B. [***]
C. [***]
D. [***]
E. [***]
F. [***]

Maintenance solution B-Amino acid solution

A. [***]
B. [***]
C. [***]
D. [***]
E. [***]

Maintenance solution B-Dextrose

A. [***]
B. [***]
C. [***]
D. [***]
E. [***]
F. [***]

3 FILLING

A. [***]
B. [***]
C. [***]
D. [***]
E. [***]

4 STERILISATION

Exhibit B

Manufacturing process

A. [***]
B. [***]
C. The sterilisation process is controlled, monitored and recorded by calibrated equipment.

5 FINISHING

Sterilised bags are visually inspected for unusual appearance and packaged in cartons.

6 CLEANING OF EQUIPMENT

All equipment that comes into contact with the product is cleaned after use.

7 REFERENCES

21 CFR Part 210- Current Good Manufacturing Practice in Manufacturing, Processing, Packing Holding of Drugs; General

21 CFR Part 211- Current Good Manufacturing Practice for Finished Pharmaceuticals

INTERCOMPANY QUALITY AGREEMENT

Fresenius Kabi AB
Rapsgatan 7
SE-751 74 Uppsala
(hereinafter called ''Fresenius"

Approved by: /s/ Ulla Sterning Ericsson Date: 2005 06 29

Ulla Sterning Ericsson
QA Director Fresenius
Kabi AB

AND

TransMedics Inc.

200 Minuteman Road, Suite 302
Andover, MA 01810

(hereinafter called "TransMedics")

Approved by: /s/ Waleed Hassanein Date: 6/7/05

Waleed Hassanein
President & CEO
TransMedics

1. QUALITY AGREEMENT

1.1. Purpose

This INTERCOMPANY QUALITY AGREEMENT (this "Quality Agreement') defines the roles and responsibilities of TransMedics and Fresenius with respect to the quality assurance of the PRODUCTS referenced in the PRODUCT DEVELOPMENT AND SUPPLY AGREEMENT entered into by and between TransMedics and Fresenius, dated as of xxx (the "DEVELOPMENT AND SUPPLY AGREEMENT").

This Quality Agreement also defines how TransMedics's Quality Operations and Fresenius's Quality Department will interact with each other.

1.2. Relationship to the DEVELOPMENT AND SUPPLY AGREEMENT

This Quality Agreement shall be attached to and made a part of the DEVELOPMENT AND SUPPLY AGREEMENT.

In the event of a conflict between any of the provisions of this Quality Agreement and the DEVELOPMENT AND SUPPLY AGREEMENT, the provisions of this Quality Agreement shall govern.

All capitalized terms, unless otherwise set forth below, shall have the meanings set forth in the DEVELOPMENT AND SUPPLY AGREEMENT.

2. PRODUCTS

The PRODUCTS prepared by Fresenius for TransMedics are set forth in the DEVELOPMENT AND SUPPLY AGREEMENT.

3. ADMINISTRATIVE INFORMATION

Fresenius contact names: See Appendix II
TransMedics contact names: See Appendix II

Emergency contact names and numbers, during and outside working hours:

Fresenius:
Name: Ulla Sterning Ericsson
Title: QA Director
Work: +46 8 581 78 041 / +46 703 96 17 49
e-mail ulla.sterning-ericsson@fresenius-kabi.com

TransMedics:
Name: [***]
Title: Manager, Solution Development
Work: [***]
e-mail [***]

Either party may appoint alternate or additional individuals to receive communications by written notice to the other party.

4. DURATION OF QUALITY AGREEMENT

The Quality Agreement will expire upon the later of the termination of the DEVELOPMENT AND SUPPLY AGREEMENT or fulfillment of the last open order of PRODUCT. The Quality Agreement will be reviewed annually to ensure that the roles and responsibilities reflect current practice. This Quality Agreement can be modified as needed with the written approval of both parties.

5. MANUFACTURING cGMP COMPLIANCE

5.1. General

The manufacturing operations for the PRODUCTS to be performed by Fresenius are defined in the DEVELOPMENT AND SUPPLY AGREEMENT and Fresenius's and TransMedics's respective responsibilities are specified in Appendix 1 of this document.

5.2. Premises

Fresenius will manufacture the PRODUCTS at its facilities located in Uppsala, Sweden. Fresenius may not change the site of manufacture or testing operations without the prior written consent of TransMedics, which will not be unreasonably withheld, and receipt of all requisite regulatory approvals and provided that Fresenius's ability to supply the PRODUCTS will not be adversely affected. All costs resulting from the change of manufacturing site, including additional costs related to the manufacture of the PRODUCTS, shall be borne by Fresenius. The premises and equipment used to manufacture the PRODUCTS, will be maintained according to current regulatory requirements, cGMP guidelines and as otherwise agreed to by the parties.

The manufacture of the PRODUCTS will be conducted in a suitably controlled environment; and such facilities will be regularly monitored for parameters critical to the process to demonstrate compliance with applicable cGMP guidelines and any conditions registered in the REGULATORY APPROVAL for the PRODUCTS.

Fresenius will maintain controlled access to the premises where the PRODUCTS and MATERIALS are manufactured, tested and stored. Visitors should sign in or have controlled access to all facilities.

5.3. cGMP Guidelines

cGMP guidelines shall include the principles detailed in the US Current Good Manufacturing Practices (21 CFR 210 and 211) and any other similar regulations in other countries in which REGULATORY APPROVAL has been obtained that cover the

standards of manufacture for any product intended for human use, as well as the Product Specifications, REGULATORY APPROVAL and any applicable product license, ANDA or NDA application, pharmacopoeia or formulary requirements.

5.4. Materials

Fresenius will ensure that only raw materials and components that have been tested in accordance with the Material Specifications are used.

5.5. Materials Procured bv Fresenius

Fresenius is responsible for auditing and qualifying vendors of actives, raw materials and components used in PRODUCTS and will provide TransMedics with a Certificate of Conformance statement for such vendors when requested. Fresenius will audit raw material vendors/suppliers at regular intervals according to a defined program. The identity of the vendors/suppliers audited, the date of audit and final audit reports will be available for review by TransMedics upon request.

Fresenius is responsible for ensuring that all materials and components procured by Fresenius for use in the PRODUCTS are in compliance with the Material Specifications. Raw materials are given a retest date upon the satisfactory completion of all initial testing. Re-testing will be performed at defined time intervals to ensure the chemical and physical stability of the raw materials.

TransMedics shall provide the FDA approved text for all labeling materials (including package insert). TransMedics may request revisions to labeling as they determine needed. TransMedics will maintain original documentation according to record retention procedures consistent with FDA requirements. Fresenius will maintain a file documenting TransMedics’s approval of printers’ proofs.

5.6. Standard Operating Procedures

Fresenius is responsible for establishing and maintaining compliance with any SOPs required to manufacture, test and store the PRODUCTS and MATERIALS at Fresenius and to support applicable cGMPs.

5.7. Methods Validation Certification

Fresenius is responsible for providing to TransMedics a Certification of Methods Validation Compliance for all critical methods practiced by Fresenius (raw materials testing, in- process product testing, product batch release, component and product stability and cleaning validation). The certifications should state, ’’The methods are appropriate for the intended purpose, are validated per relevant regulatory guidelines and are readily available in case of a regulatory inspection.’’

5.8. Batch Numbers

A unique tracking number will be assigned to each batch and each solution type prior to undertaking manufacturing activities. The batch number and the code number follow the material throughout the manufacturing process. The numbers are recorded in the batch records. This assures that the origin, receipt, the testing and the release of the material can be verified at any time and complete traceability of the material is achieved.

5.9. Dates of Manufacture and Expiration

The date of manufacture of a PRODUCT will be defined as the date that the raw materials are first placed together into a mixing vessel. Expiration dates are computed from the date of manufacture, and are listed in month/year format.

Fresenius will calculate the expiry date from the date of manufacture using the currently approved expiry period. The expiration date will be the last day of the month computed above.

5.10. Manufacturing and Equipment Data

Fresenius is responsible for keeping records of equipment usage (previous PRODUCT produced in non-dedicated equipment), cleaning and any maintenance and/or calibration performed.

5.11. Storage and Shipment

Fresenius will store the PRODUCTS under cGMP conditions with appropriate temperature control, and ensure that appropriate controls are in place to prevent interference, theft, product contamination and mixture with any other products or materials. Fresenius will be responsible for affixing all labels, container sealing and integrity, storage and shipping conditions for the PRODUCTS.

Fresenius will maintain proper segregation of the PRODUCTS. TransMedics shall be permitted to review Fresenius's segregation system. Different lots of single PRODUCT or different types of products will not be mixed on a pallet.

Fresenius will suitably pack the PRODUCTS in appropriate shippers for transit.

Fresenius will ensure that during packaging, storage and shipment of the PRODUCT there is no possibility of deterioration, contamination or admixture with any other materials. Protocols for testing of packaging components shall be mutually agreed upon by the Parties. Fresenius will only deliver PRODUCTS FCA to TransMedics carrier, or as otherwise agreed to by the parties in writing.

Only approved, finished PRODUCTS will be shipped by Fresenius to TransMedics, except as otherwise provided. Fresenius will not ship any PRODUCT that is unapproved or under quarantine, unless mutually agreed by the parties.

6. PRODUCT TESTING

6.1. General

Fresenius shall be responsible for ensuring that the PRODUCTS are manufactured in accordance with the manufacturing formula set forth in the PRODUCTION STANDARDS. No changes may be made to the formula without the prior written consent of TransMedics. The testing activities for the PRODUCTS are to be performed by Fresenius as set forth in Exhibit E and defined in the DEVELOPMENT AND SUPPLY AGREEMENT. Following Fresenius's release of the PRODUCTS to TransMedics, the TransMedics Quality Assurance will be responsible for inspecting PRODUCTS delivered by Fresenius and accepting or rejecting products manufactured by Fresenius, in accordance with TransMedics's SOP and as set forth below.

Fresenius shall ensure that all in-process and finished PRODUCT tests are conducted according to approved standard operating procedures and that such testing is documented and Fresenius shall retain all documents relating to such testing as hereafter set forth.

6.2. In-Process and Finished Product Testing

All testing must be done in accordance with Exhibit E and under cGMP guidelines.

TransMedics may perform confirmatory testing during the initial release of the PRODUCTS. Periodically thereafter, TransMedics may test material to confirm the Fresenius data.

6.3. Retain Samples

Fresenius will retain samples of the raw materials used in the manufacture of the PRODUCTS for a period of no less than three years following the labeled expiration date of that component. The amount of sample retained will be at least twice the amount necessary to carry out all of the tests required to determine if the material meets its specifications, with the exception of sterility and endotoxin testing.

Fresenius will retain samples of the PRODUCTS for at least one year beyond the expiry period. The amount of sample retained will be twice the quantity required to carry out all of the tests required to determine if the material meets its specifications, with the exception of sterility and endotoxin testing.

Fresenius will notify TransMedics prior to the destruction of any PRODUCT designated as Clinical Trial Material involved in clinical trials in which TransMedics was engaged.

6.4. Routine Stability Program

Fresenius is responsible for maintaining a routine stability testing program for the PRODUCTS and will provide a stability report to TransMedics annually. The stability program will be in compliance with the Production Standards and Testing Specifications committments. One lot of each product will be placed on stability each year. The stability program will generally follow ICH guidelines and will be subject to approval by TransMedics. Fresenius shall obtain TransMedics written consent prior to initiating any changes to the stability protocol for any PRODUCT.

Fresenius shall bear the costs for the ongoing stability, which is planned to be one batch per year after the year in which commercial launch of a PRODUCT occurs. Costs for additional stability studies requested by TransMedics should be borne by TransMedics.

Any confirmed problems that arise as a result of the stability program will be communicated by Fresenius to TransMedics in writing within ten (10) business days.

6.5. Out-of-Specification (QQS1 Investigations

Fresenius is responsible for investigating any testing performed by Fresenius that fails to meet specifications. Each investigation will be reviewed by Fresenius's designated Quality person or by the Qualified Person assigned delegate and will follow internal procedures that are in accordance with regulatory guidelines.

Fresenius will record any accidental deviations from the manufacturing process and/or testing of the PRODUCT in the batch/testing records and Fresenius shall inform TransMedics of any confirmed OOS result with respect to any PRODUCT or MATERIAL anticipated to be used in the manufacturing process.

7. QUALITY ASSURANCE

7.1. Investigations

Any deviation from the process or OOS result will be carefully documented and investigated by Fresenius Quality Assurance and appropriate area management, in accordance with controlling Fresenius SOPs. The investigation must document that any failure has not jeopardized the safety, efficacy or quality of the PRODUCT. To support this assurance, additional sampling, testing and checks may be required and these must be recorded in the batch file. Fresenius will perform any additional testing, stability and validation that are necessary as a result of any such investigation. Fresenius will keep TransMedics informed of the conduct and progress of such work if shipping schedules will be impacted.

TransMedics will be notified in advance of all investigations that could impact product quality. A copy of the final investigation report will be included in the Release

Documentation package provided to TransMedics. Fresenius shall keep TransMedics informed of the conduct and progress of any investigation that has a quality impact on the PRODUCTS.

Fresenius will notify TransMedics if any problems are discovered that may impact PRODUCT batch(es) previously shipped to TransMedics.

