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

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the year ended December 31, 2021

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM TO**

Commission File Number: 001-38891

TransMedics Group, Inc.

(Exact name of Registrant as specified in its Charter)

Massachusetts	**83-2181531**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
200 Minuteman Road Andover, Massachusetts	**01810**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (978) 552-0900

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, No Par Value	**TMDX**	**The Nasdaq Global Market**

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). YES ☒ NO ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant as of the last business day of the registrant's most recently completed second fiscal quarter, June 30, 2021, based on the last reported sale price of the registrant's common stock of $33.18 per share was $857.8 million. As of February 15, 2022, the registrant had 27,961,954 shares of common stock, no par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Definitive Proxy Statement for its 2022 Annual Meeting of Stockholders scheduled to be held on June 1, 2022, which Definitive Proxy will be filed with the Securities and Exchange Commission not later than 120 days after the registrant's fiscal year end of December 31, 2021 are incorporated by reference into Part II and Part III of this Form 10-K.

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements, which reflect our current views with respect to, among other things, our operations and financial performance. All statements other than statements of historical facts contained in this Annual Report on Form 10-K, 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 "Item 1A. Risk Factors" in this Annual Report on Form 10-K. 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 Annual Report on Form 10-K may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

The forward-looking statements included in this Annual Report on Form 10-K are made only as of the date of this report. 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 Annual Report on Form 10-K to conform these statements to actual results or to changes in our expectations.

RISK FACTORS SUMMARY

An investment in our common stock involves risks. You should consider carefully the following risks, which are discussed more fully in "Item 1A. Risk Factors", and all of the other information contained in this Annual Report on Form 10-K before investing in our common stock. These risks include, but are not limited to, the following:

- that we continue to incur losses;
- our need to raise additional funding;
- our existing and any future indebtedness, including our ability to comply with affirmative and negative covenants under our credit agreement to which we will remain subject until maturity, and our ability to obtain additional financing on favorable terms or at all;
- our ability to attract and retain key personnel;
- the fluctuation of our financial results from quarter to quarter;
- our ability to use net operating losses and research and development credit carryforwards;
- our dependence on the success of the Organ Care System, or OCS;
- our ability to expand access to the OCS through the National OCS Program;
- the rate and degree of market acceptance of the OCS;
- our ability to educate patients, surgeons, transplant centers and private and public payors on the benefits offered by the OCS;
- our ability to improve the OCS platform;
- our dependence on a limited number of customers for a significant portion of our net revenue;
- our ability to maintain regulatory approvals or clearances for our OCS products;
- our ability to adequately respond to the Food and Drug Administration, or FDA, follow-up inquiries in a timely manner;

- the timing and our ability to commercialize and market our OCS products;
- the performance of our third-party suppliers and manufacturers;
- price increases of the components of our products;
- the timing or results of post-approval studies and any 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;
- the impact of the outbreak of the novel strain of coronavirus, or COVID-19, including variants of the virus and associated containment, remediation and vaccination efforts;
- 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 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; and
- our estimates regarding revenue, expenses and needs for additional financing.

PART I

Except where the context otherwise requires or where otherwise indicated, the terms "TransMedics," "we," "us," "our," "our company," "the company," and "our business" refer to TransMedics Group, Inc. and its consolidated subsidiaries.

Item 1. 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 the use of the OCS has the potential to significantly increase the number of organ transplants and improve post-transplant outcomes. We have developed our National OCS Program, a turnkey solution to provide outsourced organ retrieval and OCS organ management, to provide transplant programs with a more efficient process to procure donor organs with the OCS.

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. By the end of the third quarter of 2021, all three of our products, OCS Lung, OCS Heart, and OCS Liver, have received Pre-Market Approval, or PMA, from the Food and Drug Administration, or FDA. OCS Lung and OCS Liver are approved for both organs donated after brain death, or DBD organs, and organs donated after circulatory death, or DCD organs. The OCS Heart is approved for DBD organs and we have submitted a PMA supplement to the FDA for use of the OCS Heart with DCD organs.

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 solid 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. With the use of cold storage, the majority of lungs and hearts donated after brain death go unutilized, and almost no available lungs and hearts donated after circulatory death 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 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 had been providing reimbursement for the OCS Lung, OCS Heart

and OCS Liver during the U.S. pivotal trials and have continued providing reimbursement for our products following FDA approval. 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 also have a geographically distributed team in the United States supporting our National OCS Program. We have additional distribution and commercial operations in Europe. As of December 31, 2021, we employed 148 people globally, most of whom were full-time employees. We generated $30.3 million and $25.6 million of net revenue during the years ended December 31, 2021 and 2020, respectively, representing an 18% increase. Growth in our business was negatively impacted by the global COVID-19 pandemic during the years ended December 31, 2021 and 2020, following net revenue growth of 81% in 2019 compared to 2018. 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.

Our Competitive Strengths

We believe the continued growth of our company will be driven by the following competitive strengths:

- **Only FDA approved, portable, multi-organ, warm perfusion platform**
  Our Organ Care System is the only portable, warm perfusion device on the market. It is also the only device that has been approved by the FDA for multiple organ indications. Portability is a critical aspect in reducing the injurious ischemic injury to the organ before transplantation, thereby reducing post-transplant complications and allowing the utilization of more organs for transplant. The multi-organ platform allows for the standardization of use across transplant programs.

- **National OCS Program**
  Our National OCS Program was developed to provide a more efficient process to procure donor organs with the OCS. As the number of transplants increases and the retrieval distance extends, the field will need alternatives to the current model in which the recipient transplant center sends its team to the donor site for retrieval. Our National OCS Program provides a turnkey solution that leverages the technical advantage of the OCS and provides transplant centers with a more efficient way to increase their volume of transplants without significantly increasing resources.

- **Significant body of strong clinical evidence**
  In order to receive FDA approval for our PMA products, we have conducted a very large number of clinical trials with very large numbers of patient participants, with the results of these trials published in leading medical journals. We have also initiated post-market registries for all of our products and will continue to provide the scientific results of these registries to the clinical user community.

- **Strong relationship with the clinical transplant community**
  The transplant community is highly concentrated in the leading academic medical centers around the world. We have developed strong clinical relationships with many of these centers through their participation in our clinical trials. In addition, many transplant surgeons at our clinical trial locations may have moved to new centers, bringing their OCS experience with them and allowing our relationships to grow to these new centers.

- **Expertise in transplant reimbursement and billing**
  The OCS has been reimbursed by the Centers for Medicare & Medicaid Services, or CMS, and private insurers during our clinical trials and continues to be reimbursed in the commercial setting. Since our customers have been billing for reimbursement for many years, we have developed a high degree of expertise in the area of transplant reimbursement and appropriate billing of insurers. We provide advice and best practices to our customers in compliance with laws and regulations.

- **Strong research and development capabilities and comprehensive intellectual property portfolio**
  We have a long history and broad experience in the development of warm machine perfusion for organ preservation. During the life of our OCS technology platform we have continued to add technological and usability enhancements to our devices. In the future, we intend to develop newer versions of the technology that continue to improve the ease of use, portability, and capability of the products.

Organ Transplant Therapy Benefits and Challenges

We believe organ transplantation is the most effective treatment for end-stage organ failure in terms of both clinical outcomes and health economics. Organ transplant provides the longest life expectancy and best quality of life compared to other therapies for end-stage organ failure. 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. 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. These improved survival rates, in turn, result in favorable economics for transplantation on the basis of quality-adjusted life years.

However, organ transplant therapy faces two major challenges. First, 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. Second, a high rate of post-transplant clinical complications needs to be reduced to improve outcomes and lower costs.

The use of cold static storage for preservation of donor organs contributes to these challenges in three ways:

- **Subjects the donor organs to severe time-dependent ischemic injury**
  Cold storage deprives the organs from oxygen, resulting in time dependent injury (ischemia). This injury correlates with post-transplant complications and restricts the viable time for organ procurement and transplant, which limits the time and distance possible between donor and recipient and results in low utilization of the donor pool and limits the number of transplant procedures performed annually.

- **No organ optimization capability**
  Given the non-physiologic environment, cold storage does not allow for any therapeutic interventions to optimize the condition of the donor organs. This further limits utilization of available donor organs for transplantation and could negatively impact post-transplant outcomes. It is well demonstrated that donor organs require some form of optimization to replenish depleted levels of substrates, hormones, and electrolytes that are significantly altered or used up during the donation process.

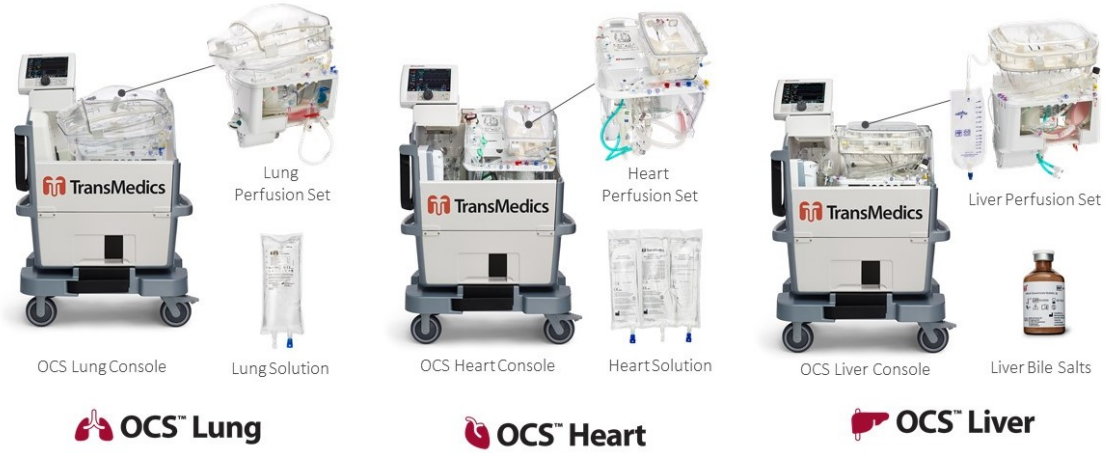
- **No organ viability assessment capability**
  During cold storage, the organs are not physiologically active, nor functioning; thus, there are no means for evaluating the suitability of these organs for transplantation. This further limits utilization of available organs as donor populations worldwide are growing older and have concomitant risk factors that require sophisticated diagnostic evaluation capabilities to ensure that the donor organ is suitable and safe to transplant.

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.

Key Advantages of the OCS Platform

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

- **Significant reduction in ischemia**
  Decreases current time and distance limitations on organ transport while also increasing the currently limited time period for retrieval during which high quality transplant outcomes can reliably be obtained. This maximizes organ utilization and enables increased access to organ transplantation, while also meaningfully improving post-transplant outcomes.

- **Enables organ optimization outside of the human body**
  Allows therapeutic optimization of donor organs from the damaging conditions of brain and circulatory death using clinically proven and safe modalities, thus significantly improving donor organ utilization and patient outcomes.

- **Allows for organ viability assessment**
  Enables diagnostic evaluation of the donor organ using currently acceptable clinical standards to evaluate the organ's suitability for transplantation and to maximize the post-transplant outcomes

We believe that by comprehensively addressing the three limitations of cold static storage, the use of the OCS will allow for increased utilization of donor organs and improve post-transplant outcomes.

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 our goal of transforming organ transplantation with our OCS platform by establishing the OCS as the standard of care for solid organ transplantation and thereby increasing the utilization of donor organs and improving clinical outcomes.

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 believe we are well-positioned 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.

- **Grow our National OCS Program, a turnkey solution to provide outsourced organ retrieval and organ management, to provide transplant programs with a more efficient process to procure donor organs with the OCS.** We have initiated a service program that leverages our clinical and logistical capabilities to provide access to and use of the OCS for transplant centers in certain regions of the United States. We believe we could become a national clinical service provider of organ retrieval and perfusion service to transplant centers throughout the United States. We believe this program has the potential to accelerate adoption of the OCS, maximize utilization of donor organs for transplantation and, by standardizing the quality of use of the OCS, deliver better clinical outcomes.

- **Expand the existing pool of utilizable donor organs by securing approval for our OCS Heart DCD PMA supplement.** We have received FDA PMA approval for OCS Lung and OCS Liver for both DBD and DCD organs. We have received FDA approval for OCS Heart for DBD organs. We submitted a PMA supplement to the FDA for use of the OCS Heart with DCD organs in November 2021 and expect to receive a decision from the FDA in 2022.

- **Develop the next generation OCS technology platform to improve user experience and facilitate our National OCS Program.** We have initiated the development of the next generation multi-organ platform to improve the usability, incorporate new technology and automation, and facilitate the use of OCS in our National OCS Program.

- **Expand internationally by accessing national reimbursement for OCS in key European countries.** We have begun the early development of submission material to various national healthcare systems throughout Europe. We believe international expansion will be an additional growth driver for us in the long term.

Commercialization

We commercialize our products through two channels. Our direct acquisition channel is provided for transplant centers who are interested in training their own teams for retrieval and organ management on the OCS. Customer users are certified on the use of OCS at our training facility. Customers in the direct acquisition channel keep inventory of OCS disposables available and order replenishment as they are used.

Our National OCS Program provides a second option for transplant centers who would like to outsource the retrieval and organ management process. We provide the full service to the transplant center, allowing the transplant center to focus their internal resources on the transplant surgery and patient care. Utilizing our National OCS Program saves the transplant center from investing in additional resources to support higher volumes and longer distance retrievals.