7.2. Batch Disposition

For each batch, Fresenius will provide release documentation as defined in Appendix 111 which complies with the provisions set forth herein.

Fresenius will provide a standard Certificate of Analysis indicating the test results and specification of each test performed, as well as a signed Certificate of Compliance confirming that the PRODUCTS have been manufactured, tested and stored according to the requirements of the Master Production Record, and in conformance to the Production Standards.

Fresenius will provide copies to TransMedics of the batch documentation (Manufacturing Work Order and Packaging Work Order) for the first three commercial lots and one per year thereafter.

7.3. Product Release

Fresenius shall ensure and certify that the PRODUCT has been made in accordance with the Production Standards by reviewing all manufacturing and control information prior to release of the PRODUCT.

Shipment of the PRODUCTS to TransMedics, once dispositioned as “released” by Fresenius and delivered to TransMedics’s carrier, is the responsibility of TransMedics’s quality department. Acceptance or rejection of released PRODUCT will be undertaken by TransMedics, based on TransMedics’s internal procedures (as set forth below), and the full document package provided by Fresenius, and completion of any release testing required by TransMedics Quality Assurance.

Product Release Procedure

1. Fresenius will provide the following items to TransMedics Quality Assurance:

   – A Certificate of Analysis (COA), executed by Fresenius, confirming that the PRODUCT has been tested, and meets the registered specifications. Test specifications and test results must be included for each test. The COA shall also contain the information set forth in Appendix III;

- A Certificate of Compliance (COC) (Not required if statement of cGMP compliance is on COA) executed by Fresenius stating the PRODUCT has been manufactured in accordance with the approved Batch record and listing all deviations and investigations related to the Batch and confirming that all deviations and investigations related to the Batch were completed in compliance with applicable SOP's, and the Quality Requirements. The COC shall also contain the information set forth in Appendix III.

- Any Quality-Analytical Investigation Report or any other significant deviation investigations related to the batch.

2. Upon receipt of finished product at its indicated distribution center, TransMedics QA will perform an appropriate statistical sampling of received product. The inspection will include verification of visual properties and label integrity.

3. Upon review of Fresenius documents, the TransMedics QA will either (i) reject the PRODUCT for non-conformance or (ii) accept the PRODUCT subject to its rights under the DEVELOPMENT AND SUPPLY AGREEMENT and issue authorization for distribution.

Batch Record Review Procedure

Validation batches: Fresenius is responsible for providing TransMedics with a validation package that includes: (1) the validation protocol, (2) full batch document packages, (3) all validation data and (4) validation report for all validation batches of the PRODUCT manufactured. TransMedics shall have the right to review the protocol and report on request.

Requests for full documentation. Fresenius commits to providing TransMedics with a full document package within ten (10) business days if requested by TransMedics for PRODUCT quality concerns, any regulatory reasons (e.g., Batch Recall) or unsatisfactory audit report.

Any problem discovered by TransMedics likely to cause rejection of the PRODUCTS will be communicated to Fresenius within 15 days from receipt of the full release documentation package in accordance with Article 9 of the DEVELOPMENT AND SUPPLY AGREEMENT (see Appendix III).

TransMedics is responsible for investigating any claims of Hidden Defects and shall report Hidden Defects discovered by or reported to it in accordance with Section 12.2.4 of the DEVELOPMENT AND SUPPLY AGREEMENT and will notify Fresenius of any complaint it receives which may impact the PRODUCT quality and may result from

manufacturing. Fresenius will provide an immediate response and a report within a maximum period of two (2) weeks from the notification.

7.4. Product Complaints and Recalls

TransMedics, or their distribution partner, is responsible for receiving and initially evaluating any PRODUCT complaints. TransMedics will promptly notify Fresenius of all technical complaints received. TransMedics is responsible for reporting complaints to the appropriate regulatory authority, including adverse drug events reports.

Fresenius is responsible to notify TransMedics immediately of any issues that could result in a PRODUCT recall. PRODUCT issues arising from stability data or other manufacturing issues that meet Field Alert Report criteria will be communicated by Fresenius to TransMedics in writing within five (5) business days.

TransMedics, with data and assistance provided by Fresenius as may be reasonably requested by TransMedics, is responsible for filing Field Alerts. Recalls of the PRODUCTS will be conducted in accordance with all applicable laws and regulations; provided, however, that the final decision concerning any recalls and the conduct of any recall shall be made by TransMedics, with such assistance by Fresenius as may be reasonably requested by TransMedics.

7.5. Records Retention

Fresenius will retain, at a minimum, batch production records for the PRODUCTS and materials for five (5) years from manufacture of lots. TransMedics will be notified in advance and provide written authorization prior to the destruction or transfer of any documents related to the development or manufacture of the PRODUCTS.

TransMedics Validation records will be indefinitely maintained.

7.6. QA Presence in the Manufacturing Facility

Fresenius will maintain adequate QA presence in the manufacturing facility during the manufacture of the PRODUCTS to ensure compliance with cGMPs.

8. REGULATORY

8.1. Regulatory Inspections

Fresenius will inform TransMedics (within 24 hours) with notice of any upcoming regulatory inspections that may involve or affect the manufacture of the PRODUCTS and permit a representative from TransMedics Quality Assurance to be present when such inspections occur; provided such inspections may proceed without the presence of a representative from TransMedics Quality Assurance.

TransMedics will promptly inform Fresenius in writing of any regulatory issue that may affect Fresenius's ability to manufacture the PRODUCTS.

8.2. Regulatory Actions

TransMedics will notify Fresenius of any regulatory actions on the PRODUCTS that may impact Fresenius or affect Fresenius's ability to manufacture the PRODUCTS within forty-eight (48) of TransMedics learning of such action.

Fresenius is responsible for supporting all batch record investigations associated with regulatory actions.

Fresenius agrees to supply TransMedics with any manufacturing, testing or storage data within forty-eight (48) hours, if requested, as the result of a regulatory inspection, or a potential regulatory exposure such as a recall or significant product complaint.

In the event any "critical" defects (i.e., cGMP deficiencies that could result in compromise of product safety or efficacy) are discovered during audits by TransMedics or regulatory authorities, no further deliveries of PRODUCT may be delivered to TransMedics until corrective actions have been completed to TransMedics's satisfaction, as reasonably determined by TransMedics.

In the case of other defects (minor cGMP issues) arising during audits by TransMedics or regulatory authorities, a satisfactory corrective action program must be in place.

8.3. Regulatory Affairs

TransMedics is responsible for ensuring all appropriate regulatory filings and import/export documentation are filed with Regulatory Agencies prior to shipment/human administration.

8.4. Right to Audit

Fresenius will allow a reasonable number of representatives from TransMedics Quality Assurance to have access to Fresenius' manufacturing, warehousing, packaging and laboratory premises and records, documentation and reference materials relating to the Products for audit purposes listed below. TransMedics representatives will be escorted at all times by Fresenius personnel. All such audits will be conducted at reasonable times during regular business hours annually and will not unduly disrupt Fresenius's operations.

TransMedics will provide at least 30 days notice for all such audits other than for For Cause Audits. Fresenius will permit TransMedics Quality Assurance to conduct preparatory audits for initiation of cGMP manufacture of the PRODUCTS or for pre-approval inspections (PAI).

Fresenius will permit TransMedics Quality Assurance to conduct additional audits to address significant product quality problems, critical defects, safety problems, or for any other cause, including those set forth Section 3.5 of the DEVELOPMENT AND SUPPLY AGREEMENT (a "For Cause Audit'). A For Cause Audit may be conducted on at least ten (10) days notice.

Fresenius will permit TransMedics Quality Assurance to perform one standard cGMP compliance audit semi annually.

8.5. Audit Closeout

An exit meeting will be held upon completion of any audit by representatives from TransMedics and Fresenius to discuss significant audit observations.

TransMedics will provide a written report of all observations within thirty (30) days to Fresenius. Within 30 days of the audit report receipt, Fresenius will provide a written response to all findings that details corrective action to be implemented which shall be subject to TransMedics approval. Fresenius will follow up to ensure that all corrective actions are implemented.

9. DISPUTE RESOLUTION

9.1. Non-Conformitv Dispute

In the event that a dispute arises between TransMedics and Fresenius regarding the non-conformity of a batch of the PRODUCTS, the supervisors of the Quality departments from both companies will in good faith promptly attempt to reach an agreement. TransMedics may only dispute a batch of PRODUCT which has been dispositioned and released by Fresenius. Financial liability will be determined according to the DEVELOPMENT AND SUPPLY AGREEMENT.

9.2. Test Result Dispute

In the event that a dispute arises between TransMedics and Fresenius in the testing performed by Fresenius for the PRODUCTS, the resolution will proceed in stages. The first stage requires direct communication between analysts from both parties to determine that the methods of analysis are the same and are being executed in the same manner at both sites. Second, carefully controlled and split samples should be sent from one site to another in an attempt to reach agreement. Should there be a failure to achieve resolution, analysts from both parties will be required to meet to work through the analysis of a mutually agreeable sample. If these actions fail to achieve resolution, and only after these avenues have been exhausted, a qualified referee laboratory will be used to achieve resolution. This laboratory must be agreeable to both parties prior to use. The results from this referee laboratory will be used as final authority to determine responsibilities, but whatever the outcome, TransMedics retains the right to determine product release status.

Financial liability will be determined according to the DEVELOPMENT AND SUPPLY AGREEMENT.

In the event that an independent third party laboratory must be retained to settle dispute between the Parties with respect to the conformity or non-conformity of a Product, Fresenius will be responsible for the technology transfer to such laboratory, and will confirm that the technology transfer had been successful and that the laboratory was capable of reproducing Fresenius laboratory results. Fresenius and TransMedics must agree that the laboratory was in compliance with cGMP.

10. CHANGE MANAGEMENT

10.1. Changes for Commercial PRODUCTS

Fresenius will obtain TransMedics's written approval of any of the following __ 072205, ____ 050627 changes which relate to the manufacture and packaging of the PRODUCT:

- Analytical Methods
- *Raw material sources or specifications
- *Packaging materials
- Labelling
- Site of manufacture
- *Facility
- *Equipment
- *Manufacturing process
- Product specifications
- *In-process test method and /or instrument
- Testing laboratory
- Any other change that could require an amendment or supplement to or otherwise

*Means addition of "Substantial changes to" ____ 050627, __ 072205,

10.2. Technical and cGMP Impact Assessment

All significant changes to the PRODUCTS that may impact product safety or efficacy proposed by Fresenius will undergo a technical and cGMP impact assessment by Fresenius's expert groups coordinated by Fresenius's Quality personnel and in accordance with Fresenius's Change Management System. Such changes will be communicated to and discussed with TransMedics Quality Assurance. TransMedics Quality Assurance and Regulatory expert groups will determine if any proposed changes are consistent with the REGULATORY APPROVAL. No such changes shall be implemented without TransMedics's prior written approval, which shall not be unreasonably withheld and, to the extent required, any applicable REGULATORY APPROVALS; provided, however,

that Fresenius shall manufacture a sufficient amount of TransMedics's requirements of PRODUCT for the reasonable period required by TransMedics's to amend its Regulatory Dossiers.

10.3. Scope

The scope of such a Change Management process includes all Manufacturing and Packaging processes. The associated changes may relate to: the Master Production Control Records (e.g. Master Formulas, Filling Work Orders, Packaging Work Orders); Bills of Materials; Analytical Standards and Test Methods (for Raw Materials and Finished Products); Stability Protocols; Purchase Specifications (for Raw Materials and Packaging Components).

11. PRODUCT AND PROCESS VERIFICATION/VALIDATION

11.1. Process Verification

Process Verification - Fresenius is responsible for the verification of the manufacturing process for the PRODUCTS, as might be required before routine production can begin. The verification should ensure that the process is capable of consistently achieving the Production Standards and Testing Specifications.

11.2. Process Validation

Fresenius is responsible for the validation of the manufacturing process for PRODUCTS, as might be required. The validation should ensure that the process is capable of consistently achieving the Production Standards and Testing Specifications. Validation protocols and reports should be available for review before shipment upon request.

11.3. Cleaning Validation

Fresenius is responsible for ensuring that adequate cleaning is carried out between batches of different products to prevent contamination. The cleaning process will be validated before the first PRODUCT Batches are made for TransMedics. TransMedics shall review the cleaning validation on an audit basis. Data should be available to support the campaign of batches of the same product, and the type of cleaning that will be performed in between manufacturing of the same product.

11.4. Equipment, Computer, Facility and Utilities Qualification

Fresenius is responsible for all equipment, computer, facility and utility qualification and calibration activities associated with the manufacture of PRODUCTS. Such qualification/calibration should be in accordance with cGMP regulations. Validation protocols and reports shall be available for TransMedics for review during an audit.

11.5. Laboratory Qualification

Fresenius is responsible for ensuring that all laboratories are in compliance with applicable cGMP guidelines. In addition, if analytical work is subcontracted by Fresenius, then Fresenius will perform an audit on such contract laboratories to be used for analytical testing. Fresenius will be responsible for ensuring that the vendors are practicing within cGMP compliance.

In the event that TransMedics Quality Assurance laboratories will perform analytical testing of a PRODUCT, Fresenius will cooperate in the technology transfer to such laboratory, and will confirm that the technology transfer has been successful and the laboratory is capable of reproducing Fresenius laboratory results.