Reimbursement

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 Medicare Severity-Diagnosis Related Group, or 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 2020 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 $1.3 million, of which only approximately $130,000 is associated with organ acquisition; overall billed charges for a heart transplant are approximately $1.7 million, of which only approximately $130,000 is associated with organ acquisition; and overall billed charges for a liver transplant are approximately $0.9 million, of which only approximately $100,000 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 our first 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, 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 FDA PMA approvals and PMA submissions for the OCS for lung, heart and liver transplantation. Many of these clinical trials and studies have been published in peer-reviewed clinical journals. 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.

The results of our clinical trials are summarized in the images below.

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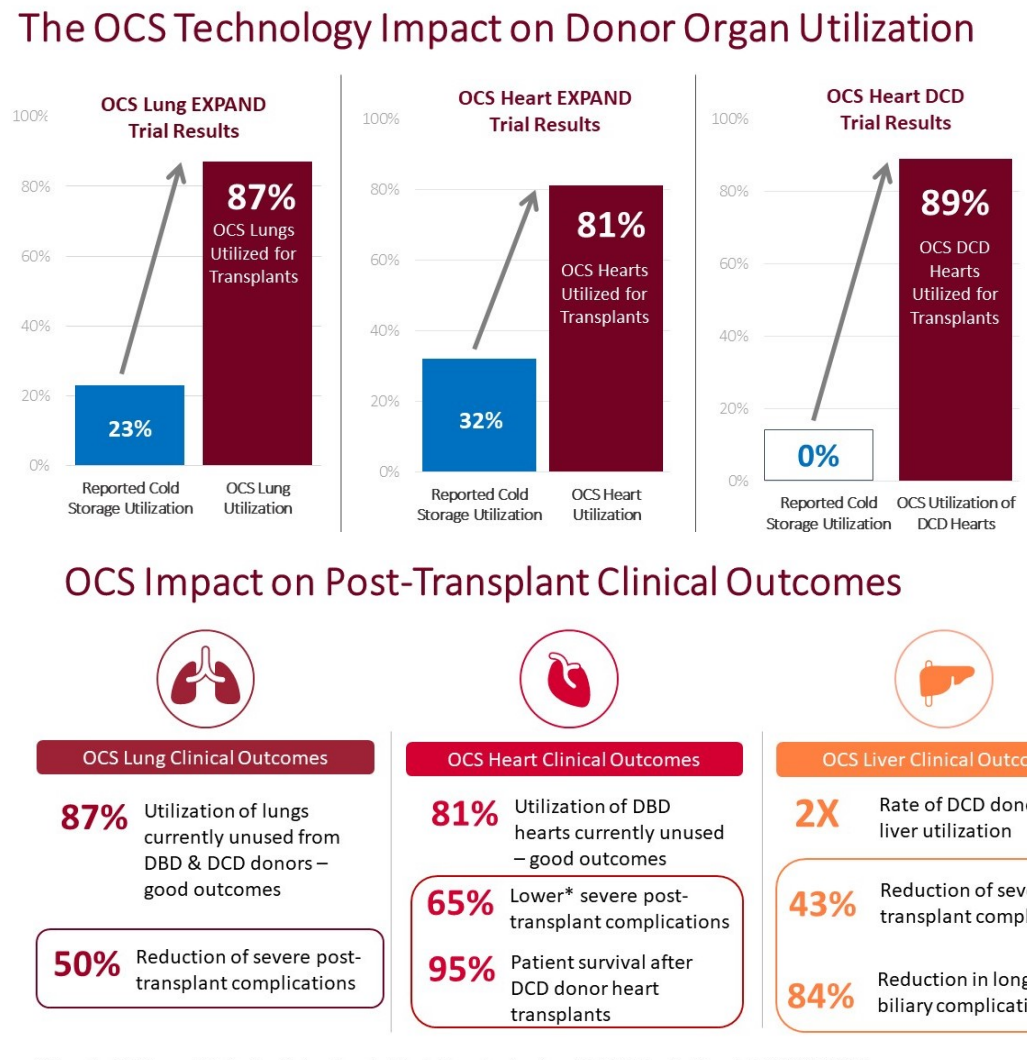

OCS Clinical Trial Overview Table

	OCS Lung		OCS Heart			OCS Liver
Trial Name	**INSPIRE**	**EXPAND Lung**	**PROCEED II**	**EXPAND Heart/CAP**	**DCD Heart/CAP**	**PROTECT/CAP**
Objective	Compare OCS to Cold Storage	Improve Utilization	Compare OCS to Cold Storage	Improve Utilization	Improve Utilization and Compare OCS to Cold Storage	Compare OCS to Cold Storage
Number of Patients	320	79	128	150	270	374
Summary Outcomes	Met primary effectiveness endpoint 50% Reduction in post-transplant complications Reduction of injurious ischemic time	Did not meet primary effictiveness endpoint Significant increase in utilization to 87% Good one year survival Reduction in PGD3	Met primary effectiveness endpoint Reduction of injurious ischemic time Post-hoc observational analysis, graft-related deaths were similar in both groups, overall deaths were higher in OCS Group	Met primary effectiveness endpoint Signficant increase in utilization to 81% Good one year survival 65% Lower incidence of PGD	Met primary effectiveness endpoint Significant increase in utilization to 89% Good 6 month survival (95%)	Met primary effectiveness endpoint 43% reduction in early allograft dysfunction 84% reduction of ischemic biliary complications at one year Higher utilization to 98%
Length of Follow-up Post-Transplantation	24 months	12 months	30 days	12 months	12 months	24 months
Number of Centers	21 U.S. and international	8 U.S. and international	10 U.S. and international	9 U.S.	25 U.S.	20 U.S.
Publication	Warnecke et al., Lancet Respiratory Medicine, April 2018	Loor et al., Lancet Respiratory Medicine, August 2019	Ardehali et al., The Lancet Journal, April 2015	Pre-publication	Pre-publication	Markmann et al., JAMA Surgery, January 2022

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 December 31, 2021, our owned and licensed patent portfolio consisted of approximately 274 issued patents and pending patent applications worldwide, including in the United States, Australia, Europe, Canada, China, Israel, New Zealand and Japan. 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 30 issued patents and 9 pending applications. Outside the United States, our owned portfolio includes about 178 issued patents and 57 pending applications. Issued patents in our portfolio are expected to expire between 2025 and 2036, 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 2025 and 2036, excluding any potential additional patent term for patent term adjustments or patent term extensions, if applicable.

As of December 31, 2021, 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, Belgium, Canada, China, Denmark, Europe, France, Germany, Ireland, Israel, Italy, Japan, Hong Kong, Netherlands, New Zealand, Spain, Sweden, and United Kingdom, 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 2029, excluding any potential additional patent term for patent term adjustments or patent term extensions, if applicable.

As of December 31, 2021, 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, Canada, China, Denmark, Europe, France, Germany, Hong Kong, Ireland, Israel, Italy, Japan, Netherlands, New Zealand, Spain, Sweden, and United Kingdom, 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 2036, excluding any potential additional patent term for patent term adjustments or patent term extensions, if applicable. We have requested patent term extension for one patent relating to the OCS Heart, U.S. Patent No. 7,651,835, which, if granted, would expire in 2032.

As of December 31, 2021, our patent portfolio relating to the OCS Liver includes a family of issued and pending patent applications with claims that are generally directed to certain systems, including perfusion circuits for perfusing a liver *ex vivo*. Such patents are issued in the United States and Australia, 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. We have requested patent term extension for one patent relating to the OCS Liver, U.S. Patent No. 10,076,112, which, if granted, would expire in 2035.

As of December 31, 2021, 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, Australia, China, Israel, Japan, New Zealand and patent applications are pending in the United States, Canada, China, Europe, Hong Kong, and New Zealand. These patents, and any patents issued from pending patent applications, are expected to expire in 2032, 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 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 “Item 1A. Risk Factors—Risks Related to Our Intellectual Property” in this Annual Report on Form 10-K.

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 an interim patent term extension until November 6, 2021 for this patent and we have not received final approval of the patent extension beyond the interim patent already requested. The maximum extension granted would be through May 2022. However, the length of the patent term extension is currently being determined by the United States Patent and Trademark Office, or USPTO, based on input from the FDA. On February 8, 2021, the FDA provided to the USPTO a determined regulatory review period for the OCS Lung. Under the FDA's analysis, the patent term extension of the '082 patent would be until November 6, 2021. We have not received communication from the USPTO, but expect that the USPTO's patent term extension for the '082 patent will maintain the November 6, 2021 expiration date. 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. The final determination of the length of the patent extension is not expected to impact our financial results. 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.

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 or temperature controlled cold storage devices.

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 warm perfusion 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;
- superior technology;
- 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.

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 years ended December 31, 2021 and 2020 our research, development and clinical trials expenses were $22.3 million and $18.8 million, respectively.

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

- developing the next generation OCS;
- 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, and;
- conducting research to investigate new clinical applications and uses for the OCS platform.

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 years of forecasted 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 2022 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 qualifies a second manufacturing plant or qualifies a reputable third party to manufacture the OCS Lung Solution and Fresenius fails to respond to this request. Our agreement with Fresenius includes an obligation to meet certain annual minimum purchase commitments based upon rolling order forecasts that we provided 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.

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 and other countries.

Our products are subject to regulation as medical devices under the Federal Food, Drug and Cosmetic Act, or 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. Regardless of whether we have or are required to obtain FDA clearance or approval for a product, we will be required to obtain the relevant authorizations/approvals before commencing clinical trials/investigations and to obtain the necessary authorizations, approvals or certifications of our products under the comparable regulatory authorities of countries outside of the United States before we can commence clinical trials/investigations or commercialize our products in those countries. In the European Union, the manufacturer of a device must affix a Conformité Européene mark, or CE Mark, which allows the device to be placed on the market anywhere in the EU and additional Member States of the European Economic Area, or EEA, (i.e., Norway, Lichtenstein and Iceland). The EU CE mark is also recognized in Turkey and, for a transitional period following the UK's withdrawal from the European Union, referred to as Brexit, in the United Kingdom.

The authorization/approval processes for devices outside 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 or EU CE marking.

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/or the user and are those for which safety and effectiveness can be reasonably assured by adherence to the FDA's general controls for medical devices, which include compliance with the applicable portions of the Quality System Regulation, or QSR, facility registration and product listing, reporting of adverse medical events and device malfunctions, 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 substantial equivalence 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. We received 510(k) clearance for the OCS Lung Solution for cold flush, storage and transportation of donor lungs in July 2021.

Devices deemed by the FDA to pose the greatest risks, such as life-sustaining, life-supporting and many 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.

Each of our OCS warm perfusion products is a Class III device. We have received a PMA for each of the following:

- OCS Lung for the preservation of standard criteria donor lungs for double-lung transplantation;
- OCS Lung for the preservation of donor lungs initially deemed unsuitable due to limitations of cold storage for double-lung transplantation;
- OCS Heart for the preservation of DBD donor hearts deemed unsuitable due to limitations of cold storage (e.g. >4 hours of cross-clamp time); and
- OCS Liver for the preservation of DBD and DCD donor livers < 55 years old, macrosteatosis < 15% and with < 30 minutes of warm ischemia time.

In the future, we also hope to obtain PMA for the OCS Heart for the preservation of DCD donor hearts.

PMA Pathway

Class III devices require an approved PMA before they can be marketed. 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. 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 one year, or even longer, from the time the PMA application is submitted to the FDA until an approval is obtained. An advisory committee 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' 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. 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. 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 committee. 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 application and may be necessary to support PMA supplements for additional indications or modified versions of a marketed device product. 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 study review and approval, informed consent, 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. 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. 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. 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. Non-significant risk device studies do not require submission of an IDE application to FDA.

In the United States, 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.

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. 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.

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 and removal reporting regulations, which require that manufacturers report to the FDA field corrections and product 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 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 our medical devices in the European Union is harmonized through Regulation (EU) 2017/745, or the MDR, which repealed and replaced the Medical Devices Directive (93/42/EEC) with effect from May 26, 2021.

However, the competent authorities in each member state enforce the standards set out in the MDR against relevant economic operators (including the manufacturer, importer, authorized representative and distributors) making medical devices available in the member state (although, under the MDR there are provisions for national competent authorities to inform other competent authorities, the European Commission and Notified Bodies, as applicable, of certain non-compliances).

Under the MDR, a medical device placed on the market in the European Union must meet the applicable General Safety and Performance Requirements, or GSPRs, laid down in Annex I of the MDR. Similar to the U.S. system, medical devices are classified into one of four classes based on risk: I, IIa, IIb and III, with class I representing the lowest risk products and class III the highest risk products. One of the most fundamental GSPRs 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 (provided that any risks posed are acceptable when weighted against the benefits). In addition, the GSPRs include (but are not limited to) that the device must achieve the performances intended by the manufacturer, be designed, manufactured and packaged in a suitable manner and the manufacturer must establish, implement, document and

maintain a risk management plan. The European Commission has adopted various standards applicable to medical devices, referred to as harmonized standards. While not mandatory, compliance with these harmonized standards is often viewed as the easiest way to satisfy the GSPRs as a practical matter. Compliance with a harmonized standard developed to implement a GSPR also creates a rebuttable presumption that the device satisfies that essential requirement. Currently the European Commission has only harmonized a relatively limited number of standards (these include, for example, standards of sterilization, biological evaluation, the quality management system, *etc.*) but the Commission will continue to harmonize more standards.

To demonstrate compliance with the GSPRs, 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.

For all devices other than low risk devices (*i.e.*, Class I non-sterile, non-measuring devices), a conformity assessment procedure requires the intervention of a notified body. 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 affix 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.

Although the MDR now applies so all new devices placed on the market must be CE marked under it, under the transition period granted by the MDR, certificates issued by notified bodies for medical devices under the Medical Devices Directive before May 26, 2021 remain valid until the period indicated on the certificate, subject to all certificates becoming void on May 27, 2024. Therefore, so long as there are no significant changes in the design and intended purpose of these devices, the devices can continue to be placed on the market until the date the Medical Devices Directive certificate becomes void.