12. ANNUAL REVIEW, ANNUAL REPORT AND DRUG LISTING

12.1. Annual Review

Fresenius will perform an Annual Product Review for the PRODUCTS. This report will cover all manufacturing and testing performed by Fresenius. It will be a review of any changes at Fresenius in the manufacturing, testing or validation of the PRODUCTS in the previous calendar year and a summary of lots made, released and rejected. In addition, process capability, control charting or trend analysis of key product parameters will be performed. Any unusual observations will be explained in the annual product review. A copy of the Annual Product Review report will be provided to TransMedics upon completion.

12.2. Annual Report

TransMedics is responsible for preparing the Chemistry, Manufacturing and Controls (CMC) section of the Annual Report to the REGULATORY AGENCY as required by applicable regulations, including 21 CFR 314.70, 314.81, and/or 601.12.

12.3. Drug Listing

The PRODUCTS are intended to be registered as a component of a medical device. In the event that the PRODUCTS are registered as a drug, TransMedics is responsible for drug listing domestic products as the REGULATORY APPROVAL holder, and distributor of the PRODUCTS. Fresenius will provide TransMedics with all reasonably required information related to Fresenius’s facility and operations needed to register the PRODUCTS.

13. APPENDIX 1 – OUTLINE OF RESPONSIBILITIES

FUNCTION	FRESENIUS	TRANSMEDICS	REMARK
Master formula and method		X	FK Will support in the development
Quality specifications		X	FK Will support in the development
Label design and art work		X	FK Will support in the development
Manufacturing	X		
In-Process testing (Pshycial, Chemical, Microbial)	X		
FP testing - Physical, Chemical	X		TransMedics may conduct as confirmation
FP Release	X	X	TransMedics to market Fresenius to TransMedics
Distribution		X	
FP Retained samples	X		
FP Stability	X		If required under pharmaceutical registration
Certificate of Analysis	X		
Batch record review/signoff	X		
Investigations into deviations and non-conformances	X		
Complaint receipts		X	
Complaint investigations (Technical)	X		
Adverse event reports		X	
Field alert reports		X	
Recalls		X	
Customer returns		X	
Raw material (Active) Orders	X		
Raw material (Active) Testing and Release	X		
Raw material (Inactives/Printed Packaging Materials) Orders	X		
Raw material (Inactives/Printed Packaging Materials) Tests and release	X		
Supplier audits (Active)	X		

FUNCTION	FRESENIUS	TRANSMEDICS	REMARK
Supplier audits (Inactives/Printed Packaging Materials)	X		
Maintenance of vendors lists	X		
Notice of proposed changes (either party may initiate)	X	X	
Document change control	X		
Annual product review	X		

14. APPENDIX II – LIST OF QUALITY CONTACTS – names to be filled in

ISSUE	FRESENIUS	TRANSMEDICS
Product Release	[***]	[***]
Laboratory Testing	[***]	[***]
Investigations	[***]	[***]
Regulatory Affairs	[***]	[***]
Stability	[***]	[***]
Validation	[***]	[***]
Compliance Audits	[***]	[***]
Product Complaints	[***]	[***]
Change Management	[***]	[***]

* [***]

APPENDIX III – RELEASE DOCUMENTATION

The Batch/Lot Release Document Package will include a Certificate of Analysis and a Certificate of Compliance.

Certificate of Analysis (CoA)
A CoA will be provided and will include the name of the PRODUCTS, batch number, date of manufacture, and analytical specifications. The CoA will list the Release tests performed by Fresenius laboratories and actual test results.

Certificate of Compliance (CoC)
This document will attest to the fact that the batch of PRODUCTS was made in accordance with all applicable regulations, licenses, and company policies. This document will include the batch quantity approved, the final batch yield, and the expiration date. It will also include a listing of all investigations for the batch.

Quality Investigations Report (QIR)
A copy of the final investigation report for any OOS or other deviation investigations where the product quality could be affected.

Exhibit D – Product and Material Specifications

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Exhibit D – Product and Material Specifications

1 BACKGROUND

This document describes the product specifications and material specifications for the TransMedics (TMI) solutions used in the POPS™ device. This specification is valid for products that will be used in clinical trials by TMI.

2 DEFINITIONS

3CB	three chamber bag
NMT	not more than
NLT	not lower than

3 COMPOSITION OF SOLUTIONS

3.1 Priming solution

Component	Quantity per liter
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

[***]

3.2 Maintenance solution

The maintenance solution will be mixed from two individual component solutions at time of use. The individual component solutions consist of a [***] and an [***] as described below.

3.2.1 [***] solution

Component	Quantity per liter
[***]	[***]

[***]

3.2.2 [***] solution

Component	Quantity per liter
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

4 FINISHED PRODUCT SPECIFICATION

4.1 Priming solution

Test	Limit
General inspection	[***]
PH	[***]
Osmolality [mosmol/kg H20]	[***]
Color	[***]
Clarity	[***]
Sodium [g/1]	[***]
Potassium [g/1]	[***]
Magnesium [g/1]	[***]
Particulate matter:	[***]

Test	**Limit**
- particles ³ 10pm	[***]
- particles ³ 25pm	[***]
Sterility	[***]
Endotoxins [EU/m]	[***]
Fill volume	[***]

4.2 Maintenance solution

4.2.1 Dextrose solution

Test	**Limit**
pH	[***]
Osmolality [mosmol/kg H20]	[***]
Dextrose [g/1]	[***]
5-Hydroxymethylfurfural	[***]
Particulate matter: - particles ³ 10pm	[***] [***]
- particles ³ 25pm	[***]
Endotoxins [EU/ml]	[***]
Fill volume	[***]

4.2.2 Amino acid solution

Test	**Limit**
pH	[***]
Osmolality [mosmol/kg H20]	[***]
Amino acids [g/1]	[***] [***]
Tyrosine/Tryptophane	[***]
Adenosine [g/1]	[***]
Color	[***]
Calcium [g/1]	[***]

Test	Limit
Magnesium [g/1]	[***]
Potassium [g/1]	[***]
Sodium [g/1]	[***]
Particulate matter: - particles ³ 10pm - particles ³ 25pm	[***] [***] [***]
Fill volume	[***]

4.2.3 Mixed solution

Component	Limit
pH	[***]
Osmolality [mosmol/kg H20]	[***]
Particulate matter: - particles ³ 10pm - particles ³ 25pm	[***] [***] [***]
Sterility	[***]
Endotoxins [EU/ml]	[***]
General inspection	[***]

5 RAW MATERIALS

Component	Grade	Component	Grade
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]

Component	Grade	Component	Grade
[***]	[***]	[***]	[***]

*[***]

6 PACKAGING MATERIALS

The Priming and Maintenance solutions will be packaged in a [***] made of the [***]. The [***] is comprised of a [***] and [***] that may be readily combined for mixing at time of use. The Priming solution will be dispensed into a [***]. Each of the two component solutions of the Maintenance solution will be combined at time of use into [***].

6.1 Packaging materials for the TransMedics solution

Type of bag	The Priming solution and each of the two components of the mixed Maintenance solution are each filled into [***]. The nominal volume of each chamber is [***].
Ports	[***]
Labelling	The label is printed directly onto the film by a hot stamp process, where the colour pigment is transferred from a carrier foil and melted onto the outer layer of the film during a short heating cycle. It is a dry process and no surface treatment is needed. The print sets immediately after impression. The print is glossy and rub resistant prior to and after sterilisation. The hot stamp foil, denoted [***]. consists of black, pigmented ink coated on a polymeric carrier foil. The label includes batch number and expiration date.
Overpouch	The filled primary [***] is placed in a [***]. An [***] is placed inside the [***].
Functional description	The [***] is removed by tearing at a notch, the primary bag and the [***] are removed. The [***] is removed from the [***] by tearing along a tear-seal. The infusion port of the Priming chamber is spiked with a [***] and the Priming solution is added directly to the [***] for priming purposes prior to [***]being added. Time for emptying of the chamber is normally less than [***]. The contents of the maintenance solution [***] are mixed by [***]. After mixing, [***]. The [***]. Time for emptying of the Maintenance solution bag is normally less than [***].

7 STERILIZATION

The [***] system containing the Priming solution and the component maintenance solutions is terminally sterilised (autoclave process) to a Sterility Assurance Level of [***].

8 VISUAL INSPECTION OF BAGS

The visual inspection is performed after the sterilisation process but prior to the packing of the bags into cardboard boxes. The bags must be free from damages that could affect the bag integrity. The welds must be free from large wrinkles and large inclusions that might have a negative effect on the weld properties.

The solutions should be free from large particles and foreign matter.

9 PACKAGING IN CARDBOARD BOXES

The [***] are packed in cardboard boxes prior to shipment. Each box shall include one direction for use. Four [***] are packed in one box.

All goods will be delivered on wooden pallets, 800 x 1200 mm.

10 BATCH CLASSIFICATION

A manufacturing batch is the product manufactured from one homogenous lot of bulk solution. One batch contains approximately [***].

11 EXPIRATION DATES

The expiration date (mm-yyyy) of the clinical trial batches will be set to [***] after date of manufacturing.

12 SHIPMENT/TRANSPORTATION

Product will be shipped in accordance with Article 6 of the Development and Supply Agreement.

13 STORAGE DIRECTION

Store products below +[***]. Do not [***]. Store protected from light. The products may be exposed to temperatures up to [***] for a maximum of [***] during transportation.

Exhibit E – Testing Specifications

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Exhibit E – Testing Specifications

1 BACKGROUND

This document describes the testing specifications for the TransMedics (TMI) solutions used in the POPS™ device. This specification is valid for products that will be used in clinical trials by TMI.

2 DEFINITIONS

NMT not more than
NLT not lower than

3 COMPOSITION OF SOLUTIONS

3.1 Priming solution

Component	Quantity per liter
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

*[***]

3.2 Maintenance solution

The maintenance solution will be mixed from two individual component solutions at time of use. The individual component solutions consist of a [***] solution and an [***] solution as described below.

3.2.1 [***]solution

Component	Quantity per liter
[***]	[***]

*pH adjustment with HC1

3.2.2 Amino acid solution

Exhibit E – Testing Specifications

Component	Quantity per liter
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

4 FINISHED PRODUCT SPECIFICATION

4.1 Priming solution

Test	Limit	Methods*
General inspection	[***]	[***]
pH	[***]	[***]
Osmolality [mosmol/kg H20]	[***]	[***]
Color	[***]	[***]
Clarity	[***]	[***]
Sodium [g/1]	[***]	[***]
Potassium [g/1]	[***]	[***]
Magnesium [g/1]	[***]	[***]

Particulate matter: - particles ³ 10pm - particles ³ 25pm	[***] [***] [***]	[***] [***] [***]
Sterility	[***]	[***]
Endotoxins [EU/ml]	[***]	[***]
Fill volume	[***]	[***]

4.2 Dextrose solution

Test	**Limit**	**Methods***
pH	[***]	[***]
Osmolality [mosmol/kg H20]	[***]	[***]
Dextrose [g/1]	[***]	[***]
5 -Hydroxymethylfurfural	[***]	[***]
Particulate matter: - particles ³ 10pm - particles ³ 25pm	[***] [***] [***]	[***] [***] [***]
Endotoxins [EU/ml]	[***]	[***]
Fill volume	[***]	[***]

[***]

4.3 Amino acid solution

Test	**Limit**	**Methods***
pH	[***]	[***]
Osmolality [mosmol/kg H2O]	[***]	[***]
Amino acids [g/1]	[***]	[***]
Tyrosine/Tryptophane	[***]	[***]
Adenosine [g/1]	[***]	[***]
Color	[***]	[***]
Calcium [g/1]	[***]	[***]

* Methods designated as “USP” are indicative of testing procedures prescribed in the United States Pharmacopeia. Methods designated by a 5-digit number are internally validated Fresenius Kabi procedures.

Exhibit E – Testing Specifications

Test	**Limit**	**Methods***
Magnesium [g/1]	[***]	[***]
Potassium [g/1]	[***]	[***]
Sodium [g/1]	[***]	[***]
Particulate matter: - particles ³ 10pm - particles ³ 25pm	[***] [***] [***]	[***] [***] [***]
Fill volume	NLT labelled volume	USP

[***]

4.4 Mixed solution

Component	**Limit**	**Methods***
pH	[***]	[***]
Osmolality [mosmol/kg H20]	[***]	[***]
Particulate matter: - particles ³ 10pm - particles ³ 25pm	[***] [***] [***]	[***] [***] [***]
Sterility	[***]	[***]
Endotoxins [EU/ml]	[***]	[***]
General inspection	[***]	[***]

[***]

* Methods designated as “USP” are indicative of testing procedures prescribed in the United Sates Pharmacopeia. Methods designated by a 5-digit number are internally validated Fresenius Kabi procedures.

THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [***] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

Exhibit F – Estimated Costs of Preliminary Activities and New Equipment

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Exhibit F – Estimated Costs of Preliminary Activities and New Equipment

1 INTRODUCTION

TransMedics, Inc. has elected to utilize Fresenius Kabi as a contract manufacturer for solutions associated with the TransMedics Portable Organ Preservation System, referred to as POPS™. The intended use of the solutions is to support and maintain a donated organ in a near-normal physiological state during transportation for eventual transplantation into a recipient patient.