The requirements of MDR are significantly more onerous than under the EU Medical Devices Directive. These apply to both devices CE marked under the MDR and the EU Medical Devices Directive that are benefitting from the transition period. The increased regulation includes the following:

- strengthening of the rules on placing devices on the market, by requiring more evidence substantiating safety and efficacy of the device and more detailed content in the technical documentation for each device;
- requiring a structured post-market clinical follow-up program for every medical device;
- necessitating more thorough post-market surveillance program, with an emphasis on active gathering and analyzing the data;
- establishing 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;
- improving the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- setting up a central database into which manufacturers and other economic operators are required to input data with the goal of providing EU competent authorities as well as provide patients, healthcare professionals and the public with comprehensive information on products available in the European Union; and
- strengthening 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 regulatory function is actively working toward being compliant with MDR and interactions with our notified body are underway. Because of the permitted transition periods under MDR, each of our medical devices will require recertification prior to September 19, 2022 (i.e., the date on which the certificates of conformity under the Medical Devices Directive become void).

Clinical Investigations

Clinical evidence is required for most medium and high risk devices. In some cases, a clinical study may be required to support a CE marking application. A manufacturer that wishes to conduct a clinical study involving the device is subject to the clinical investigation requirements of the MDR, EU member state requirements, and current good clinical practices defined in harmonized standards and guidance documents. 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 apply after a device is placed on the market. These include the obligation to have in place a post-market surveillance system and vigilance system. These requirements include that the manufacturer must report to the relevant national competent authorities any serious incident involving devices made available on the market and any field safety corrective action in respect of devices made available on the market or undertaken in a third country in relation to a device made available on the market. Additionally, the manufacturer must submit periodic safety update reports.

Authorities in the European Union also closely monitor the marketing programs implemented by device companies. The MDR prohibits making misleading claims, including promoting the product for or suggesting a use that is not part of its intended purpose. However, the obligations that companies must fulfill concerning premarketing approval of promotional material vary among member states of the European Union as beyond that requirement, advertising and promotion law is not harmonized in the European Union.

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 of Medical Devices in the United Kingdom

The Medicines and Healthcare products Regulatory Agency, or the MHRA, is responsible for regulating the UK medical devices market. The MHRA performs market surveillance of medical devices on the UK market and is able to take decisions over the marketing and supply of devices in the UK. The MHRA is also responsible for the designation and monitoring of UK conformity assessment bodies.

In the United Kingdom medical devices are regulated under the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) which, prior to the end of the transition period, gave effect in UK law to the directives listed below:

- Directive 90/385/EEC on active implantable medical devices (EU AIMDD)
- Directive 93/42/EEC on medical devices (EU MDD)
- Directive 98/79/EC on in vitro diagnostic medical devices (EU IVDD)

This means that the Great Britain route to market and UK Conformity Assessed, or UKCA, marking requirements are based on the requirements derived from the above EU legislation.

Since May 26, 2021, the EU Medical Devices Regulation (Regulation 2017/745), or the EU MDR, has applied in EU Member States and Northern Ireland. Further, the in vitro Diagnostic Medical Devices Regulation (Regulation 2017/746), or the EU IVDR, will apply in EU Member States and Northern Ireland from May 26, 2022. As these EU regulations did not take effect during the transition period, they were not EU law automatically retained by the EU (Withdrawal) Act 2018 and therefore do not and will not apply in Great Britain (England, Wales and Scotland). Since January 1, 2021, there have been a

number of changes, introduced through secondary legislation, on how medical devices are placed on the market in Great Britain (England, Wales and Scotland). These are:

- a new route to market and product marking (the UKCA marking) is available for manufacturers wishing to place medical devices on the Great Britain market;
- all medical devices, including in vitro diagnostic medical devices, or IVDs, custom-made devices and systems or procedure packs, need to be registered with the MHRA before they are placed on the Great Britain market;
- medical device manufacturers based outside the UK who wish to place a device on the Great Britain market need to appoint a single UK Responsible Person for all devices who will act on their behalf to carry out specified tasks, such as registration;
- CE marking will continue to be recognized in Great Britain until June 30, 2023;
- certificates issued by EU-recognized Notified Bodies will continue to be valid for the Great Britain market until June 30, 2023;
- the EU no longer recognizes UK Notified Bodies; and
- UK Notified Bodies are not able to issue CE certificates - and have become UK Approved Bodies.

All medical devices, including IVDs, custom-made devices and systems or procedure packs must be registered with the MHRA before being placed on the Great Britain market. In Great Britain, devices must conform to the UK MDR 2002, the EU MDR (until June 30, 2023), or the EU IVDR (until June 30, 2023) in order to be registered with the MHRA. In addition, devices that have been CE marked under the EU MDD, EU AIMDD or EU IVDD will continue to be accepted on the Great Britain market until June 30, 2023 if their certificates remain valid for the EU market under the transitional arrangements in the EU MDR and EU IVDR. Any mandatory third-party conformity assessment for the CE marking must be carried out by an EU Notified Body. This includes both EU-based Notified Bodies and Notified Bodies in countries which are listed on the EU's NANDO Information System. Certificates issued by EU-recognized Notified Bodies that are valid for the EU market, will continue to be valid for the Great Britain market until 30 June 2023. From July 1, 2023, devices that are placed on the Great Britain market will need to conform with UKCA marking requirements. The UKCA marking is a UK product marking used for certain goods, including medical devices, being placed on the Great Britain market. For the purposes of the UKCA marking, a UK Approved Body must be used in cases where third party conformity assessment is required.

Where a manufacturer is not established in the UK, they must appoint a UK Responsible Person to register and act on their behalf. The responsibilities of the UK Responsible Person are set out in the UK MDR 2002. The name and address of the UK Responsible Person, where applicable, must be included on the product labelling or the outer packaging, or the instructions for use in cases where the UKCA marking has been affixed. However, UK Responsible Person details do not need to be included on labelling for CE marked devices, unless the device bears both the CE and UKCA markings.

The MHRA Enforcement of Medical Device Regulations in the UK

To ensure that medical devices placed on the market and put into service in the UK meet applicable regulatory requirements the MHRA perform the following activities:

- assess all allegations of non-compliance brought to them, using a risk-based system;
- monitor the activity of UK Approved Bodies designated by MHRA to assess the compliance of manufacturers; and
- investigate medical devices as a result of adverse incident reports or intelligence indicating a potential problem

If MHRA considers that a person or company has committed a serious offence by failing to comply with applicable regulations or the conditions of a notice issued then a person/company may be subject to prosecution.

Clinical Investigations

In order to demonstrate compliance with the essential requirements of the UK Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) and the general safety and performance requirements of the (EU) Medical Devices Regulation 2017/745 (MDR) governing safety and performance, and in order to justify the application of UKCA/CE/CE UKNI marking, it will sometimes be necessary for the manufacturer of the device to provide clinical data with which to back up claims made for that device. This may involve the need for a specifically designed clinical investigation to:

- verify that under normal conditions of use the performance characteristics of the device are those intended by the manufacturer; and
- determine any undesirable side-effects and to assess whether these are acceptable risks when weighed against the intended performance of the device.

If such an investigation is necessary, the manufacturer must make an application to the MHRA before the investigation is due to begin, and such a clinical investigation may only proceed provided no grounds for objection are raised by the MHRA within the statutory review time constraint. The MHRA will reach a decision aided by a number of expert assessors. It is the responsibility of the manufacturer both to notify the MHRA and to submit the documentation required by the UK MDR 2002 or EU MDR to the MHRA. The clinical investigator will normally have no direct contact with the MHRA.

Post-marketing Requirements

Once a medical device has been placed on the UK market, the manufacturer is required to submit vigilance reports to the MHRA when certain incidents occur in the UK that involve their device. They must also take appropriate safety action when required. The manufacturer must also ensure their device meets appropriate standards of safety and performance for as long as it is in use. The advertising and marketing of medical devices is governed in the UK by both legislation and self-regulatory codes of practice.

New Developments: Brexit

Our notified body, BSI, previously issued from its UK entity the certificates which allow CE marking of the OCS products. Following Brexit, certificates issued by UK notified bodies shall no longer be recognized. Our notified body is based in the Netherlands and issues the certificates that allow CE marking of the OCS products. In addition, we have engaged with a new Authorized Representative based in the EU to cover Europe in separate arrangements in compliance with regulations.

Regulations Applicable Organs Intended for Transplantation

The standards for the quality and safety of organs for transplantation has been enacted into UK law through The Quality and Safety of Organs Intended for Transplantation Regulations 2012 and The Quality and Safety of Organs Intended for Transplantation (Amendment) Regulations 2014. This Act allows for the establishment of a Competent Authority for the regulation of organ transplantation. In the UK the Competent Authority is the Human Tissue Authority, which has published the “The Quality and Safety of Organs Intended for Transplantation: a documentary framework” which details mandatory requirements as well as guidance on how those requirements may be met. While we are not directly affected by this Regulation and guidelines, our UK customers are, and our products may either help or impede their compliance with this Regulation.

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.

Internationally, the approaches to product defects will vary. A product may be recalled in one country but not in others.

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 UK are governed by the code of Association of British Healthcare Industries, or ABHI, 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 the Foreign Corrupt Practices Act, or the FCPA, the UK Bribery Act 2010 and the General Data Protection Regulation, or 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 UK and in the United States include the offence of bribing a foreign public official.

Data Privacy and Security Laws

We are, and 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.

The Health Insurance Portability and Accountability Act of 1996, or 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 PHI by covered entities as well as business associates, which are defined to include subcontractors that create, receive, maintain, or transmit PHI on behalf of a business associate. These regulations also set forth certain rights that an individual may have with respect to his or her PHI maintained by a covered entity, including the right to access or amend certain records containing PHI, or to request restrictions on the use or disclosure of PHI. HIPAA security regulations set forth requirements for safeguarding the confidentiality, integrity, and availability of protected health information that is electronically transmitted or electronically stored. The Health Information Technology for Economic and Clinical Health Act, among other things, provides certain health information security breach notification requirements. Under these laws, the covered entity must notify any individual whose PHI is breached as required under the breach notification rule. Although we believe that we currently are neither a "covered entity" nor a "business associate" directly 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. States are increasingly regulating the privacy and security of individually identifiable information, including financial information and health information. For example, the California Consumer Privacy Act, or CCPA gives California residents certain rights, including the right to ask covered companies to disclose the types of personal information collected and delete a consumer's personal information, and imposes several obligations on covered companies to provide notice to California consumers regarding their data processing activities and limitations on covered companies' ability to sell personal information. These protections will be expanded by California Privacy Rights Act of 2020, or CPRA, which will be operational in most key respects in 2023, along with new privacy laws in Virginia and Colorado. We expect additional federal and state legislative and regulatory efforts to regulate consumer privacy in the future.

In the European Economic Area, or EEA, 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. Following Brexit, the UK has substantively retained the same privacy rules as it had when a member of the European Union. 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 EEA 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 E-Privacy Directive into its own national data privacy regime and therefore the laws may differ by jurisdiction, sometimes significantly. The GDPR was retained post-Brexit in the UK as the UK GDPR. In addition, many EEA 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 EEA. The UK has done the same. We need to ensure compliance with the rules in each jurisdiction where we are established. Even if not established in the EEA (or the UK), we may otherwise be subject to local privacy laws in those regions. For example, we may be subject to the GDPR even when processing personal data in connection with offering goods or services to persons located in the EEA or monitoring the behavior of persons located in the EEA.

GDPR requirements include that personal data may only be collected for specified, explicit and legitimate purposes based on a certain legal bases set forth in GDPR, 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 EEA 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 EEA. 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 (including the safety and efficacy of medical devices) or scientific research. The same rules apply to us in the UK under the UK GDPR and in relation to transfers out of the UK.

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, encourages the use of pseudonymization techniques (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 EEA 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. The July 2020 invalidation by the Court of Justice of the European Union of the EU-U.S. Privacy Shield framework, one of the mechanisms used to legitimize the transfer of personal data from the EEA to the U.S., has led to increased scrutiny on data transfers from the EEA to the U.S. generally and may increase our costs of compliance with data privacy legislation. All these points apply equally to the UK (and in relation to transfers from the UK to the U.S.).

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 EEA (or the UK), 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. Additional healthcare reform efforts have sought to address certain issues related to the COVID-19 pandemic. 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, however the tax was suspended in 2016 and permanently repealed in 2019. The Affordable Care Act also implemented payment system reforms, including bundled payment models and Medicare value-based purchasing plans. Additionally, the Affordable Care Act has expanded eligibility criteria for Medicaid programs and provided incentives to programs that increase the federal government’s comparative effectiveness research, including the creation of a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. Since its enactment, there have been and likely will be judicial, administrative, executive, and legislative challenges to certain aspects of the Affordable Care Act. For example, tax reform legislation was enacted at the end of 2017 that eliminates the tax penalty for individuals who do not maintain sufficient health insurance coverage beginning in 2019 (the so-called “individual mandate”). More recently, on June 17, 2021, the U.S.

Supreme Court dismissed the latest judicial challenge to the Affordable Care Act brought by several states without specifically ruling on the constitutionality of the Affordable Care Act. Changes resulting from any successful challenges or other future modifications have a material impact on our business.

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, as amended, among other things, included reductions to Medicare (but not Medicaid) 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 2030 (except May 1, 2020 to March 31, 2021) 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. We cannot, however, predict the ultimate content, timing or effect of any healthcare reform legislation or action, or its impact on us, and healthcare reform could increase compliance costs and may adversely affect our future business, operations and financial results.

Human Capital

Our human capital strategy is comprehensive and leverages our work practices and collaborative culture. We foster a strong relationship with and among our employees with various efforts such as training and development programs, and other programs, including skill development courses, manager training and leadership development opportunities. As of December 31, 2021, we had approximately 148 employees, most of whom were full-time employees. Except for certain European employees, our employees are not subject to collective bargaining agreements, and we believe we have a strong relationship with our employees.

Corporate Information and Organizational Transactions

TransMedics Group, Inc., was incorporated in the Commonwealth of Massachusetts in October 2018 to facilitate our initial public offering, or IPO. TransMedics, Inc., an operating company and wholly-owned subsidiary of TransMedics Group, Inc., was incorporated in the State of Delaware in August 1998. Our principal executive offices are located at 200 Minuteman Road, Andover, Massachusetts 01810, and our telephone number at that address is (978) 552-0900.

Available Information

Our Internet address is www.transmedics.com. Our website and the information contained on, or that can be accessed through, the website will not be deemed to be incorporated by reference in, and are not considered part of, this Annual Report on Form 10-K. Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, including exhibits, proxy and information statements and amendments to those reports filed or furnished pursuant to Sections 13(a), 14, and 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, are available through the “Investors” portion of our website free of charge as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. In addition, our filings with the SEC may be accessed through the SEC’s Electronic Data Gathering, Analysis and Retrieval system at *http://www.sec.gov*. All statements made in any of our securities filings, including all forward-looking statements or information, are made as of the date of the document in which the statement is included, and we do not assume or undertake any obligation to update any of those statements or documents unless we are required to do so by law.

Item 1A. 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 Annual Report on Form 10-K 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 "Forward-Looking Statements" in this Annual Report on Form 10-K.

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 successful commercialization of our OCS products. We generated net revenue of $30.3 million and $25.6 million for the years ended December 31, 2021 and 2020, respectively, and incurred net losses of $44.2 million and $28.7 million for these same years. As of December 31, 2021, we had an accumulated deficit of $442.4 million. To date, we have funded our operations primarily with proceeds from sales of equity, borrowings under loan agreements and revenue from clinical trials and commercial sales of our OCS products. Our losses have resulted principally from costs incurred in connection with our research and development, clinical trials, manufacturing and commercialization activities, including the development of our National OCS Program.

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 commercial team, which will pursue increasing commercial sales of our OCS products; scaling our manufacturing operations; continuing research and development for our next generation OCS products; and seeking regulatory clearance for new products and product enhancements, including new indications, in both the U.S. and select non-U.S. markets. 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. commercial 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 costs incurred in our efforts to develop our National OCS Program;
- 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.

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.

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.

Although we fund a portion of our operations from net revenue from sales of our OCS products, we expect that we will need to finance our operations through a combination of equity offerings, debt financings and strategic alliances until such time, if ever, that we can generate substantial net revenue sufficient to achieve profitability. We also may elect to raise additional funds sooner because we believe market conditions are attractive or as a risk mitigation measure. 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 significantly delay, scale back or discontinue our development or commercialization activities, sell or license to third parties some or all of our assets or merge with another entity or may be forced to reduce or terminate our operations any of which could result in a loss of all or part of your investment.

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 December 31, 2021, our outstanding principal balance of long-term debt under our credit agreement with OrbiMed Royalty Opportunities II, LP, or OrbiMed, was $35.0 million, 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. We may not have sufficient funds, and may be unable to arrange for additional financing, to pay the amounts due under or refinance our indebtedness under the Credit Agreement, which matures in June 2023.

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, could result in the acceleration of our obligations under the Credit Agreement, which are also 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. If such acceleration were to occur, it would materially and adversely affect our business, financial condition, operating results, cash flows and prospects.

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 “Item 7. Management’s Discussion and Analysis-Long-term Debt” in this Annual Report on Form 10-K.

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 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. Our revenue from sales may 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.

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 31, 2021, we had U.S. federal and state net operating loss, or NOL, carryforwards of $368.1 million and $304.0, respectively, which may be available to offset future taxable income. Our U.S. federal NOL carryforwards began to expire in 2022 and our state NOL carryforwards begin to expire in 2030. The Company's federal net operating losses include $156.4 million, which can be carried forward indefinitely. As of December 31, 2021, we also had U.S. federal and state research and development tax credit carryforwards of $8.0 million and $5.3 million, respectively, which may be available to offset future tax liabilities. Our U.S. federal research and development tax credit carry forwards began to expire in 2021 and our state research and development tax credit carryforwards begin to expire in 2024. A material portion of 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. 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 annual taxable 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.

The transition away from LIBOR may adversely affect our cost to obtain financing.

On July 27, 2017, the UK Financial Conduct Authority announced that it intends to stop persuading or compelling banks to submit London Interbank Offered Rate, or LIBOR, rates after 2021. The Financial Conduct Authority and the ICE Benchmark Administration recently announced that LIBOR may continue for legacy contracts until June 2023. The Alternative Reference Rates Committee, a steering committee comprised of U.S. financial market participants, selected and the Federal Reserve Bank of New York has recommended the Secured Overnight Finance Rate, or SOFR, as an alternative to LIBOR. SOFR is a broad measure of the cost of borrowing cash in the overnight U.S. treasury repo market. Rates linked to SOFR or associated changes related to the adoption of SOFR may not be as favorable to us as LIBOR and may result in an effective increase in the applicable interest rate on our current or future debt obligations, including our Credit Agreement.

Risks Related to Product 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, educating surgeons, transplant centers, Organ Procurement Organizations and private and public payors of the benefits of the OCS and providing services related to the OCS. Although we have received PMAs from the FDA for preservation of donor lungs for the transplantation of DBD and DCD donor organs, for the preservation of donor hearts for the transplantation of DBD donor organs and for the preservation of donor livers from DBD and certain DCD donor organs, we might not successfully commercialize the OCS for these 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 primarily 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, Organ Procurement Organizations and private and public 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. 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 and public payors often are slow to adopt new products, technologies and treatment practices that require additional upfront costs and training. The cost of the OCS significantly exceeds 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, Organ Procurement Organizations and private and public 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.

We must continue to educate surgeons, transplant centers and private and public payors and demonstrate the merits of the OCS compared with cold storage or new competing technologies.

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 and public payors as to the distinctive characteristics, perceived medical and economic benefits, safety, ease of use and cost-effectiveness of the OCS. If program directors, other surgeons and private and public 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, most universal national healthcare systems outside of the United States 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 following transplantation are not yet known. Certain surgeons, transplant centers and private and public 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 expand access to the OCS through our National OCS Program.

We are developing a National OCS Program, a turnkey solution to provide outsourced organ retrieval and OCS organ management, to provide transplant programs with a more efficient process to procure donor organs with the OCS. We believe the National OCS Program will expand access and use of the OCS. However, we may not be successful in the continued

development of our National OCS Program, which will depend on recruiting and retaining qualified surgeons and coordinating with transplant centers and regional Organ Procurement Organizations. We may not be able to recruit and retain surgeons and other qualified personnel, including due to demand for their capabilities and competitive compensation offered by other employers. In order to recruit and retain such highly qualified employees, we also may need to increase the level, or change the form or composition, of the compensation that we pay to them, which would increase our expenses.

In addition to our own surgical and clinical personnel, we utilize a network with a limited number of partners for a portion of our organ retrieval, organ preservation and transportation services offered through our National OCS Program. If our partners are unable to fulfill their obligations under their contracts, it could harm our operations. If any of these relationships are interrupted or terminated, or if one or more partners are unable or unwilling to fulfill their obligations for whatever reasons, National OCS program services to our customers may be interrupted, and business and financial results may be negatively impacted. Further, we may not be able to identify or negotiate with additional partners on terms that are commercially reasonable to us. In addition, as the National OCS Program expands access to the OCS, transplant surgeons may increasingly rely on information provided to them by our clinical specialists and surgeons. We are responsible for the accuracy of information about the OCS that is provided to transplant surgeons who participate in the National OCS Program.

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 commercialization effort.

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 have limited experience in directly marketing and selling our products, and if we are unable to successfully expand our sales infrastructure and adequately address our customers' needs, it could negatively impact sales and market acceptance of our products and we may never generate sufficient revenue to achieve or sustain profitability.

We have limited experience in directly marketing and selling our products in the United States. Our operating results are dependent upon our sales and marketing efforts. If we fail to adequately promote and market our products, our sales may not grow or could significantly decrease.

We believe it is necessary to utilize a sales force that incorporates a specialized group consisting of sales representatives and clinical specialists who have experience with products to support our customers' needs. Competition for sales representatives and marketing employees is intense and we may be unable to attract and retain sufficient personnel to

maintain an effective sales and marketing force. If we are unable to adequately address our customers' needs, it could negatively impact sales and market acceptance of our products, and we may not generate sufficient revenue to achieve or sustain profitability.

Our future success will depend largely on our ability to continue to hire, train, retain and motivate skilled surgeons, sales representatives and clinical specialists, and ensuring our sales program offerings satisfy the needs of our customers. New hires require training and take time to achieve full productivity. If we fail to train new hires adequately, if we experience high turnover in our sales force in the future, or if our sales program offerings do not satisfy the needs of our customers, new hires may not become as productive as may be necessary to maintain or increase our sales.

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 year ended December 31, 2021, Duke University accounted for 11% 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. 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 some 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. In addition, if these suppliers are unable to deliver components to us, whether due to a labor shortage, slow down or stoppage, or for any other reason, we would be required to seek alternative suppliers. 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 also may choose to establish our own manufacturing process of certain components and we may not be successful in doing so. For example, we will need to seek FDA approval for any component design we choose to manufacture, which may not be granted in a reasonable time, or at all. In addition, the components we design may not be successful or may not provide a functional or economic benefit compared to similar components manufactured by third parties. If we choose to establish our own manufacturing process of components of the OCS, we may be required to procure additional raw materials for such processes, which may not be available. 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 development of the next generation 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 lead to additional regulatory obligations that could impact our marketing ability, 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.

Our results of operations could be materially harmed if we are unable to accurately forecast customer demand for our products and manage our inventory.

We seek to maintain sufficient levels of inventory in order to protect ourselves from supply interruptions, but keep limited components, sub-assemblies, materials and finished products on hand. To ensure adequate inventory supply and manage our operations with our suppliers, we forecast anticipated materials requirements and demand for our products in order to predict inventory needs and then place orders with our suppliers based on these predictions. Our ability to accurately forecast demand for our products could be negatively affected by many factors, including the rate of transplantations, product recalls, failure to accurately manage our commercial strategy, product introductions by competitors, an increase or decrease in customer demand for our products, our failure to accurately forecast customer acceptance of new products, changes to hospital capacity, staffing, procedure and protocol changes, unanticipated changes in general market conditions or regulatory matters and weakening of economic conditions or consumer confidence in future economic conditions.

Inventory levels in excess of customer demand may result in a portion of our inventory becoming obsolete or expiring, as well as inventory write-downs or write-offs. Conversely, if we underestimate customer demand for our products or our own requirements for components, subassemblies and materials, our manufacturing partners and suppliers may not be able to deliver components, sub-assemblies and materials to meet our requirements and our manufacturing may be affected by the impact of COVID-19 on our suppliers, which could result in inadequate inventory levels or interruptions, delays or cancellations of deliveries to our customers, any of which would damage our reputation, customer relationships and business. In addition, several components, sub-assemblies and materials incorporated into our products require lengthy order lead times, and additional supplies or materials may not be available when required on terms that are acceptable to us or our manufacturing partners, or at all, and our manufacturing partners and suppliers may not be able to allocate sufficient capacity in order to meet our increased requirements, any of which could have an adverse effect on our ability to meet customer demand for our products and our results of operations.

We will need to increase our manufacturing capacity in the future and may encounter problems at our manufacturing facility or otherwise.

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.

We may not be able to achieve or maintain satisfactory pricing and margins for our products.

Manufacturers of medical devices have a history of price competition, and we can give no assurance that we will be able to achieve satisfactory prices for our products or maintain prices at the levels we have historically achieved. Any decline in the amount that payors reimburse our customers for OCS Products could make it difficult for customers to continue using, or to adopt, our products and could create additional pricing pressure for us. If we are forced to lower the price we charge for our products, our gross margins will decrease, which will adversely affect our ability to invest in and grow our business. If we are unable to maintain our prices, or if our costs increase and we are unable to offset such increase with an increase in our prices, our margins could erode. We will continue to be subject to significant pricing pressure, which could harm our business and results of operations.

Price increases of the components used to manufacture our products and supply shortages could adversely affect our business and operating results.

The supply of raw materials to our component parts suppliers could be interrupted for a variety of reasons, including availability and pricing. We have experienced supply chain disruptions related to the COVID-19 pandemic, and continued disruptions to the supply chain could adversely affect our ability to meet commitments to customers. Significant price increases could adversely affect our results of operations and operating margins. In particular, inflation, changes in trade policies, the imposition of duties and tariffs and public health crises (such as the COVID-19 pandemic) could adversely impact the price or availability of raw materials and the components of our products. We may not be able to pass along increased component part prices to customers in the form of price increases or our ability to do so could be delayed. Consequently, our results of operations and financial condition may be adversely affected.

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 COPD, which includes emphysema and chronic bronchitis, could limit the demand for lung transplants. Alternative products, procedures and therapies including ventricular assist devices, cardiac rhythm management products, total artificial hearts, and drug therapies for the heart and surgical procedures could limit demand for heart transplants. 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. 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.