Fresenius Kabi will perform development and other services for the manufacture of priming and maintenance solutions. During the Development Phase Fresenius Kabi will develop a process to manufacture and analyze the solutions according to specifications approved by TransMedics, Inc. Exhibit A of the Development and Supply Agreement outlines the scope of the preliminary activities of the agreement. These activities are presented below in summary.

2 SCOPE

The scope of the preliminary activities includes the following:

- Optimization of finished product formulations.
- Manufacture of a feasibility batch in December 2004.
- Validation of a suitable container bag system for use with the TransMedics, Inc. solutions.
- Ensure regulatory compliance for raw materials through analysis to USP and/or EP Standards.
- Validate analytical methods for analysis of finished product under stability programs and product release.
- Manufacture batches for a formal stability program.
- Initiate the formal stability program.
- Manufacture a batch to be used in clinical trials.
- Provide regulatory compliant documentation at all appropriate stages of the Development Phase

3 EXECUTION

The project activities are:

- Purchasing of raw materials and bags
- Optimization and validation of equipment prior to stability batches
- Set up of methods for analysis of raw materials
- Qualification/Validation of raw material methods
- Set up and validation/qualification of finished product analytical methods

- Validation of microbiological methods
- Preparing documentation for batch records
- Manufacturing of batch for pre-clinical testing
- Manufacturing of batches for stability testing
- Set up of stability testing program including multiple temperature conditions, light stability and transport stability
- Compiling of documentation for registration purposes according to specifications from TransMedics Inc.
- Manufacturing of batch for clinical testing

4 ESTIMATED COSTS OF PRELIMINARY ACTIVITIES

The costs of preliminary activities are divided into the following categories:

- **Project Management ([***] hours @ [***]/hour)**
  - Preparation of a project plan
  - Supervision and coordination of all development activities in order to safeguard the execution of the program according to schedule
- **Process Development ([***] hours @ [***]/hour)**
  - Formulation Laboratory Trials
  - Manufacturing Optimization Batch
  - Stability Batches (3)
  - Clinical Batch
  - Optimization work to be able to fill batches according to cGMPs
  - Validation work to fulfill cGMP requirements for the clinical batch and manufacturing
- **QC-Raw Materials Testing ([***] hours @ [***]/hour)**
  - Set up methods for USP testing of raw materials, as required
  - Validation of methods for raw materials according to applicable guidelines
  - Adopt quality systems for raw materials
- **QC-Finished Product Testing ([***] hours @ [***]/hour)**
  - Assay Components
  - Adopt HPLC method for Adenosine; set up and transfer validation o Additional method validation activities for (6) existing methods
- **Microbiological Development ([***] hours @ [***]/hour)**

- Development of microbiological validation of sterilization o Validation/Qualification of methods for finished product and new raw materials

- **Stability Program ([***] hours @ [***]/hour)**
  - Set up and monitor stability program as per Appendix G.
  - Analysis of stability endpoints

- **Purchasing ([***] hours @ [***]/hour)**
  - Investigations and purchase activities for all materials, including USP/EP grade raw materials

The Parties hereby acknowledge that the preliminary activities contemplated in this Agreement are partially complete and that certain parts of the work have already been invoiced by Fresenius and paid for by TransMedics. Appendix I to this Exhibit F represents the status of hours worked and billed as of April 30, 2005.

5 REFERENCES

Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General, 21 CFR, Part 210.

Current Good Manufacturing Practice for Finished Pharmaceuticals, 21 CFR, Part 211.

6 NEW EQUIPMENT

There are no new equipment requirements for the program.

THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [***] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

APPENDIX I TO EXHIBIT F

Cost Report for Preliminary Activities for TransMedics in April 2005

Fresenius Kabi
Rapsgatan 7
751 74 Uppsaia
Sweden

Customer:

TransMedics
Att. Paul Lezberg
200 Minuteman Rd, Suite 302
Andover, MA 01810, USA

Ref: Purchase order [***]
Part of hours described.

Activity	Jan. Cost Est	Prev invoiced	Hours used April.	Hours left
Project management	**[***]**	**[***]**	**[***]**	**[***]**
Process development	**[***]**	**[***]**	**[***]**	**[***]**
QA/QC Raw materials	**[***]**	**[***]**	**[***]**	**[***]**
QA/QC Finished product	**[***]**	**[***]**	**[***]**	**[***]**
Microbiology	**[***]**	**[***]**	**[***]**	**[***]**
Stability program	**[***]**	**[***]**	**[***]**	**[***]**
Purchasing	**[***]**	**[***]**	**[***]**	**[***]**
Total	**[***]**	**[***]**	**[***]**	**[***]**

Material	Previous	April
Cost/Hour = 1200 SEK/hour according to LOI		
Hours Cost SEK	**[***]**	**[***]**
Sub total Cost SEK	**[***]**	**[***]**
Cost according to invoices		
Bags for up to Clinical batch		**[***]**
Total cost SEK		**[***]**

Activities performed:

- Optimisation batches and manufacturing of empty bags.
  Equipment validation to secure production quality.
- Preparations for the clinical batch.
- Preparing documentation for the clinical batch.
- Finalising the methods in the raw material laboratory for the USP analyses.
- Setting up and analysing finished product from the optimisation batches, starting method validations/verifications for finished product analysis.

One of the optimisation batches (the third batch) was enrolled into stability testing. The study is planned for 6 months.

Exhibit G – Estimated Costs of Stability Testing

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Exhibit G – Estimated Costs of Stability Testing

1 INTRODUCTION

Fresenius-Kabi will prepare and execute a formal Stability Program for the three TransMedics solutions, The duration of the study will be 24 months and will meet the minimum requirements of *ICH Q1A: Stability Testing of New Drug Substances and Products*, current revision. Additional stability elements may be incorporated in order to obtain relevant stability data corresponding to additional time points. The Stability Program Plan is presented in Appendix I of this document. The plan is subject to change by mutual written agreement of TransMedics and Fresenius-Kabi.

2 SCOPE

The scope of the Stability Program activities includes the following:

- Validate analytical methods for analysis of finished product
- Develop a Stability Plan of up to 24 months duration including storage conditions of [***] and light stability. Transport stability will also be set up and monitored.
- Manufacture three batches for the formal Stability Program
- Initiate the formal Stability Program for each batch
- Monitor sampling time points and select representative samples for analysis
- Provide interim stability reports for each sampling time point
- Provide a comprehensive stability report upon completion of the Stability Program

3 ESTIMATED COSTS OF STABILITY TESTING

The costs of Stability Testing are as follows:

- **Stability Testing ([***] hours @ [***]/hour)**

4 REFERENCES

Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General, 21 CFR, Part 210.

Current Good Manufacturing Practice for Finished Pharmaceuticals, 21 CFR, Part 211.

Exhibit G – Estimated Costs of Stability Testing

ICH Q1A, Stability Testing of New Drug Substances and Products, International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, current revision.

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Development and Supply Agreement-TransMedics Inc.

Exhibit G – Estimated Costs of Stability Testing

5 APPENDIX I, STABILITY PROGRAM

Product: [***] POPS solutions (TransMedics)

Batch No: TBD ([***] independent batches)

Product Manufacturing: Pilot Plant Fresenius Kabi, Uppsala, Sweden
Manufacturing date: March-April 2005

Package description
[***] in Biofine bag container
with HVL 9003 overpouch

Comments: *It is assumed that 3 months data from all three stability batches are to be used for IDE submission. If 6 months data are to be used a full analytical program should be performed at 6 months at 25°C and a reduced program are to be used at 3 months at 40°C.*

Storage conditions		**25°C/40 %RH**								**40C/N MT25**			**Light**	
Storage (months)		**0**	**1**	**3**	**6**	**9**	**12**	**18**	**24**	**1**	**3**	**6**	**2**	**3**
General inspection	41065	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**
Fill volume	USP	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**
Weight loss	40289	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**
A-Priming solution														
[***]	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**
[***]	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**
[***]	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**
[***]	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**
[***]	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**
[***]	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**
[***]	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**
[***]	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**	**[***]**

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Development and Supply Agreement-TransMedics Inc.

Exhibit G – Estimated Costs of Stability Testing

Storage conditions		**25°C/40 %RH**								**40C/N MT25**			**Light**	
Storage (months)		**0**	**1**	**3**	**6**	**9**	**12**	**18**	**24**	**1**	**3**	**6**	**2**	**3**
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]														
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]														
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]														
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]

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Exhibit H – Purchase Price

The price to be paid by TRANSMEDICS to FRESENIUS for formulating and filling the Product in accordance with the provisions of the Agreement (such price, for the avoidance of doubt, to include all work carried out by FRESENIUS, all raw materials and components to be supplied by FRESENIUS, delivery ex works and the compliance by FRESENIUS with any other provisions of the Agreement) shall be as follows:

Quantity per year [No. of Setsl	**Price [US$]**
1-5,000	[***]
5,001-10,000	[***]
10,001 -20,000	[***]
20,001+	[***]

One “Set” means a three-chamber bag comprising a priming solution in one chamber, a dextrose solution in a second chamber, and an amino acid solution in a third chamber. The solutions and the three-chamber bag are more particularly defined in Exhibit D.

Exhibit I – Offered Item

The offered item is what is internally within Fresenius Kabi in Uppsala referred to as the Pilot plant. The pilot plant consists of [***] "Pharmadule" modules, which can be disconnected from the fixed buildings and from each other and moved to a different location. The modules have all the facilities that are required for a pharmaceutical plant in terms of HVAC, WFI, and clean room lockers.

The equipment within the pilot plant consists of a formulation department, a filling department and a sterilization unit. The facility for the formulation and the filling does fulfill the requirements for clean rooms as defined in EU GMP and the cGMP.

The pilot plant equipment and facility is defined according to Appendix I to this exhibit.

Appendix I
Equipment list

List of equipment Pilot plan Uppsala

Equipment number	Description of equipment
[***]	

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CONTRACT MANUFACTURING AGREEMENT

This Contract Manufacturing Agreement (the "**Agreement**") is effective as of April 1st, 2015 (the **"Effective Date")** by and between

(1) Fresenius Kabi Austria GmbH, Hafnerstrasse 36, A-8055 Graz, Austria ("FRESENIUS")

and

(2) TransMedics Inc., 200 Minuteman Road, Suite 302, Andover, MA 01810, USA ("COMPANY").

Recitals

(A) WHEREAS, COMPANY holds one or more market authorisations of the Product (as defined herein).

(B) WHEREAS, COMPANY desires to obtain manufacture and supply of the Product from FRESENIUS.

(C) WHEREAS, FRESENIUS desires to manufacture the Product and supply it to COMPANY.

(D) WHEREAS, the Parties have agreed to enter into this Agreement to set forth the general terms and conditions on which the manufacture and supply of any particular Product under a Product Schedule (as defined herein) will be carried out,

NOW, THEREFORE, the Parties agree as follows;

1. Definitions

Unless otherwise specifically provided in this Agreement, the following terms shall have the following meanings:

1.1. "Affiliates" means, with respect to a Person, any Person that controls, is controlled by or is under common control with such first Person. For purposes of this definition only, "control" means' (a) to possess, directly or indirectly, the power to direct the management or policies of a Person, whether through ownership of voting securities or by contract relating to voting rights or corporate governance, or (b) to own, directly or indirectly, more than fifty percent (50%) of the outstanding voting securities or other ownership interest of such Person.

1.2. ''Batch" means the quantity of units of a Product produced from a single homogeneous mix.

1.3. "cGMP" means the current good manufacturing practices as they relate to that part of quality assurance which ensures that medicinal products are consistently produced and controlled to the quality standards appropriate to their intended use in each jurisdiction in which regulatory approval has been obtained, including without limitation, the principles and guidelines specified in Chapter II of European Commission Directive 91/356/EEC (as amended), and the regulations set forth in Title 21 of the U.S. Code of Federal Regulations, Parts 210-211, 820 and Subchapter C (Drugs), quality system regulations and the requirements thereunder imposed by the FDA. In case of conflict with respect to the laws in such jurisdictions, the laws with the strictest interpretation shall control.

1.4. "Confidential Information" means all information disclosed by or on behalf of the relevant Party to the other Party pursuant to this Agreement in written, oral or any other form.

1.5. "Disclosing Party" means the Party disclosing Confidential Information.

1.6. ''Effective Date" is defined in the preamble to this Agreement.

1.7. "First Price Review Date" means the date on which the then current Price for a Product will first be reviewed and negotiated, as specified in item C.4 of the relevant Product Schedule.

1.8. "Fixed Price Term" means the term for which the Price specified in the relevant Product Schedule at the time of signing will remain fixed, as specified in item C.3 of the relevant Product Schedule.

1.9. "Forecast" means a listing of the quantities of the relevant Product that COMPANY expects to order from FRESENIUS within a rolling time-frame.

1.10. "Intellectual Property" means all know-how, copyright, trademarks, patents, design, information and documentation, drawings and other intellectual property of any kind (whether or not protected under patent, trademark, copyright or similar laws).

1.11. "Invoice Currency" means the currency in which each Product will be invoiced and paid, as specified in item C.2 of the relevant Product Schedule.

1.12. "Loss" means any and all liabilities, damages and expenses, including interest, penalties, and reasonable lawyers' fees and disbursements.