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

Clinical trials are necessary to support PMA applications and may be necessary to support future PMA supplements for modified versions of our marketed device products. Conducting clinical trials is a complex and expensive process, can take many years and outcomes are inherently uncertain. For the development of the next generation of OCS products, we may 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.

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, which may delay clearance or approval of products.

Clinical trials often require enrollment of large numbers of subjects, who may be difficult to identify, recruit and maintain as participants in the clinical trial. As a condition to our PMA approvals, we are required to conduct 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 potentially 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 any clinical trial:

- we have been required and, prior to collecting clinical data in the future to support new PMA applications, may 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 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, 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.

Failure can occur at any stage of clinical testing. For example, our clinical studies may produce negative or inconclusive results, and, in the future, we may decide, or regulators may require us, to conduct clinical and non-clinical testing in addition to those we have planned. After submission of our PMA applications for OCS Lung and OCS Heart, the FDA requested certain additional clinical analyses, technical information and clarifications as part of the agency's normal review process. The FDA ultimately approved both PMAs. The FDA could ask us to conduct additional clinical trials or submit additional evidence to support PMA applications in the future. Our failure to adequately demonstrate the safety and effectiveness of 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 marketing authorization from regulatory authorities in those countries. Authorization 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.

Risks Related to Our Operations and Business

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. 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. 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.

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. 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. 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.

As the cyber-threat landscape evolves, attacks are growing in frequency, sophistication and intensity, and are becoming increasingly difficult to detect. New and expanding threats to our information systems, including computer viruses, ransomware and phishing attacks and more sophisticated and targeted cyber-related attacks, as well as cybersecurity failures resulting from human error and technological errors, pose a risk to the security of our systems and the systems of our customers, business partners and suppliers, as well the confidentiality, availability and integrity of the data we process. In addition, there are numerous and evolving risks to cybersecurity, including criminal hackers, hacktivists, state-sponsored intrusions, industrial espionage, employee malfeasance and human or technological error.

We also have access to sensitive, confidential or personal data or information that is subject to privacy and security laws, regulations or customer-imposed controls. Despite our implementation of controls to protect our systems and sensitive, confidential or personal data or information, we may be vulnerable to material security breaches, theft, misplaced, lost or corrupted data, employee errors and/or malfeasance (including misappropriation by departing employees) that could potentially lead to the compromising of sensitive, confidential or personal data or information.

While we attempt to mitigate these risks by employing a number of measures, including employee training and maintenance of protective systems, such measures may not prove adequate to prevent cyberattacks, and we remain potentially vulnerable to additional known or unknown threats. The impact from such threats could be material. A significant cybersecurity incident could result in a range of potentially material negative consequences for us, including lost revenue; unauthorized access to, disclosure, modification, misuse, loss or destruction of company systems or data; theft of sensitive, regulated or confidential data, such as personal identifying information or our intellectual property; the loss of functionality of critical systems through ransomware, denial of service or other attacks; business delays, service or system disruptions, damage to equipment and injury to persons or property, and increased insurance premiums. The costs and operational consequences of defending against, preparing for, responding to and remediating an incident may be substantial. Further, we could be exposed to litigation, regulatory enforcement or other legal action as a result of an incident, carrying the potential for damages, fines, sanctions or other penalties, as well injunctive relief requiring costly compliance measures. A cybersecurity incident could also impact our brand, harm our reputation and adversely impact our relationship with our customers, employees and stockholders.

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, 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 years ended December 31, 2021 and 2020, 28% and 25%, respectively, of our net revenue was generated from customers located outside of the United States. We anticipate that international sales will continue to represent a meaningful 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 UK's exit from the European Union;
- 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 FCPA, and UK 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, the impacts of the COVID-19 pandemic 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. Our National OCS Program, a turnkey solution to provide outsourced organ retrieval and OCS organ management, may also require additional capital expenditures. 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.

If we pursue acquisitions, such acquisitions may expose us to additional risks.

We may review acquisition and strategic investment opportunities to expand our current product offerings, increase the size and geographic scope of our operations or otherwise offer growth and operating efficiency opportunities. There can be no assurance that we will be able to identify suitable candidates or consummate these transactions on favorable terms. If required, the financing for these transactions could result in an increase in our indebtedness, dilute the interests of our shareholders or both. The purchase price for some acquisitions may include additional amounts to be paid in cash in the future, a portion of which may be contingent on the achievement of certain future operating results of the acquired business. If the performance of any such acquired business exceeds such operating results, then we may incur additional charges and be required to pay additional amounts.

Our failure to successfully complete the integration of any acquired business or to achieve the long-term plan for such business, as well as any other adverse consequences associated with our acquisition and investment activities, could have an adverse effect on our business. Any acquisition may also disrupt our ongoing business, divert resources, increase our expenses, and distract our management from our ongoing operations.

The outbreak of the novel strain of coronavirus (COVID-19) impacts our business, financial condition, operating results, cash flows and prospects.

The COVID-19 pandemic, including efforts to contain the spread of the coronavirus, has impacted, and may continue to impact, our business, financial condition, operating results and cash flows, including as a result of the impact of new variants. Impacts to our business as a result of COVID-19 have included the temporary disruption of transplant procedures at many of the organ transplant centers who purchase OCS products; customer delays or reductions in customer capital expenditures and operating budgets and the related impact on our product sales; disruptions to our manufacturing operations and supply chain caused by facility closures, reductions in operating hours, staggered shifts and other social distancing efforts; labor shortages; decreased productivity and unavailability of materials or components; delays of reviews and approvals by the FDA and other health authorities; delays in our clinical trial enrollment; limitations on our employees' and customers' ability to travel; and delays in product installations, trainings or shipments to and from other affected countries and within the United States.

In the event that governmental authorities introduce new restrictions, our employees conducting manufacturing activities may not be able to access our manufacturing facilities, and our core activities may be significantly limited or curtailed, possibly for an extended period of time. We also may face limitations in employee resources that would otherwise be focused on our commercial, manufacturing or clinical activities, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people.

In response to the pandemic, healthcare providers have, and may need to further, reallocate resources, such as physicians, staff, hospital beds and intensive care unit facilities, as they prioritize limited resources and personnel capacity to focus on the treatment of patients with COVID-19. These actions significantly delay the provision of other medical care such as organ transplantation and reduce the number of transplant procedures that are performed, which negatively impacts our revenue and cash flows. These measures and challenges may continue for the duration of the COVID-19 pandemic.

The COVID-19 pandemic has also impacted, and may continue to impact, our third party suppliers, including through the effects of facility closures, reductions in operating hours, staggered shifts and other social distancing efforts, labor shortages, decreased productivity and unavailability of materials or components. While we maintain an inventory of finished products and raw materials used in our OCS products, a further prolonged pandemic could lead to shortages in the raw materials necessary to manufacture our products. The extent to which COVID-19 impacts operations of our third-party

partners will depend on future developments, which are highly uncertain and cannot be predicted with confidence. If we experience a prolonged disruption in our manufacturing, supply chains, or commercial operations, we would expect to experience a material adverse impact on our business, financial condition, results of operations and prospects.

Risks Related to Our Intellectual Property

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. 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 an interim patent term extension until November 6, 2021. We have not received final approval of the patent extension beyond the interim patent already requested. The maximum extensions 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, or USPTO, based on input from the FDA. On February 8, 2021, the FDA provided to the USPTO a determined regulatory review period for the OCS Lung. Under the FDA's analysis, the patent term extension of the '082 patent would be until November 6, 2021. We have not received communication from the USPTO, but expect that the USPTO's patent term extension for the '082 patent will maintain the November 6, 2021 expiration date. 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 2025 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. Additionally, 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 became effective on March 16, 2013. It is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. 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. 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 Act, 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 Act. 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, through May 2022. The Hatch-Waxman Act permits 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 revenue 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.

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, hospitals or other third parties. 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 maintain necessary FDA approval for the OCS, or obtain necessary FDA approval for future uses of the OCS, 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. As of September 2021, we have obtained a PMA for each of the OCS Lung, OCS Liver and OCS Heart.

Unforeseen requirements or delays in obtaining clearances or approvals from the FDA for any future indications of the OCS or future products could result in unexpected and significant costs for us and consume management’s time and other resources. The COVID-19 pandemic may result in delayed review and approval timelines. The pandemic has and may continue to cause disruptions in global regulatory agencies’ daily operations. Any delay in regulatory review resulting from such disruptions could materially affect our development and commercialization plans, which could adversely affect our business and results of operations. The duration and severity of the COVID-19 pandemic is unpredictable and difficult to assess.

PMA approval could be withdrawn or other restrictions imposed if post- market data demonstrate safety issues or inadequate performance. For 510(k) cleared devices, the FDA can use its enforcement authorities to require removal of a device from the market in case of safety issues.

If we are not able to maintain the necessary regulatory approvals for the OCS, or obtain the necessary regulatory 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.

If we fail to maintain the CE Mark in the European Union, Northern Ireland and the UKCA mark (as applicable) in Great Britain, we will not be able to commercially sell and market the OCS in the EU.

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. Our notified body, BSI is based in the Netherlands and issues the certificates that allow CE marking of the OCS products. We have CE Marks for each of the OCS Heart, the OCS Lung, and the OCS Liver, which were renewed in September 2017. These CE Marks 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 during the transitional period, we will have to meet the conditions set out in the transitional provisions in the MDR.

Post-Brexit the MDR applies in Northern Ireland in accordance with the Northern Irish Protocol but does not apply in Great Britain (England, Wales and Scotland). The UK Medical Devices Regulations 2002 provided a transitional period under which the UK will recognize EU CE marks until June 30, 2023. To be placed on the market in Great Britain after this date, medical devices must have undergone a conformity assessment in accordance with the UK Medical Devices Regulations 2002 and have the UKCA mark affixed. However, even devices that benefit from the transition period must still comply with the other requirements of the UK Medical Devices Regulations; for example, there are broader registration requirements with the Medicines and Healthcare Products Regulatory Agency, or the MHRA, and if the manufacturer is located outside the UK, a UK Responsible Person must be appointed. To continue to place products on the market in the European Union and United Kingdom after expiry of our existing notified body certificate, we will need to apply for their re-certification under the new MDR. We might not be able to continue to place the devices on the market in the European Union and/or United Kingdom for any current use of the OCS. If:

- we are not able to obtain re-certification of our products for their current use under the MDR and/or obtain cortication under the UK Medical Devices Regulations when required;
- 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 revenue 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, Northern Ireland and Great Britain.

Additionally, we have appointed a UK responsible person and have registered with the Medicines and Healthcare Products Regulatory Agency in the UK.

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 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 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. Alternatively, we may be required to enter into risk sharing arrangements with payers.

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), and the Quality and Safety of Organs Intended for Transplantation Regulations 2012 (Statutory Instrument (SI) 2012 No. 1501) (the Regulations) in the United Kingdom 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 CE marking of 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. Additionally, devices that are relying on a notified body certificate under the Medical Devices Directive under the MDR transition period will no longer benefit from the transition period if significant changes are made to the design and/or intended purpose of the device. If we make such changes we would need to CE Mark the devices under the MDR in order to continue to place them on the market in the European Union and/or United Kingdom.

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 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 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 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.

For our currently marketed OCS Lung, OCS Heart and OCS Liver, as part of the conditions of approval, we must complete PMA post-approval studies. For example, three post-approval studies must be competed for OCS Lung including, the OCS Lung INSPIRE Continuation PAS, which is a two-arm observational study intended to evaluate long-term outcomes of the OCS Lung INSPIRE Trial patients, the OCS Lung EXPAND Continuation PAS, which is a single arm study intended to evaluate long-term outcomes of the OCS Lung EXPAND Trial patients, and our OCS Lung Thoracic Organ Perfusion PAS 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 for both donor lungs currently utilized and unutilized for transplantation. The OCS Lung INSPIRE Continuation PAS, the OCS Lung EXPAND Continuation PAS 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.

We also are 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 incidents which meet the criteria for reporting, and to provide periodic safety update reports and trend reports. Additionally, national competent 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.

In addition, certain changes and other events with respect to regulatory approvals may cause an event of default under our Credit Agreement, including the initiation of a regulatory enforcement action or issuance of a warning letter with respect to the Company or any of its products or manufacturing facilities that causes the discontinuance of marketing or withdrawal of any products or causes delay in manufacturing. See "Item 7. Management's Discussion and Analysis -Long-Term Debt," in this Annual Report on Form 10-K.

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 relevant EU competent 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 to 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. For example, in the European Union the MDR includes detailed requirements for clinical investigations, which are in line with the international standard ISO 14155:2011 on good clinical practical, or GCP. 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 recalled certain OCS 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.

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 required without delay to take corrective action against a device (including withdrawal/recall of a device) and notify other national competent authorities, the European Commission and notified bodies (as applicable) of any devices that present an unacceptable risk to the health or safety of patients, users or other persons, or other aspects of the protection of public health. Other non-compliance with the MDR may also lead to corrective action being taken and notifications being sent if the non-compliance is not rectified within a given time period (as determined by the competent authority). 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 and the Medical Devices Regulations 2002 (UK MDR 2002) in Great Britain. Our notified body in the Netherlands, BSI, could determine either itself or at the request of a competent authority that our OCS products do not meet the regulatory requirements for CE marking, which would result in withdrawal of the certificates that allow the CE marking required to market the OCS products in the European Union. In addition, we may not be able to affix the CE Mark to new or modified products and 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. While we implement corrective and preventive action related to any inspection observations, 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. 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. 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, transplant surgeons may cease using the OCS as often or at all, 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 global 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 as required. 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, 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.