1.13. "Manufacturing Activities" means production by FRESENIUS of Product for regular sale by COMPANY.

1.14. "Parties" means FRESENIUS and COMPANY. "Party" means either FRESENIUS or COMPANY.

1.15. "Person" means any individual or entity.

1.16. "Price," with respect to each Product, means the amount payable for such Product, as determined in accordance with the terms hereof and the relevant Product Schedule.

1.17. "Product(s)" means the product to be supplied pursuant to this Agreement, and as detailed in Part A (Specification) of each Product Schedule.

1.18. "Product Schedule" means a schedule executed and delivered by the Parties in accordance with Section 2.

1.19. "Product Schedule Effective Date" means, with respect to each Product Schedule, the date on which such Product Schedule becomes effective, as set forth in such Product Schedule.

1.20. "Purchase Order" means a binding order for such quantities of a Product as COMPANY commits to order from FRESENIUS from time to time during the Term, with a statement of the date on which delivery of such shipment shall be required.

1.21. "Quality Agreement/' means the Quality Agreement(s) entered into by and between the Parties.

1.22. "Receiving Party" means the Party to whom Confidential Information is disclosed.

1.23. "Specification(s)," with respect to each Product, means the specifications for such Product, as specified in Part A of the relevant Product Schedule, as the same may be updated from time to time in accordance with the current Quality Agreement.

1.24. "Term", means the period beginning on the Effective Date and continuing until the earlier of (a) the date of expiration of the Product Schedule that has the latest expiration date and (b) the date upon which this Agreement is terminated in accordance with Article 16.

1.25. "Third Party" means any Person other than the Parties and their Affiliates.

2. Product Schedules

2.1. The Parties shall enter into a Product Schedule for the supply of each Product they wish to be governed by the terms and conditions of this Agreement, each of which shall be attached hereto as part of Exhibit 1.

2.2. Any number of Product Schedules may be executed pursuant to this Agreement during the Term. Each Product Schedule will govern the supply of the Product set forth therein.

2.3. Each Product Schedule will operate for the term specified in the preamble of that Product Schedule unless earlier terminated in accordance with Sec. 16 of this Agreement.

3. Forecasting: Minimum Order Quantity

3.1. Part B.3 of each Product Schedule sets forth a binding Forecast of Product, which COMPANY will order beginning from the date of the signature of such Product Schedule, subject to the terms and conditions in such Product Schedule.

3.2. For every Product, at least [***] prior to the first day of each January, April, July and October, COMPANY shall submit to FRESENIUS a good faith, estimated rolling Forecast of the quantity of Products COMPANY expects to order for production on a monthly basis during the next [***]. The first [***] of any given Forecast shall be binding to COMPANY and COMPANY shall place Purchase Orders for all Product forecasted therein during the month indicated by the Forecast. The Forecast for the fourth, fifth and sixth months shall be “semi-firm”, and COMPANY shall place Purchase Orders for between [***]% and [***]% of the quantities of the Product specified in the Forecast for such months. The succeeding [***] of any Forecast are non-binding estimations and shall be used by FRESENIUS for planning purposes only; the Forecasts concerning this time period may be changed without FRESENIUS’ written consent.

3.3. With respect to the MOQs in Part B.3 of each Product Schedule, if COMPANY does not issue Purchase Orders for such quantities within the specified time period, FRESENIUS can demand compensation as defined in Part C.5 of the relevant Product Schedule.

3.4. With respect to the binding and semi-binding portions of Forecasts, if COMPANY does riot issue Purchase Orders for the forecasted quantities within the specified time period in accordance with Section 3.2, FRESENIUS may issue to COMPANY an invoice for storage fees of [***], per calendar week per full pallet of already delivered but unused raw materials ordered by FRESENIUS to satisfy such forecasted quantities, which invoice shall list the actual number of pallets and identify the specific raw materials actually on hand corresponding to such forecasted but unordered quantities of Products. COMPANY shall pay any such properly documented invoice within thirty (30) days after receipt.

3.5. FRESENIUS shall (a) allocate sufficient manufacturing capacity, components and parts for manufacture of the Products in sufficient quantity to meet the binding and semi-binding portions of each Forecast, and (b) promptly inform COMPANY of any significant unavailability of capacity, components or parts it might face in fulfilling COMPANY’S Forecasts. Notwithstanding anything to the contrary in this Agreement or the applicable

Product Schedule, COMPANY shall have no obligation with respect to any Forecast to the extent of any unavailability of capacity, components or parts.

3.6. If COMPANY requests and FRESENIUS does not object within thirty (30) days after receipt of such request, FRESENIUS shall, at COMPANY'S expense and pursuant to a mutually agreed plan and budget, fully qualify a second manufacturing plant for Products that is in a different country in Europe than its initial manufacturing plant or with COMPANY'S prior written consent, qualify a reputable Third Party manufacturer with a physically distinct manufacturing facility to produce the Products. COMPANY shall be entitled to visit and inspect all proposed manufacturing facilities for the Products.

4. Orders: Delivery: Acceptance/Rejection

4.1. COMPANY shall submit to FRESENIUS Purchase Orders for its planned requirements of Product not later than three (3) months prior to the applicable delivery date. Each Purchase Order shall detail the COMPANY purchase order number, COMPANY Product code, and COMPANY Product names as well as the required quantities per delivery date. All Purchase Orders shall be in writing, and shall be confirmed by FRESENIUS in writing within ten (10) working days after receipt of each firm purchase order, confirming the calendar week of delivery.

4.2. FRESENIUS shall accept and confirm all Purchase Orders that are consistent with the most recent Forecast and the three (3) month lead time, and shall use reasonable efforts to accommodate Purchase Orders for quantities In excess of those in the most recent Forecast and/or with delivery dates earlier than three (3) months after the date of the Purchase Order.

4.3. All Products shall be handled, packaged, labeled and shipped by FRESENIUS according to the Specifications and to any reasonable instructions from COMPANY, and shall be accompanied by an appropriate certificate of analysis. FRESENIUS shall provide COMPANY by e-mail with a copy of the certificate of analysis and the part of the Batch documentation required for release of the Product. All Products shall be appropriately labeled with traceable Batch numbers and date of manufacture. FRESENIUS shall mark the Products and packaging with the country of origin as required, and provide a certificate of origin and any other documents required for customs purposes. FRESENIUS shall deliver each shipment to COMPANY or COMPANY'S designee in accordance with the applicable Product Schedule. At the request of COMPANY, FRESENIUS will give assistance in arranging transport of the Products in which case FRESENIUS shall follow the instructions of COMPANY.

4.4. Unless otherwise set forth in the applicable Product Schedule, all freight and insurance costs in respect of the Products shall be borne by COMPANY and title, risk of loss, delay or damage in transit shall be with COMPANY from and after delivery to COMPANY'S designated carrier.

4.5. FRESENIUS shall fully deliver and Company shall fully pick up in accordance with this Sec. 4 all Products ordered pursuant to a confirmed Purchase Order within two (2) weeks before or after the confirmed calendar week of delivery, Any failure to deliver Product by

the date that is four (4) weeks after the confirmed calendar week of delivery shall be considered a material breach of this Agreement by FRESENIUS.

4.6. Other than for Hidden Defects as described in Sec. 4.10, COMPANY shall have thirty (30) days after delivery of any Batch of Products pursuant to this Article 4 to reject such Batch. COMPANY may reject a Batch of Products, or a portion thereof, for the (a) failure of such Batch to meet the Specifications; or (b) failure of such Batch to meet FRESENIUS's warranties set forth herein, Failure of COMPANY to reject a Batch of the Products in the manner set forth above within thirty (30) days after delivery of such Batch shall constitute acceptance thereof.

4.7. If only a portion of a Batch should be rejected, the Parties shall cooperate and endeavor, to allow the sale of that portion of the Batch than can be sold in compliance with all applicable laws, rules and regulations, and the portion so allowed, if any, will be considered as purchased and delivered as required under this Agreement.

4.8. Should COMPANY rightfully reject any Batch of Product, or part thereof, pursuant to Section 4,6 and FRESENIUS agrees that such rejection is justified, FRESENIUS shall not charge COMPANY for such rejected part of the) Batch and shall reimburse COMPANY for the shipping costs for such (rejected part of the) Batch incurred by COMPANY. FRESENIUS shall have no further liability to COMPANY in respect of such Batch except that FRESENIUS shall have the obligation to replace the rejected (part of the) Batch as promptly as possible. The Parties shall agree how to destroy any such rejected (part of the) Batch. Costs related to the disposal, destruction and/or return of such Batch shall be borne by FRESENIUS.

4.9. Should COMPANY reject any Batch, or part thereof, pursuant to Section 4.6 and FRESENIUS and COMPANY, after good faith negotiation, fail to agree that such rejection is justified, the Parties shall mutually agree on an independent Third Party to evaluate all documentation relating to such Batch of Products and other relevant information developed by both Parties relating thereto to ascertain whether the rejection is justified. If the Third Party determines that COMPANY'S rejection is justified, FRESENIUS shall pay for the costs of the independent Third Party's review and Sec. 4.8 applies to the same extent as if FRESENIUS had agreed the rejection is justified. If the Third Party determines that COMPANY'S rejection is not justified, COMPANY shall pay for the costs of the independent Third Party's review, and COMPANY shall pay FRESENIUS for such Batch, and FRESENIUS will have no further liability to COMPANY with respect thereto.

4.10. If it is found that a Batch of Products has not been manufactured in accordance with the Specifications and/or FRESENIUS's warranties hereunder, which could not reasonably have been found by diligent and adequate inspection by COMPANY (a "Hidden Defect"), Section 4.6 above applies *mutatis mutandis*, except that the relevant event for the time to reject is the discovery of such Hidden Defect and not the delivery of the Batch. In any case COMPANY must reject a faulty Batch (or part thereof) within twelve (12) months after the delivery of said Batch of Products.

4.11. Any rejection by COMPANY must be In writing and must reference the date of COMPANY'S applicable Purchase Order and FRESENIUS' invoice as well as the date of delivery and if applicable the discovery of a Hidden Defect.

5. Representations and Warranties: Quality; Audits

5.1. FRESENIUS represents and warrants that ail quantities of the Products supplied hereunder shall (a) meet the Specification as determined by the analytical methods set out in the Part A of the relevant Product Schedule, (b) conform to cGMP, the Quality Agreement, and ail applicable laws as such laws exist at the time of delivery of such Product, the manufacturing, testing and supplying thereof shall comply with the Quality Agreement, and the manufacturing thereof shall adhere to all governmental laws, rules and regulations applicable to the manufacture of the Products in the United States and Europe, (c) not be adulterated, misbranded or otherwise in violation of the U.S. Federal Food, Drug and Cosmetic Act, and its foreign equivalents, as such laws exist at the time of delivery of such Product, (d) be free and clear of any liens and/or encumbrances by any Third Party, including but not limited to any geographic or other restriction imposed on the sale of such Product, and (e) to the best of FRESENlUS's knowledge, have been manufactured in a manner that does not infringe on any Third Party's intellectual property rights.

5.2. FRESENIUS represents and warrants that it has received, and shall maintain at all relevant times, ail governmental permits, licenses and approvals enabling FRESENIUS lawfully and properly to perform its obligations under this Agreement, including ail approvals required by all applicable regulatory agencies for the operation of the facility where Products are manufactured as a cGMP manufacturing facility and necessary to operate such facility in compliance with all applicable local laws, rules and regulations in Austria.

5.3. As regulated under the Quality Agreement, FRESENIUS shall permit authorized representatives of COMPANY at reasonable times to audit Batch records and/or the plant where Product is manufactured in the following cases:

(a) Once per two (2) years under the express condition that such audits are performed at least three (3) weeks after announcement thereof, provided that the time of the audit does not coincide with an important activity of the plant (e.g., audit of another customer or an authority),

(b) in the event of a Batch-related rejection or investigation as contemplated in Sec. 4,

(c) in the event FRESENIUS shall receive a "Warning Letter" from the FDA relating to the manufacture, packaging or labelling of the Products by FRESENIUS or otherwise affecting the Products or similar notification from a regulatory agency, auditing FRESENlUS's operation, and/or

(d) in accordance with the procedures set forth in the Quality Agreement to ensure that the principles of cGMP and the provisions of this Agreement are followed in connection with the production of the Products.

Representatives of COMPANY may be present during any investigation or action by any regulatory authority that is specific to or involves a Product. In case of emergency, the Parties will mutually agree in good faith, on the date of a short-dated special quality audit. FRESENIUS will rectify any deficiencies noted during the course of an audit, If COMPANY requests FRESENIUS to implement changes over and above cGMP, and if FRESENIUS agrees to implement such changes, the costs therefor will be borne by COMPANY.

5.4. FRESENIUS shall provide to COMPANY copies of ail correspondence from applicable regulatory agencies relating to any Product, and all inspection reports issued by such regulatory agencies during the Term to the extent they relate to the manufacture of the Products as such reports and correspondence becomes available. FRESENIUS agrees to notify COMPANY promptly of any governmental inspection activity or actions relating to any of the Products, or to any process, equipment or facilities used to manufacture any Product. Such notification shall apply to any unannounced inspection by COMPANY'S European Notified Body for any Product, and FRESENIUS shall allow any such inspection.

5.5. All materials needed to manufacture the Products shall be tested by FRESENIUS to ensure that they meet applicable specifications and quality standards as set forth in the Quality Agreement.

5.6. Further quality relevant issues and the allocation of the responsibilities are listed in the Quality Agreement.

6. Price

6.1. The Price of each Product is exclusive of Value Added Tax, which, if payable, shall be borne and paid by COMPANY against the provision by FRESENIUS of an appropriate VAT invoice. The Price is payable in the applicable Invoice Currency, item C.2 of the relevant Product Schedule.

6.2. For each Product, the Price(s) specified in item C.l of the relevant Product Schedule at the time of signing will remain fixed for the Fixed Price Term, item C.3 of the relevant Product Schedule. On the First Price Review Date (item C.4 of the relevant Product Schedule) and on each anniversary of such First Price Review Date, the Price(s) will be adjusted (up or down) by the change in the index level specified in the Austrian Industrial Producer Price Index published by Statistics Austria mttp://www.stati5tik,at/web_en/statistics/Prices/industri3l_output_priceJndex/) over the twelve (12) months period ending on October 31 of the preceding calendar year; provided, however, that any such annual adjustment to any Price shall be capped at [***] above or below the previous Price.

6.3. The reference purchase price for [***] is [***], which corresponds to direct raw material costs for [***] for a unit of Product of [***] €, If these direct raw material costs to FRESENIUS for [***] for a unit of Product have changed (up or down) by more than [***], FRESENIUS will notify COMPANY of such price change.' Following such notification,

the Price for subsequent Purchase Orders shall increase or decrease on a Euro-for-Euro basis by the amount by which such costs have changed in excess of [***]. For example, if the Price is €[***],-, the direct raw material cost to FRESENIUS for [***] for a unit of Product is €[***],-, and such cost decreases to €[***],-, the Price for subsequent Purchase Orders would decrease to €[***],-.

7. Invoicing and Payment

7.1. FRESENIUS shall issue an invoice to COMPANY for the applicable Price for ail Products delivered to COMPANY, The invoice shall contain a reference identifying this Agreement and the relevant Product Schedule, and shall state FRESENIUS s registered VAT number.

7.2. COMPANY shall pay all invoices in full within thirty (30) days after the date of the relevant invoice to FRESENIUS.

8. Appointed Suppliers

8.1. The Parties may agree that FRESENIUS will order certain or all raw material or packaging, which are needed to manufacture the Product, from certain COMPANY-appointed suppliers (“Appointed Suppliers”). If the Parties agree on this, these Appointed Suppliers will be listed in the relevant Annex of the Quality Agreement.

8.2. COMPANY is responsible for auditing and qualification of ail Appointed Suppliers. If an Appointed Supplier does not deliver in the quality demanded or if its deliveries suffer shortfalls, damages or defects, COMPANY and FRESENIUS will negotiate further actions. Under no circumstances shall any failure to supply the Product by FRESENIUS to COMPANY caused by a delay or default of the delivery of materials of an Appointed Supplier to FRESENIUS be deemed a breach of any contractual obligation by FRESENIUS.

9. [RESERVED]

10. Liability Claims and Expire

10.1. EXCEPT AS OTHERWISE EXPLICITLY STATED HEREIN, NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY AMOUNTS REPRESENTING ITS LOSS OF PROFITS, LOSS OF BUSINESS, LOSS OF GOODWILL, LOSS OF ECONOMIC OPPORTUNITY, OR INDIRECT, SPECIAL, EXEMPLARY, CONSEQUENTIAL OR PUNITIVE DAMAGES, ARISING FROM THE PERFORMANCE OR NON-PERFORMANCE OF THIS AGREEMENT OR ANY ACTS OR OMISSIONS ASSOCIATED THEREWITH OR RELATED TO THE USE OF ANY ITEMS OR SERVICES FURNISHED HEREUNDER, WHETHER THE BASIS OF THE LIABILITY IS BREACH OF CONTRACT, TORT (INCLUDING NEGLIGENCE AND STRICT LIABILITY), STATUTES OR ANY OTHER LEGAL THEORY).

10.2. Except in connection with a Party’s obligations under Section 11 (Indemnification) or breach of obligations under Section 14 (Confidentiality), in any and all other cases, each Party’s liability for any breach of this Agreement shall be limited in the aggregate for each

calendar year to the greater of (a) [***] or (b) the [***] for the [***] such breach occurred.

10.3. Nothing herein shall limit either Party's liability for death or personal injury due to that Party's negligence.

10.4. Statutory rules on the burden of proof remain unaffected by the above rules.

11. Indemnification; Insurance

11.1. COMPANY shall defend, indemnify and hold harmless FRESENIUS, its officers, agents and employees from any Losses in connection with any Third Party claim, demand or cause of action ("Claim") arising out of or related to; (a) the alleged infringement or violation of a Third Party's Intellectual Property rights to the extent relating to the use of know-how included in COMPANY Intellectual Property in accordance with the terms of this Agreement or COMPANY'S other instruction; (b) COMPANY'S negligent, willful or reckless acts or omissions with respect to the distribution, marketing and/or sale of the Products; (c) COMPANY'S breach of this Agreement or applicable law, rules or regulations; or (d) personal injury to consumers relating to the Products, other than injury due to FRESENIUS' gross negligent, willful or reckless acts or omissions, breach of this Agreement or applicable law, rule or regulation, or failure to manufacture, label or package the Products in accordance with the Specifications.

11.2. FRESENIUS shall defend, indemnify and hold harmless COMPANY its officers, agents and employees from Losses in connection with any Claim arising out of or related to: (a) FRESENIUS' negligent, willful or reckless acts or omissions with respect to the manufacture, labeling or packaging of the Products, including any personal injury to consumers relating to the Products arising as a result thereof; (b) FRESENIUS' breach of this Agreement or applicable law, rule or regulation, including without limitation failure to manufacture the Products in accordance with the Specifications; or (c) infringement or violation of a Third Party's Intellectual Property rights as a result of FRESENIUS's use of a manufacturing process for the manufacture of the Products hereunder to the extent such process does not involve know-how included in COMPANY'S Intellectual Property or any formulation or composition of the Products that is not a direct result of the written instructions of COMPANY or the direct compliance with the Specifications.

11.3. In the event either FRESENIUS or COMPANY seeks indemnification under this Article 11 from the other, it shall inform such other Party of a Claim as soon as reasonably practicable after it receives notice of the Claim, shall permit the indemnifying Party to: assume direction and control of the defense of the Claim (including the right to settle the Claim solely for monetary consideration), and shall reasonably cooperate as requested by and at the expense of, the indemnifying Party in the defense of the Claim. In addition, either Party may be represented by its own counsel at its own expense.

11.4. COMPANY and FRESENIUS shall each maintain throughout the Term commercial liability insurance covering product liability and other consumer injuries arising from the

sale of the Products in an amount of at least [***]. At the request of either Party, the other Party shall provide documentation sufficient to show proof of coverage.

12. Product Recall

COMPANY shall have sole discretion over whether and under what circumstances to require the recall of a Product. Each Party will inform the other Party pursuant to Section 17,2 immediately after receiving knowledge of reasons for a Product recall.

13. Intellectual Property

13.1. COMPANY shall solely own any improvement and/or invention relating specifically to the Products (including the manufacture thereof) and all Intellectual Property rights therein ("Product Improvements") and FRESENIUS hereby irrevocably assigns and transfers to COMPANY ail right, title and interest in and to all Product Improvements as they are made, and agrees to perform such actions as COMPANY may reasonably request to cause sole ownership of the Product Improvements to vest in COMPANY. FRESENIUS covenants that each of its employees and independent contractors conducting activities hereunder is obligated to assign ail of his or her rights, title and interest in and to any Product Improvements to FRESENIUS and, as between the Parties, FRESENIUS is responsible for payment of any compensation that may be due in connection with such assignment. COMPANY shall solely own and shall be entitled to apply for patent protection on Product Improvements at its expense and risk.

13.2. FRESENIUS shall solely own any improvement and/or invention generated and/or derived by FRESENIUS in the conduct of Manufacturing Activities that is applicable generally to manufacturing both of the Product and of other products and all Intellectual Property rights therein ("Manufacturing Improvements"). FRESENIUS shall solely own and shall be entitled to apply for patent protection on Manufacturing Improvements at its expense and risk. FRESENIUS hereby grants COMPANY and its Affiliates a royalty free non-exclusive license to use the Manufacturing Improvements in connection with the Products during the term of this Agreement.

13.3. For clarity, nothing in this Agreement shall alter the ownership of any Intellectual Property owned or controlled by a Party as of the Effective Date or that is obtained by a Party independently of this Agreement.

14. Confidentiality

14.1. Except as otherwise provided in this Agreement, any Confidential Information which is disclosed by or on behalf of a Disclosing Party to the Receiving Party will remain the property of the Disclosing Party.

14.2. The Receiving Party undertakes

14.2.1 to use the Disclosing Party's Confidential Information solely and exclusively for the purposes of this Agreement (or such other purpose as is agreed in writing between the Parties at the time of disclosure), and not to use such Confidential Information for any other purpose whatsoever, including the development, manufacture, marketing, sale or licensing of any process or product or any other commercial purpose anywhere in the world, unless the Parties enter into an agreement specifying otherwise; and

14.2.2 to maintain the confidentiality of the Disclosing Party's Confidential Information and not to disclose it directly or indirectly to any other company, organisation, individual or third Person, except as expressively permitted;

14.2.3 at the request of the Disclosing Party, to return, delete or destroy all copies of the Disclosing Party's Confidential Information, in whatever form it is held.

14.3. Notwithstanding Section 14.2, the Receiving Party may disclose the Disclosing Party's Confidential Information to any of its Affiliates, and its and Its Affiliate's directors, employees and professional advisers who need to know such Confidential Information in order to fulfill the purpose of this Agreement, provided that the Receiving Party procures that prior to such disclosure, each such Person to whom such Confidential Information is to be disclosed is made aware of the obligations contained in this Agreement, and adheres to these terms as if it were a party to this Agreement.

14.4. Nothing in Section 14.2 will preclude disclosure of any Confidential Information required by any governmental, quasi-governmental or regulatory agency or authority or court entitled by law to disclosure of the same, or which is required by law or the requirements of a national securities exchange or another similar regulatory body to be disclosed, provided that the Receiving Party promptly notifies the Disclosing Party when such requirement to disclose has arisen to enable the Disclosing Party to seek an appropriate protective order, to make known to the relevant agency, authority, court or securities exchange the proprietary nature of such Confidential Information, and to make any applicable claim of confidentiality. The Receiving Party agrees to co-operate in any action which the Disclosing Party may decide to take. If the Receiving Party is required to make a disclosure in accordance with this clause, it will only make a disclosure to the extent to which it is obliged.

14.5. The provisions of Section 14.2 will not apply to any of the Disclosing Party's Confidential Information which the Receiving Party can demonstrate, to the reasonable satisfaction of the Disclosing Party:

14.5.1 was already in the possession of the Receiving Party or any of its Affiliates and at the Receiving Party's or any of its Affiliates' free use and disposal or in the public domain (through in each case no fault of the Receiving Party or any of its Affiliates or no breach of this Agreement by the Receiving Party) prior to its disclosure by the Disclosing Party under this Agreement;

14.5.2 is purchased or otherwise legally acquired by the Receiving Party or any of its Affiliates at any time from a third Person having and the right to disclose it;

14.5.3 comes into the public domain, otherwise than through the fault of the Receiving Party or any of its Affiliates; or

14.5.4 is independently generated by the Receiving Party or any of its Affiliates without any recourse or reference to the Disclosing Party's Confidential Information.

14.6. The obligations of each Party in this Article 14 will survive for a period of five (5) years after the date of expiration or effect of termination of this Agreement.

15. Exclusivity

15.1. FRESENIUS undertakes to manufacture and supply the Products exclusively to COMPANY.

15.2. 15.2 COMPANY agrees to purchase from FRESENIUS the minimum order quantities of Product in accordance with the applicable Product Schedule and any quantities in excess thereof contained in any binding or any semi-binding (subject to adjustment as permitted by Section 3.2) portion of any Forecast, subject to FRESENlUS's ability to deliver such quantities in accordance with Article 4 and the warranties set forth in Article 5

15.3. Provided that COMPANY complies with its obligations in the Section 15.2, COMPANY shall be free to obtain supplies of Products from sources other than FRESENIUS.

16. Term and Termination

16.1. This Agreement shall become effective at the Effective Date and shall extend for a period of five (5) years ("Initial Term"), unless earlier termination as described in Articles 16.2 and 16.3. The Agreement shall be automatically extended for subsequent periods of twenty-four (24) months (each, an "Extension Term") unless either Party terminates this Agreement by giving the other Party a written notice by registered mail twelve (12) months prior to the end of the Initial Term or prior to the end of the then-current Extension Term, but not before the date of expiration of the Product Schedule that has the latest expiration date.