Our OCS products have been approved for marketing 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 commercial team to not promote the OCS for uses outside of the approved indications for use/intended purpose, 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/ by any foreign regulatory body or for which they are CE marked 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, or that the materials or training are false or misleading, 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 violations that do not necessitate a warning letter, injunction, seizure, civil fine or criminal penalties. In the EU the MDR expressly prohibits misleading claims in the form of off-label promotion and the MDR grants enforcement powers to national competent authorities. It is also possible that other federal, state or foreign enforcement authorities might take action under other regulatory authority, such as false claims laws or consumer protection 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 may be 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.

In the EU, Regulation (EU) 2017/745, or the MDR, which repealed and replaced the Medical Devices Directive (93/42/EEC) with effect from May, 26 2021. Although the MDR now applies so all new devices placed on the market must be CE marked under it, under the transition period granted by the MDR, certificates issued by notified bodies for medical devices under the Medical Devices Directive before May 26, 2021 remain valid until the period indicated on the certificate, subject to all certificates becoming void on May 27, 2024. Post-Brexit the MDR applies in Northern Ireland in accordance with the Northern Irish Protocol but does not apply in Great Britain (England, Wales and Scotland). The UK Medical Devices Regulations 2002 provided a transitional period under which the UK will recognize EU CE marks until June 30, 2023. To be placed on the market in Great Britain after this date, medical devices must have undergone a conformity assessment in accordance with the UK Medical Devices Regulations 2002 and have the UKCA mark affixed.

We recognize that our products will have to be re-certified under the MDR by September 2022 (as they currently benefit from the MDR transition period) and we are actively working with our notified body to meet the MDR requirements.

However, if we do not manage to re-certify our products under this regulation or can no longer rely on the transitional provisions (e.g., if a substantial change is made to the design or intended purpose), we may have to take our products off the EU market until this is the case.

We also recognize that our products will need to be certified and have a UKCA mark affixed to be placed on the market in Great Britain from July 1, 2023. However, in 2021 the MHRA ran a consultation on the future regulation of medical devices in the UK. This might lead to substantial changes in the regulatory framework/requirements imposed on medical devices. This could slow our ability to obtain the necessary certification and we may have to take our product off the market in Great Britain until we could obtain a UKCA mark.

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;

- 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: the FCPA, 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 UK 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 FCPA, 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 U.S. 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 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. The substantive offences of offering or receiving a bribe will be committed by an individual where either the bribery takes place in the U.K, or the person paying or receiving the bribe has a close connection with the UK An organization which is either incorporated in or carries on part of its business in the U.K will be liable under the Bribery Act if a person associated with the organization (being persons performing services for it) pays a bribe anywhere in the world intending to obtain or retain business for the organization. This is a strict liability offense with the only defenses available being that the organization implemented "adequate procedures" to prevent bribery or it was reasonable for it to not have such procedures in place. 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. For example, the CCPA affords California residents expanded privacy rights and protections, including civil penalties for violations and statutory damages under a private right of action for data security breaches. These protections will be expanded by CPRA, which will be operational in most key respects on January 1, 2023. Similar legislative proposals have passed or are being advanced in other states. 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. Our ongoing efforts to comply with evolving laws and regulations may be costly and require ongoing modifications to our policies, procedures and systems. Failure to comply with laws regarding data protection would expose us to risk of enforcement actions and penalties under such laws. Even if we are not determined to have violated applicable data laws, government investigations into these issues can be expensive and lengthy and generate adverse publicity, which could harm our business, financial condition, results of operations or prospects.

The EEA and the UK, as well as other international jurisdictions, also have laws and regulations dealing with the collection, use and processing of personal data concerning individuals who are located there. Those laws are often more restrictive than those in the United States. For example, we are subject to the requirements of the GDPR, which imposes 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 pseudonymized (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, including laws and regulations limiting the processing of genetic, biometric or health data, which could limit our ability to use and share personal data or cause our costs to increase, and harm our business and financial condition. If we do not comply with our obligations under the GDPR, we could be exposed to enforcement activity from EU regulators, including substantial fines and litigation. In addition, EU law restricts transfers of personal data to the United States unless certain requirements are met. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. For example, in July 2020, the Court of Justice of the European Union invalidated the U.S.-EU Privacy Shield Framework, which has led to increased scrutiny of data transfers from the EEA and the UK to the United States generally and may increase our costs of compliance with data privacy legislation. We rely on a mixture of mechanisms to transfer personal data from our European business to the United States. We are also subject to the laws of each EU member state implementing any EU directive applicable to our processing activities, including Directing 2002/58/EC.

We are subject to the requirements of the UK Data Protection Law as amended and superseded from time to time. UK Data Protection Law means: (i) the GDPR as it forms part of UK law by virtue of section 3 of the European Union (Withdrawal) Act 2018; (ii) the Data Protection Act 2018; (iii) the Privacy and Electronic Communications (EC Directive) Regulations 2003 as they continue to have effect by virtue of section 2 of the European Union (Withdrawal) Act 2018; and (iv) any other laws in the field of data protection in force in the UK from time to time applicable (in whole or in part) to us.

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 or potential future legislation reforming the U.S. healthcare system, could harm our business, financial condition and results of operations.

We operate in a highly-regulated industry. The U.S. and state governments continue to propose and pass legislation or take administrative action that may affect the availability and cost of healthcare. Healthcare reform initiatives 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. For example, the Affordable Care Act, which was enacted in 2010, substantially revised the coverage, delivery and payment of health care services. For example, the Affordable Care Act:

- 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 health care coverage through Medicaid expansion and the implementation of the so-called “individual mandate” for health insurance coverage.

Since its enactment, there have been and likely will be judicial, administrative, executive, and legislative challenges to certain aspects of the Affordable Care Act. For example, tax reform legislation was enacted at the end of 2017 that eliminates the tax penalty for individuals who do not maintain sufficient health insurance coverage beginning in 2019 (the so-called “individual mandate”). More recently, on June 17, 2021, the U.S. Supreme Court dismissed the latest judicial challenge to the Affordable Care Act brought by several states without specifically ruling on the constitutionality of the Affordable Care Act. Changes resulting from any successful challenges or other future modifications have a material impact on our business.

Beyond the Affordable Care Act, there have been and will likely continue to be ongoing healthcare reform efforts. These reform efforts have and may continue to focus on coverage and payment for organ procurement and transplant. For example, the Centers for Medicare & Medicaid Services issued regulations in 2020 and 2021 that revised Medicare conditions of participation for organ procurement organizations as well as organ acquisition payment policies for organ procurement organizations, transplant centers and donor hospitals.

We expect additional state and federal healthcare policies and reform measures to be adopted in the future, any of which could limit coverage or 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, coverage or reimbursement of services provided by organ procurement organizations, transplant centers or hospitals could affect demand for the OCS, which in turn could have a material adverse effect on our business, financial condition and results of operations.

In addition, other broader legislative changes have been adopted that could have an adverse effect upon, and could prevent, our products’ commercial success. The Budget Control Act of 2011, as amended, or the Budget Control Act, includes provisions intended to reduce the federal deficit, including reductions in Medicare payments to providers through

2030 (except May 1, 2020 to March 31, 2022). Any significant spending reductions affecting Medicare, Medicaid, or other publicly funded or subsidized health programs, or any significant taxes or fees imposed as part of any broader deficit reduction effort or legislative replacement to the Budget Control Act, or otherwise, could have an adverse impact on our anticipated product revenue.

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 General Risks

The market price of our common stock has been and may continue to be volatile and could subject us to securities class action litigation.

Over the last twelve months, the price per share of our common stock has ranged from as low as $17.20 to as high as $49.50. 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 post-approval studies or clinical trials relating to next generation products for 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 or changes in the status of, or developments relating to, 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.

An active trading market may not be sustained.

You may not be able to sell your shares quickly or at a recently reported market price if trading in our common stock does not remain active. The lack of an active market may also reduce the fair market value of your shares. An inactive market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration.

If securities or industry analysts issue an adverse or misleading opinion regarding our business or do not publish research or publish unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us or our business. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. Moreover, if any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model or our stock performance, or if our operating results fail to meet the expectations of the investor community, one or more of the analysts who cover our company may change their recommendations regarding our company, and our stock price could decline.

We have adopted 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 grant the chairperson presiding over any meetings of shareholders the right to adjourn such meeting. 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 designate the Business Litigation Session of the Superior Court of Suffolk County, Massachusetts (or, if and only if the Business Litigation Session of the Superior Court of Suffolk County, Massachusetts lacks jurisdiction, another state or federal court 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 designate the Business Litigation Session of the Superior Court of Suffolk County, Massachusetts (or, if and only if the Business Litigation Session of the Superior Court of Suffolk County, Massachusetts lacks jurisdiction, another state or federal court located within the Commonwealth of Massachusetts) as the sole and exclusive forum for any action under Massachusetts statutory or common law: brought derivatively on our behalf, asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our shareholders, asserting a claim arising pursuant to any provision of the Massachusetts Business Corporation Act or 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 restated articles of organization provide that any person or entity purchasing or

otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the foregoing provisions. This provision will not apply to actions arising under the Exchange Act, or the Securities Act of 1933, as amended, or the Securities Act. Additionally, 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 the Business Litigation Session of the Superior Court of Suffolk County, Massachusetts or 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 venues or jurisdictions, which could materially and adversely affect our business, financial condition, operating results, cash flows and prospects.

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.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, as amended, our management is required to report on, and our independent registered public accounting firm is required to attest to, the effectiveness of our internal control over financial reporting. This assessment includes disclosure of any material weakness identified by our management in our internal control over financial reporting. In addition, we are required to comply with the SEC's rules implementing Section 302 of the Sarbanes-Oxley Act, which requires management to certify financial and other information in our quarterly and annual reports, and we are required to disclose significant changes made in our internal controls and procedures on a quarterly basis.

If we identify a material weakness in our internal control over financial reporting, we may not be able to remediate the material weakness identified in a timely manner or maintain all of the controls necessary to remain in compliance with our reporting obligations. 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 controls over financial reporting are effective, or if our independent registered public accounting firm is unable to express an unqualified opinion as to the effectiveness of our internal control over financial reporting in future periods, 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.

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.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our corporate headquarters and manufacturing and clinical training facilities are located in Andover, Massachusetts, where we lease 105,479 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, 2027 with an option to extend the term beyond the expiration date for one additional period of five years.

We believe that our current facilities are adequate to meet our current needs, although we may seek to negotiate new leases or evaluate additional or alternate space for our operations. We believe appropriate alternative space would be readily available on commercially reasonable terms.

Item 3. Legal Proceedings.

We are not currently subject 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.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Certain Information Regarding the Trading of Our Common Stock

Our common stock trades under the symbol "TMDX" on the Nasdaq Global Market and has been publicly traded since May 2, 2019. Prior to this time, there was no public market for our common stock.

Holders of Our Common Stock

As of February 15, 2022, there were approximately 24 holders of record of shares of our common stock. These amounts do not include stockholders for whom shares are held in "nominee" or "street" name.

Securities authorized for issuance under equity compensation plans

Information about our equity compensation plans will be included in our definitive proxy statement to be filed with the SEC with respect to our 2022 Annual Meeting of Stockholders and is incorporated herein by reference.

Recent Sales of Unregistered Equity Securities

None.

Use of Proceeds from Initial Public Offering

Our IPO was effected through a Registration Statement on Form S-1 (File No. 333-230736), which was declared effective by the SEC on May 1, 2019 and a registration statement on Form S-1MEF (File No. 333-231166), which was automatically effective upon filing with the SEC on May 1, 2019. The net offering proceeds to us, after deducting underwriting discounts and commissions and other offering expenses, were $91.4 million. None of the net proceeds were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning 10.0% or more of any class of our equity securities or to any other affiliates, other than payments in the ordinary course of business to officers for salaries and to non-employee directors as compensation for board or board committee service. As of December 31, 2021, we estimate that we have used approximately $80.6 million of the net proceeds from our IPO for commercialization of our OCS products, research and development, and general corporate purposes. We are holding a significant portion of the remaining net proceeds in money market funds, U.S. Treasury securities and U.S. government agency bonds. There has been no material change in our planned use of the net proceeds from the IPO as described in the final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act, with the SEC, on May 2, 2019.

Issuer Purchases of Equity Securities

We did not purchase any of our registered equity securities during the period from September 30, 2021 to December 31, 2021.

Dividends

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.

Item 6.

Reserved

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Item 1A. Risk Factors" section of this Annual Report on Form 10-K, 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 the use of the OCS has the potential to significantly increase the number of organ transplants and improve post-transplant outcomes. We have developed our National OCS Program, a turnkey solution to provide outsourced organ retrieval and OCS organ management, to provide transplant programs with a more efficient process to procure donor organs with the OCS.

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. We have commercialized the OCS Lung and OCS Heart outside of the United States. By the end of the third quarter of 2021, all three of our products, OCS Lung, OCS Heart, and OCS Liver have received Pre-Market Approval, or PMA, from the Food and Drug Administration, or FDA, as follows:

- OCS Lung for the preservation of standard criteria donor lungs for double-lung transplantation;
- OCS Lung for the preservation of donor lungs initially deemed unsuitable due to limitations of cold storage for double-lung transplantation;
- OCS Heart for the preservation of DBD donor hearts deemed unsuitable due to limitations of cold storage (e.g. >4 hours of cross-clamp time); and
- OCS Liver for the preservation of DBD and DCD donor livers $\leq$ 55 years old, macrosteatosis <15% and with $\leq$ 30 mins of warm ischemia time.

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; commercializing our products; developing our market and distribution chain and providing general and administrative support for these operations. To date, we have funded our operations primarily with proceeds from sales of preferred stock, borrowings under loan agreements, proceeds from the sale of common stock in our public offerings and revenue from clinical trials and commercial sales of our OCS products.

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 $30.3 million and $25.6 million for the years ended December 31, 2021 and 2020, respectively. We incurred net losses of $44.2 million and $28.7 million, respectively, for those same years. As of December 31, 2021, we had an accumulated deficit of $442.4 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 United States and select non-U.S. markets, including growing our commercial team, which will pursue increasing commercial sales of our OCS products; scaling our manufacturing operations; building our commercial operations, continuing research, development and clinical trial efforts; seeking regulatory clearance for new products and product enhancements, including new indications, in both the United States and select non-U.S. markets; and 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 our cash, cash equivalents and marketable securities, will be sufficient for us to fund our operating expenses, capital expenditure requirements and debt service payments for at least 12 months following the filing of our Annual Report on Form 10-K. 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".

COVID-19

The COVID-19 pandemic, including efforts to contain the spread of the coronavirus, has impacted, and may continue to impact, our business, financial condition, operating results and cash flows, including as a result of the impact of new variants. Impacts to our business as a result of COVID-19 have included the temporary disruption of transplant procedures at many of the organ transplant centers who purchase OCS products; customer delays or reductions in customer capital expenditures and operating budgets and the related impact on our product sales; disruptions to our manufacturing operations and supply chain caused by facility closures, reductions in operating hours, staggered shifts and other social distancing efforts; labor shortages; decreased productivity and unavailability of materials or components; delays of reviews and approvals by the FDA and other health authorities; delays in our clinical trial enrollment; limitations on our employees' and customers' ability to travel, and delays in product installations, trainings or shipments to and from other affected countries and within the United States.

In response to the pandemic, healthcare providers have, and may need to further, reallocate resources, such as physicians, staff, hospital beds and intensive care unit facilities, as they prioritize limited resources and personnel capacity to focus on the treatment of patients with COVID-19. These actions significantly delay the provision of other medical care such as organ transplantation and reduce the number of transplant procedures that are performed, which negatively impacts our revenue and cash flows. These measures and challenges may continue for the duration of the COVID-19 pandemic.

The COVID-19 pandemic has also impacted, and may continue to impact, our third party suppliers, including through the effects of facility closures, reductions in operating hours, staggered shifts and other social distancing efforts, labor shortages, decreased productivity and unavailability of materials or components. While we maintain an inventory of finished products and raw materials used in our OCS products, a further prolonged pandemic could lead to shortages in the raw materials necessary to manufacture our products. The extent to which COVID-19 impacts operations of our third-party partners will depend on future developments, which are highly uncertain and cannot be predicted with confidence. If we experience a prolonged disruption in our manufacturing, supply chains, or commercial operations, we would expect to experience a material adverse impact on our business, financial condition, results of operations and prospects.

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 OCS 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 and Organ Procurement Organizations 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 contracts have multiple-performance obligations that contain promises consisting of OCS Perfusion Sets and OCS Solutions. In some of those contracts, the promises also include an OCS Console, whether sold or loaned to the customer.

We have customer agreements under which we loan our OCS Consoles to the customer for the duration of the agreement. In such cases, we place an organ-specific OCS Console at the customer site for its use free of charge, and the customer separately purchases from us the OCS disposable sets used in each transplant procedure. 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 OCS disposable sets. For these reasons, we have determined that part of the selling price for the disposable set is an implied rental payment for use of the OCS Console.

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

Under some of our customer clinical trial agreements, we made payments to our customers for reimbursements of clinical trial materials and for specified clinical documentation related to their use of our OCS products. Because some of these payments did not provide us with a separately identifiable benefit, we recorded such payments as a reduction of revenue from the customer, resulting in our net revenue presentation. We recorded reimbursable clinical trial costs as a reduction of revenue of $1.1 million and $2.7 million for the years ended December 31, 2021 and 2020, respectively.

Through December 31, 2021, all of our sales outside of the United States have been commercial sales (unrelated to any clinical trials).

We expect that our net revenue will increase over the long term as a result of receiving PMAs for the OCS Lung, OCS Heart and OCS Liver in the United States. Additionally, commercial sales of OCS disposable sets generally have a higher average selling price than clinical trial sales of OCS disposable sets. We also expect that our net revenue will increase over the long term 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 OCS disposable sets are the costs of our OCS Lung, OCS Heart and OCS Liver Solutions. We expect that cost of revenue will increase or decrease in absolute dollars primarily as, and to the extent that, our net revenue increases or decreases.

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 overhead costs, direct labor, the selling price of our OCS products and fluctuations in amounts paid by us to customers related to reimbursements of their clinical trial expenses during clinical trials.

We expect that cost of revenue as a percentage of net revenue will moderately decrease and gross margin and gross profit will moderately increase over the long term as our sales and production volumes increase and our cost per unit of our OCS disposable sets decreases due to economies 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. 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 continue 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 over the long term 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 other served geographies, as well as 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 commercial 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 show costs 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 commercial 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 over the long term as we increase our headcount to support the expected continued sales growth of our OCS products. We also anticipate that we will continue to incur increased accounting, audit, legal, regulatory, compliance and director and officer insurance costs as well as investor and public relations expenses associated with our continued operation as a public company.

Other Income (Expense)

Interest Expense

Interest expense consists of interest expense associated with outstanding borrowings under our loan agreement as well as the amortization of debt discount associated with such agreement.

Other Income (Expense), Net

Other income (expense), net includes interest income, realized and unrealized foreign currency transaction gains and losses and other non-operating income and expense items unrelated to our core operations.

Interest income consists of interest earned on our invested cash balances. Foreign currency transaction gains and losses result from intercompany transactions 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. We record provisions for foreign income taxes of an insignificant amount related to the operations of one of our foreign subsidiaries.

As of December 31, 2021, we had U.S. federal and state net operating loss carryforwards of $368.1 million and $304.0 million, respectively, which may be available to offset future taxable income and begin to expire in 2022 and 2030, respectively. Our federal net operating loss carryforwards include $156.4 million that can be carried forward indefinitely. As of December 31, 2021, we also had U.S. federal and state research and development tax credit carryforwards of $8.0 million and $5.3 million, respectively, which may be available to offset future tax liabilities and begin to expire in 2022 and 2024, respectively. As of December 31, 2021, 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.

Comparison of the Years Ended December 31, 2021 and 2020

The following table summarizes our results of operations for the years ended December 31, 2021 and 2020:

	Year Ended December 31,		
	2021	2020	Change
	(in thousands)		
Net revenue	$ 30,262	$ 25,639	$ 4,623
Cost of revenue	9,103	9,004	99
Gross profit	21,159	16,635	4,524
Operating expenses:			
Research, development and clinical trials	22,304	18,831	3,473
Selling, general and administrative	38,283	24,188	14,095
Total operating expenses	60,587	43,019	17,568
Loss from operations	(39,428)	(26,384)	(13,044)
Other income (expense):			
Interest expense	(3,874)	(3,985)	111
Other income (expense), net	(877)	1,653	(2,530)
Total other expense, net	(4,751)	(2,332)	(2,419)
Loss before income taxes	(44,179)	(28,716)	(15,463)
Provision for income taxes	(36)	(32)	(4)
Net loss	$ (44,215)	$ (28,748)	$ (15,467)

Net Revenue

	Year Ended December 31,		
	2021	2020	Change
	(in thousands)		
Net revenue by geography:			
United States	$ 21,861	$ 19,239	$ 2,622
Outside the U.S.	8,401	6,400	2,001
Total net revenue	$ 30,262	$ 25,639	$ 4,623
Net revenue by OCS product:			
OCS Lung net revenue	$ 10,665	$ 6,194	$ 4,471
OCS Heart net revenue	17,683	14,196	3,487
OCS Liver net revenue	1,914	5,249	(3,335)
Total net revenue	$ 30,262	$ 25,639	$ 4,623

Net revenue from customers in the United States was $21.9 million in the year ended December 31, 2021 and increased by $2.6 million in the year ended December 31, 2021 compared to the year ended December 31, 2020 primarily due to higher sales volumes of our OCS Lung and OCS Heart disposable sets, partially offset by lower sales volumes of our OCS Liver disposable sets. Net revenue from sales of OCS Lung disposable sets in the United States increased from $5.4 million in the year ended December 31, 2020 to $9.8 million in the year ended December 31, 2021. The increase was due primarily to higher sales volume of OCS Lung disposable sets as the year ended December 31, 2020 was negatively impacted by the COVID-19 pandemic. Net revenue from OCS Heart disposable sets sold to customers commercially and for use in our ongoing clinical trials in the United States increased by $1.5 million during the year ended December 31, 2021. The increase was due to higher sales volume of OCS Heart disposable sets following approval from the FDA for commercial use in September 2021. Net revenue from OCS Liver disposable sets sold in the United States decreased by $3.3 million during the year ended December 31, 2021. The lower sales volume of OCS Liver disposable sets was primarily a result of the completion of enrollment in our OCS Liver PROTECT CAP Trial early in the first quarter of 2021. This decrease was partially offset by commercial sales of OCS Liver disposable sets sold following FDA approval in September 2021.

Net revenue from customers outside the United States was $8.4 million in the year ended December 31, 2021 compared to $6.4 million in the year ended December 31, 2020. The increase in net revenue from customers outside the United States was primarily due to higher sales volume of OCS Heart disposable sets. Net revenue from OCS Heart disposable sets increased by $2.0 million from the year ended December 31, 2020 to the year ended December 31, 2021.

Cost of Revenue, Gross Profit and Gross Margin

Cost of revenue increased by $0.1 million in the year ended December 31, 2021 compared to the year ended December 31, 2020. Gross profit increased by $4.5 million in the year ended December 31, 2021 compared to the year ended December 31, 2020. Gross margin was 70% and 65% for the years ended December 31, 2021 and 2020, respectively. Gross profit and gross margin increased primarily as a result of increased sales volume and increased sales of higher margin OCS disposable sets.

Operating Expenses

Research, Development and Clinical Trials Expenses

	Year Ended December 31,		
	2021	2020	Change
	(in thousands)		
Personnel related (including stock-based compensation expense)	$ 8,292	$ 7,853	$ 439
Clinical trials costs	3,180	4,708	(1,528)
Consulting and third-party testing	4,212	1,432	2,780
Laboratory supplies and research materials	2,837	2,095	742
Other	3,783	2,743	1,040
Total research, development and clinical trials expenses	$ 22,304	$ 18,831	$ 3,473

Total research, development and clinical trials expenses increased by $3.5 million from $18.8 million in the year ended December 31, 2020 to $22.3 million in the year ended December 31, 2021. Personnel related costs increased by $0.4 million as a result of increased stock-based compensation expense due to additional grants to new and existing employees and an increase in the respective grant date fair values from the increased price of our stock. Clinical trials costs decreased by $1.5 million due to the completion of enrollment in the OCS Heart DCD CAP Trial and completion of our OCS Liver PROTECT CAP Trial in 2021. Consulting and third-party testing costs increased by $2.8 million due primarily to increased activity in our next generation program and increased regulatory activity, including costs related to preparation for both FDA advisory committee panels in April and July 2021 for the OCS Heart and OCS Liver, respectively. The increase in laboratory supplies and research materials costs of $0.7 million was driven by increased research activity related to our next generation program and other product enhancement initiatives. The increase in other costs of $1.0 million was due primarily to increased product development activities and increased spending on facilities, travel, and risk management as restrictions related to COVID-19 were relaxed in 2021 as compared to the previous year.

Selling, General and Administrative Expenses

	Year Ended December 31,		
	2021	2020	Change
	(in thousands)		
Personnel related (including stock-based compensation expense)	$ 21,202	$ 12,292	$ 8,910
Professional and consultant fees	7,032	5,479	1,553
Tradeshows and conferences	1,445	931	514
Other	8,604	5,486	3,118
Total selling, general and administrative expenses	$ 38,283	$ 24,188	$ 14,095

Total selling, general and administrative expenses increased by $14.1 million from $24.2 million in the year ended December 31, 2020 to $38.3 million in the year ended December 31, 2021. Personnel related costs increased by $8.9 million as a result of the continued expansion of our commercial team including National OCS Program resources to support commercial sales of our OCS Lung, OCS Heart and OCS Liver products in the United States. Stock-based compensation expense also increased by $3.7 million due primarily to additional grants to new and existing employees and an increase in the respective grant date fair values from the increased price of our stock. Professional and consultant fees increased by $1.6 million as a result of additional public company compliance costs. Tradeshows and conferences costs increased by $0.5 million due to a partial return of tradeshow and conference activity as restrictions implemented in response to the COVID-19 pandemic were eased. Other costs increased by $3.1 million as a result of increased spending on travel and insurance as restrictions related to COVID-19 were relaxed in 2021 as compared to the previous year and we expanded our organization.

Other Income (Expense)

Interest Expense

Interest expense was $3.9 million and $4.0 million for the years ending December 31, 2021 and 2020, respectively.

Other Income (Expense), Net

Other income (expense), net for the years ended December 31, 2021 and 2020 included interest income of $0.1 million and $0.7 million, respectively, resulting from interest earned on invested cash balances. Other income (expense), net also included $1.0 million of realized and unrealized foreign currency transaction losses and $1.0 million of realized and unrealized foreign currency transaction gains, respectively. Interest income decreased from 2020 to 2021 as a result of lower invested balances.

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, proceeds from the sale of common stock in our public offerings and revenue from clinical trials and commercial sales of our OCS products.

As of December 31, 2021, we had cash, cash equivalents, and marketable securities of $92.5 million.