16.2. In addition to any other provision of this Agreement expressly providing for termination of this Agreement, this Agreement may be terminated immediately by either Party upon notice to the other Party:

- in the event of a material breach of this Agreement by the other Party, where such breach is capable of cure and such breach remains uncured for thirty (30) days after notice of such breach;
- in the event of a breach of this Agreement by the other Party where such breach is not capable of cure;
- if the other Party shall file in any court or agency, pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an the appointment of a receiver or trustee of such other Party or of its assets, or if the other Party proposes a written agreement of composition or extension of its debts, or if the other Party shall be served with an involuntary petition against it filed in any insolvency proceeding that is not stayed or dismissed within sixty (60) days, or if the other Party shall propose or be a party to any dissolution or liquidation, or if the other Party shall make an assignment for the benefit of its creditors;
- if any creditor or lienholder takes possession of any material part of the assets of the other Party;
- if any distress, execution or other such process is levied or enforced upon or against any of the material assets of the other Party;
- if the other Party ceases or threatens to cease to carry on the whole or substantially the whole of its business or that part of its business to which this Agreement (or all Product Schedules, as the case may be) relates.

Further, COMPANY shall have the right to terminate this Agreement upon twelve (12) months' prior written notice if FRESENIUS objects or fails to respond in accordance with Section 3.6 to COMPANY'S request made thereunder.

16.3. Without prejudice to any other rights or remedies which either Party may have, upon the termination of this Agreement, howsoever the same occurs, each Party shall:

- immediately pay to the other Party ail undisputed sums which at the date of termination are due and payable to the other Party under this Agreement;
- immediately cease all use of any property of the other Party, including any Intellectual Property rights of the other Party that are not irrevocably licenses to such Party; and
- within twenty eight (28) days after such termination, at its own expense, return to the other Party any property of the other Party in its possession, custody or control, including subject to Sec. 14.2.3 all Confidential Information of that Party and copies of it.

16.4. Sec. 1, 10, 11, 12, 13, 14 (as provided in Sec. 14.6), 17, 18, 19 and Sections 16.3 and 16.4 will survive expiration or termination of this Agreement, howsoever the same occurs.

16.5. This Sec. 16 applies for the term and termination of any individual Product Schedule as well, except to the extent the term or the termination is regulated differently in the Product

Schedule. A termination of this Agreement automatically leads to a termination of all Product Schedules, subject to Section 16.1 in the case of non-renewal.

17. Notices

17.1. Notices of pharmacovigilance including but without being limited to notices of recalls and complaints as well as address and person in charge are governed by the Quality Agreement and its relevant Annex.

17.2. Any notice, request, demand, waiver, consent, approval or other communication permitted or required under this Agreement shall be' in writing and shall be deemed given only if delivered-by hand or sent by facsimile transmission (with transmission confirmed) or by internationally recognised overnight delivery service that maintains, records of delivery, addressed to the Parties at their respective addresses specified in this Agreement or to such other addresses of which notice shall have been given. Such Notice shall be deemed to have been given as of the date delivered by hand or transmitted by facsimile (with transmission confirmed) or on the second delivery day after deposit with an internationally recognised overnight delivery service. Any notice delivered by facsimile shall be confirmed by a hard copy delivered as soon as practicable thereafter. This Section is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement.

18. Miscellaneous

18.1. This Agreement contains the entire understanding between the Parties and supersedes any and all prior agreements, understandings and arrangements, whether written or oral, with respect to the subject matter hereof.

18.2. No amendments, changes, modifications or alterations of the terms and conditions of this Agreement shall be binding upon either Party unless in writing -and signed by both Parties.

18.3. Neither Party may assign its rights or obligations under this Agreement without the prior written consent of the other Party, which consent shall not be withheld or delayed unreasonably; provided, however, that (a) either Party may assign this Agreement, in whole but not in part, without such consent, to one of its Affiliates or to an assignee who acquires all or substantially ail of such Party's business, business division relevant to the Products, or in the event of such Party's merger or consolidation or similar transaction; and (b) the assigning Party shall promptly notify the non-assigning Party of any such assignment. Any permitted assignee shall assume all obligations of its assignor under this Agreement. No assignment shall relieve any Party of responsibility for the performance of any obligation hereunder. This Agreement shall be binding upon and inure to the benefit of each of the Parties and its successors and permitted assigns.

18.4. Both Parties hereby expressly state that it is the intention of neither Party to violate any existing rule, law or regulations. If any of the provisions of this Agreement are held to be void or unenforceable, then such void or unenforceable provisions shall be replaced by valid and enforceable provisions which will achieve as far as possible the economic business intentions of the Parties.

18.5. Any amendment or modification of this Agreement must be in writing and signed by an authorised representative of each Party.

18.6. If there is any inconsistency between a Product Schedule, a Quality Agreement or any other Exhibit, on the one hand, and this Agreement on the other hand, the terms of this Agreement shall govern unless such other document expressly provides that its terms (or a single term) shall govern. The Quality Agreement prevails in matters of quality.

19. Law and Jurisdiction

This Agreement shall be governed, construed and interpreted in accordance with the laws of England, without reference to its conflict of law provisions and excluding specifically the UN Convention on Contracts for the International Sale of Goods. Place of exclusive jurisdiction shall be London.

SIGNED for and on behalf of
Fresenius Kabi Austria GmbH

/s/ Anton Gerdenitsch
Signature

Name: Anton Gerdenitsch

Title: Head of Contract Manufacturing
Market Unit PP
May 28, 2015

SIGNED for and on behalf of
TransMedics Inc.

/s/ Waleed Hassanein
Signature

Name: Waleed Hassanein

Title: CEO

Signed for and on behalf of
Fresenius Kabi Austria GmhH

/s/ Jorg Heinrich
Signature

Name: Dr. Jorg Heinrich

Title: Plant Manager
28 May 2015

/s/ Waleed Hassanein
Signature

Name: Waleed Hassanein

Title: CEO

Exhibit 1: Product Schedule(s)

THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [***] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

Product Schedule No 1

FOR CONTRACT MANUFACTURING

to the CONTRACT MANUFACTURING AGREEMENT dated Apr 1st, 2015 (the "Agreement"), entered into between:

(1) Fresenius Kabi Austria GmbH, Hafnerstrasse 36, A-8055 Graz, Austria ("FRESENIUS")

and

(2) TransMedics Inc., 200 Minuteman Road, Suite 302, Andover, MA 01810, USA ("COMPANY").

This Product Schedule is made effective as of the day of its signature (the "Product Schedule Effective Date"), and is subject to all of the terms and conditions contained in the Agreement. Together, this Product Schedule and the Agreement form a binding agreement between the parties hereto in relation to the details set out in this Product Schedule.

The term of this Product Schedule is [***] beginning from the Product Schedule Effective Date. It will be extended and can be terminated according to Article 16 of the Agreement. In addition, COMPANY shall have the right to terminate this Product Schedule upon written notice and with a notice period of three (3) months to FRESENIUS if (a) the Product or the OCS Lung System is no longer covered by a CE Mark for any reason whatsoever or (b) if COMPANY does not receive FDA approval to market (i) the Product with an approved indication for the flushing of donor lungs for preservation during transplantation and (ii) the OCS Lung System in the United States by December 31, 2016. With respect to the binding and semi-binding portions of Forecasts in place at the time that COMPANY provides such notice of termination, if COMPANY does not issue Purchase Orders for U1e forecasted quantities within the specified time period in accordance with Section 3.2, FRESENIUS may issue to COMPANY an invoice for its cost of already delivered but unused raw materials ordered by FRESENIUS to satisfy such forecasted quantities, which invoice shall identify the specific raw materials actually on hand corresponding to such forecasted but unordered quantities of Products and the cost thereof. COMPANY shall pay any such properly documented invoice within thirty (30) days after receipt and, if requested by COMPANY, FRESENIUS shall ship such raw materials to COMPANY in accordance with COMPANY's written instructions and at COMPANY'S cost.

This Product Schedule consists of the following parts:

Part A: Product Specification

Part B: Delivery terms and orders

Part C: Pricing and Payment

PART A: PRODUCT SPECIFICATION

1. Product:

OCS™ Lung Solution in 1 liter IV bags

2. Product Specification

The Product Specifications are regulated in the Quality Agreement and its relevant Annexes. A copy of the Product Specifications as of the Product Schedule Effective Date is attached hereto as Exhibit A. FRESENIUS shall provide COMPANY with a copy of any revised Product Specifications.

PART B: DELIVERY TERMS AND ORDERS

1. Delivery Term (Incoterms 2010)

FCA Graz, Austria

2. Packaging and Labelling

4-10 bags will be packaged into 1 labelled or pre-printed cardboard box, whereas several of these are packaged in a labelled shipper.

3. Minimum Order Quantities (MOQs)

Company guarantees to purchase the following yearly minimum order quantities of Product:

Year	2014	2015	2016	2017	2018
Number of Bags	[***]	[***]	[***]	[***]	[***]

*The minimum order quantities for years 2016-2018 are contingent on the attainment of Product shelf life of at least [***] years. If such shelf life is not attained, the MOQs for such years shall be as follows: 2016: [***] / 2017: [***] / 2018: [***]

Any termination of the Agreement shall result in a pro rata adjustment to the MOQ for the 12-month period during which such termination becomes effective.

No individual order shall be less than one full batch of [***] liter.

PART C: PRICING AND PAYMENT

1. Price

	OCS™ LUNG Solution
Price [€/bag] Ordered bags per year less than [***] bags	**[***]**
Price [€/bag] Ordered bags per year [***] bags	**[***]**
Price [€/bag] Ordered bags per year more than [***] bags	**[***]**

- Prices are based on batch size of [***] liter.
- The Price/bag will be fixed For a calendar year based on Company's First Forecast for that calendar year as set forth in Section 3 of the Agreement.
- If the actual quantity ordered in a calendar year would result in the application of a different tier as set forth above, then, within 60 days after the end of that calendar year, one Party will make a true-up payment to the other Party to cover the difference in the Price that was paid during such calendar year and the Price that should have been paid. For example, if the Forecast during 2016 is [***] units, the Price paid by COMPANY for each unit will be €[***],-. If COMPANY actually orders [***] units during 2016, FRESENIUS will make a true-up payment to COMPANY by 1 March 2017 of €[***] x [***] = €[***] to reflect the pricing of the tier applicable to the actual quantity ordered.

2. Invoice Currency

Euro

3. Fixed Price Term

Until 31st December 2015

4. First Price Review Date

1st January 2016

5. Compensation in case COMPANY does not purchase MOQs

- If COMPANY does not purchase the yearly minimum order quantities as defined in B.3. of this Product Schedule, COMPANY needs to pay a compensation fee to FRESENIUS to cover the lost sales. This compensation fee shall be COMPANY's sole liability and FRESENIUS's sole remedy with respect to any failure by COMPANY to purchase the yearly minimum order quantities as defined in B.3. of this Product Schedule. This compensation fee shall be calculated by taking the gap between the actual quantity ordered and minimum ordered quantity of the respective year multiplied by the applicable price in the table below:

	OCS LUNG Solution (without [***])
Price [€/bag] MOQ per year [***] bags	**[***]**
Price [€/bag] MOQ per year more than [***] bags	**[***]**

- In the event that COMPANY purchases in any year exceed the minimum order quantity for that year, the excess in that year will be applied to the minimum order quantity commitment for the following year. The amount that can be carried over to [8.1.4] the next year will be limited to [***].
- In the event that COMPANY purchases in any year less than the minimum order quantity for that year, COMPANY may apply purchases in excess of the minimum order quantity in the following year to meet the prior year shortfall. The excess purchased amount that can be so applied to meet the minimum order quantity in any shortfall year will be limited to [***]% of the applicable next year's minimum order quantity. Any compensation fee paid under this part C.5 in respect of shortfalls covered by purchased amounts applied from following years will be promptly refunded to COMPANY.
- The minimum commitment will not apply following any termination of the Contract Manufacturing Agreement.

THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [***] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

THIS PRODUCT SCHEDULE IS EXECUTED by the authorised representatives of the Parties as of the date first written above.

SIGNED for and on behalf of **FRESENIUS**	SIGNED for and on behalf of
/s/ Anton Gerdenitsch Signature	/s/ Waleed Hassanein Signature
Name: Anton Gerdenitsch	Name: Waleed Hassanein
Title: Head of Market Unit PP May 28th, 2015	Title: CEO
SIGNED for and on behalf of **FRESENIUS**	SIGNED for and on behalf of
/s/ Dr. Jörg Huund Signature	/s/ Waleed Hassanein Signature
Name: Dr. Jörg Huund	Name: Waleed Hassanein
Title: Plant Manager 28 May 2015	Title: CEO

THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [***] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

EXHIBIT A

PRODUCT SPECIFICATIONS

[to be attached]

Product Schedule No. 1 - 6

Rev	Author	Brief Description of the Change	DCO Approved	DCO Release Date
1	J. Carey	Initial Release	12208	15-May-2014
2	M. O'Hara	Update shelf life based on latest stability data and make minor corrections.	12280	2-Oct-2014
3	R. Bringham	Update Lung Solution Spec, [***], with new expiration date format, updated titles and formatting.	12473	11/10/2015
4	J. Sullivan	Update shelf life to [***]	12833	07/29/2016
5	P. Lezberg	Update acceptance criteria for magnesium and updated packaging requirements	12984	08/30/2017

"Suppliers shall not make changes in specifications, materials, processes or work covered by this document without prior written notification to and authorization from TransMedics, Inc".

Signature	Date		Purchased Component Specification	
Drawn By:	John Carey	5/5/2014	**OCS™ Lung Solution. [***]**	
Approvals:	Wendy Lambert	5/15/2014		
			Size **A**	Number: [***]

1. Component Specification:

- **Description**

  The purpose of this document is to define the purchased component specification for the OCS™ Lung Solution.

- **Performance requirement**

  Refer to following pages

- **Properties & Tolerances**

  Refer to following pages

- **Supplier Records**

  Fresenius Kabi Austria-GmbH will provide a Certificate of Analysis and a Certificate of Conformity with statement of conformance with each batch. The current version of the Purchased Component Specification to which the product was manufactured will be documented in the Quality Agreement. The Certificate of Conformity will note conformance to the Quality Agreement.

- **Labeling Requirements**

  The following labels will appear on the product and product packaging:
  - The primary container will be labeled per Label, Product, Lung Solution, REF [***] ([***]).
  - The shipping package will be labeled per Label, Packaging, Lung Solution, REF [***] ([***]).

  Upon receipt at TransMedics each lot of Solution will be inspected according to Quality Procedure, OCS Lung Solution ([***]). The inspection will include verification of the expiration date based on the procedure found below in “Product Expiration Date.”

- **Packaging Requirements**
  - Bags shall be shipped in a cardboard box containing [***] units per box.
  - Bags shall be oriented in the box perpendicular to the long edge
  - Note that the unit of measure for [***] is [***].

- **Storage Requirements**
  - Storage of the OCS Lung Solution is recommended as follows.
    - Do not store above [***].
    - Do not [***].
    - Upon receipt, the bags will be inspected according to Quality Procedure, OCS Lung Solution ([***]).
    - Inspect carefully for indication of damage prior to distribution to end-users.

- **Safety and Handling Requirements**

  Not applicable

- **Handling Requirements**

  Not applicable

- **Approved Manufacturers**

The manufacture and testing of the OCS Lung Solution includes participation of (4) vendors. Their contact information and participation are as follows:

Vendor	Vendor Participation
Fresenius Kabi Austria-GmbH Hafnerstrasse 36 8055 Graz-Austria (P) +43 (0) 316 249 0 (F) +43 (0) 316 249 1505	■ Project Management ■ Raw Material Testing ■ Formulation/Fill ■ Sterilization ■ Labeling ■ Lot Release including Testing
Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH (AGES) Institut für medizinische Mikrobiologie und Hygiene Beethovenstrasse 6, A-8010 Graz, Austria	■ Sterility Testing
SGS Life Science Services SGS INSTITUT FRESENIUS Berlin GmbH & Co. KG Tegeler Weg 33 D-10589 Berlin Germany	■ Raw Material Testing-[***] 40
Pharmacosmos A/S Roervangsvej 30 DK—4300 Holbaek Denmark	■ Raw Material Provider -[***]

- **Inspection Requirements**

Each batch will be inspected visually for damage upon receipt per [***], Quality Procedure (-QP) OCS™ Lung Solution.

- Each Lung Solution box must:
  - Be affixed with a label in compliance with Label Specification [***]
  - Have no visible damage to the package
- Each Lung Solution bag must:
  - Be labeled in compliance with Label Specification [***]
  - Have no visible damage to the container
- Each Lung Solution batch must:
  - Include a Certificate of Analysis and a Certificate of Conformity

- **Product Expiration Date**

The shelf life for a batch manufactured using the current revision of this specification is [***]. Product expiration will be based on the following information:

- The date of manufacture
- Validated stability (shelf life) data available at the time of manufacture
- The expiration date (end of shelf life) will be calculated as follows:
  - Manufacturing day plus [***]

2. Properties & Tolerances of the OCS™ Lung Solution Set

2.1. The OCS™ Lung use model incorporates the use of an OCS Lung Solution.

2.1.1. The OCS Lung Solution is a sterile, [***] solution that may be mixed with [***] in the OCS, and pumped through an explanted donor lung in order to maintain and assess the organ. Additionally, the OCS Lung Solution may be used to flush the donated lung.

2.1.2. The OCS Lung Solution is provided in a [***] with a container closure system capable of accepting a line spike for addition of the OCS Lung Solution to the OCS™ Lung Perfusion Module (LPM).

2.2. Raw Materials

2.2.1. The raw materials used in the manufacture of the OCS Lung Solution will be purchased as compendial grade, that is, United States Pharmacopeia (USP) or European Pharmacopoeia (Ph.Eur.).

2.2.2. Table 1 identifies the specified grade and compendial monograph associated with each raw material used for the manufacture of the OCS Lung Solution

Table 1: Raw Material Specifications for OCS Lung Solution Components

Component	Compendial grade	Monograph
[***]	**[***]**	**[***]**
[***]	**[***]**	**[***]**
[***]	**[***]**	**[***]**
[***]	**[***]**	**[***]**
[***]	**[***]**	**[***]**
[***]	**[***]**	**[***]**
[***]	**[***]**	**[***]**
[***]	**[***]**	**[***]**
[***]	**[***]**	**[***]**

2.3. Packaging Components and Specifications

2.3.1. Primary Container ([***])

2.3.1.1. Foil—The primary packaging foil is a multi-layer tube foil commonly used for parenteral nutrition solution Sets and has a thickness of [***]. All additives conform to the valid versions of [***].

2.3.1.2. Port and cap—The Ship-Shape Infusion Corpus Port (SSC) is designed to withdraw solution Set from the infusion bag using an infusion Set or syringe. The port consists of [***].

2.3.1.3. A partial view of the primary container system is pictured in Figure 1.

[***]

2.4. Finished Product

2.4.1. Specification for Batch(s)

Each batch of OCS Lung Solution will be manufactured using predetermined specifications. The specifications are defined in Table 2.

Table 2: Raw Material Specification for OCS Lung Solution Components

Component	Formula	Quantity (gm/L)
[***]	**[***]**	**[***]**
[***]	**[***]**	**[***]**
[***]	**[***]**	**[***]**
[***]	**[***]**	**[***]**
[***]	**[***]**	**[***]**
[***]	**[***]**	**[***]**
[***]	**[***]**	**[***]**
[***]	**[***]**	**[***]**
[***]	**[***]**	**[***]**

3. Performance Requirements

3.1. The OCS Lung Solution is evaluated post-sterilization according to the acceptance criteria provided in Table 3. Testing performed by Fresenius Kabi Austria is designated as FKA while testing performed by Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH is designated as AGES. Methods are further described in Section 3.2 this document. The OCS Lung Solution is terminally sterilized to a Sterility Assurance Level of at least [***].

Table 3: Methods and Acceptance Criteria for the OCS Lung Solution

Test	Limit	Methods	Responsible Laboratory
Appearance	[***]	[***]	FKA
Identification-Glucose	[***]	[***]	FKA
Identification-Sodium	[***]	[***]	FKA
Identification-Potassium	[***]	[***]	FKA
Identification-Magnesium	[***]	[***]	FKA
Identification-Phosphate	[***]	[***]	FKA
pH	[***]	[***]	FKA
Volume in containers	[***]	[***]	FKA
Osmolality [mOsmol/kg]	[***]	[***]	FKA
Glucose [g/L]	[***]	[***]	FKA
Sodium [mmol/L]	[***]	[***]	FKA
Potassium [mmol/L]	[***]	[***]	FKA
Magnesium [mmol/L]	[***]	[***]	FKA
Total Phosphates	[***]	[***]	FKA
5-HMF	[***]	[***]	FKA
Visible particles	[***]	[***]	FKA
Sub-visible particles: - particles ≥ 10um - particles ≥ 25um	[***]	[***]	FKA
Endotoxins [IU/mL]	[***]	[***]	FKA
Sterility	[***]	[***]	AGES

3.2. Each batch of OCS Lung Solution will be subjected to specification release testing.
  3.2.1. [***] will be utilized for release testing, when applicable.
  3.2.2. Where a [***] is not available, [***] will be validated prior to use.

3.3. The methods associated with release testing as defined in Table 3 are described below.
  3.3.1. Appearance-Color ([***])Color is determined according to [***] Degree of Coloration of Liquids
  3.3.2. Appearance-Clarity ([***])Clarity is determined according to [***] Clarity and Degree of Opalescence of Liquids
  3.3.3. Identification-Glucose ([***])Glucose identification is an enzymatic determination performed according to [***]
  3.3.4. Identification-Sodium ([***]Sodium identification is determined by [***] *Qualitative and quantitative determination of* [***]
  3.3.5. Identification-Potassium ([***])Potassium identification is determined by [***] *Qualitative and quantitative determination of* [***] *by measuring* [***]
  3.3.6. Identification-Magnesium ([***])Magnesium identification is determined by [***] according to [***] *Qualitative and quantitative determination of* [***] *by measuring* [***]

3.3.7. Identification-Phosphate ([***])Phosphate identification is a photometric determination performed according to [***]
3.3.8. pH ([***])pH is determined according to [***]
3.3.9. Volume in containers ([***])Volume in containers is determined according to [***]
3.3.10. Osmolality ([***])Osmolality is determined according to [***]
3.3.11. Glucose ([***])Glucose quantitation is an enzymatic determination performed according to [***]
3.3.12. Sodium ([***])Sodium quantitation is determined by[***] *Qualitative and quantitative determination of* [***] *by measuring the* [***]
3.3.13. Potassium ([***])Potassium quantitation is determined by [***] *Qualitative and quantitative determination of* [***] *by measuring the* [***]
3.3.14. Magnesium ([***])Magnesium quantitation is determined by [***] *Qualitative and quantitative determination of* [***] *by measuring the* [***]
3.3.15. Total Phosphates ([***])Phosphate quantitation is a photometric determination performed according to [***]
3.3.16. 5-HMF ([***])5-HMF determination is performed by [***]
3.3.17. Visible Particles ([***])Determination of visible particle is performed according to [***]
3.3.18. Sub-visible particles ([***]Determination of sub-visible particles is performed according to [***] Quantitation is made for particles of sizes [***]
3.3.19. Bacterial Endotoxins ([***])Bacterial endotoxin is determined according to [***] *Bacterial Endotoxins Test*
3.3.20. Sterility ([***])Sterility is determined according to [***]

4. Stability

4.1. OCS Lung Solution stability and determination of product shelf life was demonstrated through enrollment of the OCS Lung Solution in stability studies of up to [***]. Accelerated stability conditions were applied to the Technical batch with sample withdrawals scheduled throughout a [***] period. Real-time and accelerated stability conditions were applied to a minimum of [***] Stability batches with sample withdrawals scheduled throughout the enrollment period. The shelf life of existing clinical batches may be updated periodically based on the most current aging data available.

4.1.1. Technical Batch: Accelerated stability was assessed at [***] for [***]. The planned time points for the batch were [***], [***], [***], and [***] months. Solution stability was demonstrated under the planned test conditions to [***] months.

4.1.2. Stability Batches: Real-time stability was assessed at [***] for [***]. The planned time points for the batches were [***], [***], [***], [***], [***], [***] and [***] months. In addition, (2) two of the batches were assessed at [***] months. Solution stability was demonstrated under the planned test conditions to [***] months.

4.1.3. Stability Batches: Accelerated stability was assessed at [***] for [***] months. The planned time points for the stability batches were 0, 3 and 6 months. In addition, (2) of the batches were assessed at [***] month. Solution stability was demonstrated under the planned test conditions to [***] months.

4.2. Supplemental stability data may be generated from additional full-scale batches. Sampling or withdrawal time points may vary based on the data required for the study (i.e. early withdrawal time points may be omitted).

5. Sterility

5.1. OCS Lung Solution sterility is assessed for lot release (Time 0) and at the final time point of the stability study at [***].

5.2. A sterilization cycle has been validated for the OCS Lung Solution.

5.3. The sterilization cycle is designed to achieve a Sterility Assurance Level (SAL) of at least [***].

5.4. Pyrogenicity will be measured as a function of lot release using the [***] Test. The test will also be performed at the final time point of the stability study under real-time conditions ([***]).

6. Change Control

6.1. Any and all design or component changes shall require TransMedics' written approval.

6.2. Any and all temporary deviations shall require TransMedics' written approval.

7. Reference Documents

7.1. Label, Product, OCS Lung Solution ([***])

7.2. Label, Packaging, OCS Lung Solution, REF 2300 ([***])

7.3. Quality Procedure, OCS Lung Solution ([***])

7.4. United States Pharmacopeia, USP 36/NF 31, 2010

7.5. European Pharmacopoeia, EP 8th Edition, 2014

7.6. ICH Q1A (R2): Stability Testing of New Drug Substances and Products[1]

7.7. Stability Plan OCS Lung Solution Set (acc)-1000 mL-bag, (FKA Kipdips 96,689)

7.8. Stability Plan OCS Lung Solution Set (ICH)-1000 mL-bag (FKA Kipdips 96,672)

7.9. Analysis of Glucose (FKA G242))

7.10. Analysis of Sodium (FKA G201)

7.11. Analysis of Magnesium (FKA G201)

7.12. Analysis of Potassium (FKA G201)

7.13. Analysis of Total Phosphates ((FKA G251)

[1] The OCS Lung Solution is a component of a system (the Organ Care System) and is regulated as a medical device, not a pharmaceutical. It is not administered to a patient, and does not have contact with either the donor or the recipient during a lung transplant. Nonetheless, the ICH standards for testing new drugs provide well-recognized methods for evaluating solution stability and consequently will be relied upon to demonstrate that the device meets its performance specifications.