Cash Flows

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

	Year Ended December 31,	
	2021	2020
	(in thousands)	
Cash used in operating activities	$ (28,864)	$ (30,265)
Cash provided by (used in) investing activities	29,267	(41,598)
Cash provided by financing activities	1,393	75,549
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(797)	803
Net increase in cash, cash equivalents and restricted cash	$ 999	$ 4,489

Operating Activities

During the year ended December 31, 2021, operating activities used $28.9 million of cash, primarily resulting from our net loss of $44.2 million, partially offset by net non-cash charges of $12.3 million and net cash provided by changes in our operating assets and liabilities of $3.0 million. Net cash provided by changes in our operating assets and liabilities for the year ended December 31, 2021 consisted primarily of an increase in accounts payable and accrued expenses and other current liabilities of $10.0 million and a decrease in accounts receivable of $0.8 million, partially offset by an increase in inventory of $4.9 million and an increase in prepaid expenses and other current assets of $3.2 million.

During the year ended December 31, 2020, operating activities used $30.3 million of cash, primarily resulting from our net loss of $28.7 million and net cash used by changes in our operating assets and liabilities of $5.6 million, partially offset by net non-cash charges of $4.1 million. Net cash used by changes in our operating assets and liabilities for the year ended December 31, 2020 consisted primarily of a $3.9 million decrease in accounts payable and accrued expenses and other current liabilities, a $1.7 million increase in inventory and a $0.8 million increase in prepaid expenses and other current assets, partially offset by a $0.9 million increase in deferred rent.

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 and timing of invoices and payments.

Investing Activities

During the year ended December 31, 2021, net cash provided by investing activities of $29.3 million consisted of proceeds from sales and maturities of marketable securities of $104.8 million, partially offset by $72.0 million in purchases of marketable securities and $3.5 million in purchases of property and equipment.

During the year ended December 31, 2020, net cash used in investing activities of $41.6 million consisted of $121.8 million in purchases of marketable securities and $0.5 million in purchases of property and equipment, partially offset by proceeds from sales and maturities of marketable securities of $80.7 million.

Financing Activities

During the year ended December 31, 2021, net cash provided by financing activities of $1.4 million consisted of proceeds from the issuance of common stock upon exercise of stock options of $1.0 million and proceeds from the issuance of common stock in connection with the employee stock purchase plan of $0.4 million.

During the year ended December 31, 2020, net cash provided by financing activities of $75.5 million consisted primarily of proceeds from the issuance of common stock in our May 2020 public offering of $75.7 million and our employee share ownership plans of $0.6 million, both partially offset by payments of offering costs of $0.7 million.

Long-Term Debt

We have a Credit Agreement with OrbiMed, pursuant to which we borrowed $35.0 million. Borrowings under the Credit Agreement bear interest at an annual rate equal to the 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. 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 financial covenants include maintaining a minimum liquidity amount of $3.0 million; the requirement, on an annual basis, to deliver to OrbiMed annual audited financial statements with an unqualified audit opinion from our independent registered public accounting firm; 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), failure to comply with certain covenants, including the minimum liquidity and unqualified audit opinion covenants, and a material adverse change in our business, operations or other financial condition. As of December 31, 2021, we were in compliance with all of the covenants under the Credit Agreement.

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. While we do not expect that the transition from LIBOR, including any legal or regulatory changes made in response to its future phase out, or the risks related to its discontinuance will have a material effect on our financing costs, the impact is uncertain at this time.

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 commercial team, grow our National OCS Program, scale our manufacturing operations, continue research, development and clinical trial efforts, and seek regulatory approval for new products and product enhancements, including new indications, both in the United States and in select non-U.S. markets. In addition, following the closing of our IPO, we have incurred and expect to continue 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 post-approval studies or 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 associated with building our commercial operations;
- 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.

We believe that our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses, capital expenditure requirements, and debt service payments for at least 12 months following the filing of our annual report on Form 10-K.

We may need to raise additional funding, which might not be available on favorable terms or at all. See "Item 1A. Risk Factors—Risks Related to Our Financial Position and Need for Additional Capital" in this Annual Report on Form 10-K.

Material Contractual Obligations

Our contractual obligations include amounts payable as principal and interest payments under the Credit Agreement. As of December 31, 2021, our outstanding principal balance was $35.0 million and is due in 2023. We estimate we will pay $3.3 million in interest payments during 2022. Our estimate of payments is based on an assumed rate of 9.5%, which was the interest rate in effect at December 31, 2021. Because such interest rate is below the PIK interest threshold of 11.5%, we did not include PIK in our calculated payments.

We lease our facilities under non-cancelable operating leases that have remaining lease terms of six years as of December 31, 2021. As of December 31, 2021, we had fixed lease payment obligations of $12.4 million, of which $1.9 million is payable during 2022.

In January 2021, we entered into an unconditional $9.5 million purchase commitment in the ordinary course of business, for goods with specified annual minimum quantities to be purchased through December 2029. The contract is not cancellable without penalty. As of December 31, 2021, our remaining purchase commitment is $8.0 million.

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 discussion 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. The preparation of our consolidated financial statements and related disclosures requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenue, costs and expenses, and related disclosures. We evaluate our estimates 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 Annual Report on Form 10-K, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated 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 OCS disposable set for use on the customer's existing organ-specific OCS Console.

We recognize revenue from sales to customers applying the following five steps: (1) identification of the contract, or contracts, with a customer, (2) identification of the performance obligations in the contract, (3) determination of the transaction price, (4) allocation of the transaction price to the performance obligations in the contract, and (5) recognition of revenue when, or as, performance obligations are satisfied.

Substantially all of our customer contracts have multiple-performance obligations that contain deliverables consisting of OCS Perfusion Sets and OCS Solutions. In some of those customer contracts, the deliverables also include an OCS Console. We evaluate each promise within a multiple-performance obligation arrangement to determine whether it represents a distinct performance obligation. The primary performance obligations in our customer arrangements from which we derive revenue are the OCS Perfusion Sets, the OCS Solutions and the OCS Console. Revenue for each OCS Perfusion Set and OCS Solutions is recognized at the point in time at which control is transferred to the customer, which is when title transfers to the customer, typically upon arrival at the customer site.

When a customer order includes an OCS Console, we have determined that customer training and the equipment set-up of the OCS Console, each performed by us, are not distinct 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. In addition, we have determined that the OCS Console itself is not distinct because the customer cannot benefit from the OCS Console without the training and equipment set-up having been completed. As a result, when the order includes an OCS Console, we have concluded that training, OCS Console equipment set-up, and the OCS Console itself are highly interdependent and represent a single, combined performance obligation. We recognize revenue from the single, combined performance obligation only once the OCS Console has arrived at the customer site and the training and equipment set-up have been completed by us.

Customer orders may include the loan of an OCS Console as well as OCS disposable sets. 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 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 of OCS 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. Therefore, we allocate the arrangement consideration between the lease deliverables (i.e., the OCS Console) and non-lease deliverables (i.e., the OCS disposable sets) based on the relative estimated standalone selling price of each distinct performance obligation. To date, the amounts allocated to lease deliverables have been insignificant.

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

Revenue is recognized when control of the OCS product or products is transferred to the customer in an amount that reflects the consideration we expect to be entitled to in exchange for the product or products.

Payments Made to Customers

Under our customer arrangements that include a customer clinical trial agreement, we make payments to that customer for reimbursements of clinical trial costs, materials, and for specified clinical documentation related to the customer's use of our OCS products. We also make payments to customers involved in post-approval studies for information related to the transplant procedures performed. We determine the appropriate accounting treatments for these payments depending on the nature of the payment and whether they are for distinct goods or services.

Other Revenue Considerations

Revenue is reported net of taxes. We do not consider shipping to be a contract performance obligation, therefore shipping costs incurred and billed to customers are recorded as revenue and cost of revenue.

We only include estimated variable amounts in the transaction price to the extent it is probable that a significant reversal of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is resolved. We do not assess whether promised goods or services are performance obligations if they are deemed immaterial in the context of the contract with the customer. Additionally, we do not assess whether a contract has a significant financing component if the expectation at contract inception is that the period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less.

Stock-Based Compensation

We measure stock-based option awards granted to employees, directors and non-employees 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 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. We account for forfeitures as they occur and record compensation cost assuming all option holders will complete the requisite service period. If an award is forfeited, we reverse compensation expense previously recognized in the period the award is forfeited.

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.

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. The reserve for excess and obsolete inventory was $0.3 million as of December 31, 2021 and 2020.

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 statements 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 Annual Report on Form 10-K, 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 December 31, 2021 and 2020, we had backlog of $1.1 million and $0.5 million, respectively. Of the amount of backlog as of December 31, 2021, 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, as defined in the rules and regulations of the SEC.

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 Annual Report on Form 10-K.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

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 $1.0 million during the year ended December 31, 2021.

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 on our consolidated balance sheets. We recorded a foreign currency translation loss of less than $0.1 million during the year ended December 31, 2021.

For the year ended December 31, 2021, 25% of our net revenue and 6% 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 31, 2021, we had cash, cash equivalents, and marketable securities of $92.5 million, which consisted of cash, money market funds and short-term investments. 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.

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 December 31, 2021 borrowings outstanding under the Credit Agreement totaled $35.0 million and the interest rate applicable to such borrowings was 9.5%. An immediate 10% change in LIBOR would not have a material impact on our debt-related obligations, financial position or results of operations.

Item 8. Financial Statements and Supplementary Data.

TRANSMEDICS GROUP, INC.
Index to Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of TransMedics Group, Inc.

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of TransMedics Group, Inc. and its subsidiaries (the "Company") as of December 31, 2021 and 2020, and the related consolidated statements of operations, of comprehensive loss, of convertible preferred stock and stockholders' equity and of cash flows for the years then ended, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2021, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2021, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Change in Accounting Principle

As discussed in Note 2 to the consolidated financial statements, the Company changed the manner in which it accounts for leases in 2021.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Annual Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting 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 in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements 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. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Emphasis of Matter

As disclosed in Note 8 to the consolidated financial statements, the Company has $35.0 million of debt maturing in June 2023. Management's evaluation of the events and conditions related to future funding are described in Note 1.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as

necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Revenue Recognition

As described in Note 2 to the consolidated financial statements, the Company recorded $30.3 million in total revenues for the year ended December 31, 2021. 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 Organ Care System (OCS) products. Substantially all of the Company's customer contracts have multiple-performance obligations that contain deliverables consisting of OCS Perfusion Sets and OCS Solutions. In some of those customer contracts, the deliverables also include an OCS Console, whether sold or loaned to the customer. Management evaluates each promise within a multiple-performance obligation arrangement to determine whether it represents a distinct performance obligation. Management has concluded that training, OCS Console equipment set-up, and the OCS Console itself are highly interdependent and represent a single, combined performance obligation. Revenue is recognized when control of the OCS product or products is transferred to the customer in an amount that reflects the consideration the Company expects to be entitled to in exchange for the product or products. Control is transferred for the OCS products typically only after the product has arrived at the customer site and, in addition for OCS Consoles, the training and equipment set-up have been completed by the Company.

The principal considerations for our determination that performing procedures relating to revenue recognition is a critical audit matter are the high degree of auditor effort in performing procedures and in evaluating audit evidence related to management's determination of the point in time when control of the OCS product or products is transferred to the customer and revenue is recognized.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to the revenue recognition process, including controls over the existence and point in time when control is transferred to the customer. These procedures also included, among others, evaluating, for a sample of transactions, the existence of transactions recognized as revenue, as well as evaluating the appropriate timing of revenue recognition by obtaining and inspecting customer purchase orders and, where applicable, invoices, customer agreements, shipping documents and cash receipts from customers.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts
March 1, 2022

We have served as the Company's auditor since 2001.

TRANSMEDICS GROUP, INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except share amounts)

	December 31,	
	2021	2020
Assets		
Current assets:		
Cash and cash equivalents	$ 25,580	$ 24,581
Marketable securities	66,872	101,061
Accounts receivable	5,934	6,864
Inventory	14,859	11,934
Prepaid expenses and other current assets	5,460	2,326
Total current assets	118,705	146,766
Property and equipment, net	9,841	4,754
Restricted cash	500	500
Operating lease right-of-use assets	5,847	—
Other long-term assets	—	6
Total assets	$ 134,893	$ 152,026
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 6,651	$ 1,206
Accrued expenses and other current liabilities	16,337	10,410
Deferred revenue	250	263
Total current liabilities	23,238	11,879
Long-term debt, net of discount and current portion	35,197	34,657
Operating lease liabilities, net of current portion	8,604	—
Deferred rent, net of current portion	—	1,599
Total liabilities	67,039	48,135
Commitments and contingencies (Note 13)		
Stockholders' equity:		
Preferred stock, no par value; 25,000,000 shares authorized; no shares issued or outstanding	—	—
Common stock, no par value; 150,000,000 shares authorized; 27,791,615 shares and 27,175,305 shares issued and outstanding at December 31, 2021 and 2020, respectively	510,488	502,217
Accumulated other comprehensive loss	(188)	(95)
Accumulated deficit	(442,446)	(398,231)
Total stockholders' equity	67,854	103,891
Total liabilities and stockholders' equity	$ 134,893	$ 152,026

The accompanying notes are an integral part of these consolidated financial statements.

TRANSMEDICS GROUP, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except share and per share amounts)

	Year Ended December 31,	
	2021	2020
Net revenue	$ 30,262	$ 25,639
Cost of revenue	9,103	9,004
Gross profit	21,159	16,635
Operating expenses:		
Research, development and clinical trials	22,304	18,831
Selling, general and administrative	38,283	24,188
Total operating expenses	60,587	43,019
Loss from operations	(39,428)	(26,384)
Other income (expense):		
Interest expense	(3,874)	(3,985)
Other income (expense), net	(877)	1,653
Total other expense, net	(4,751)	(2,332)
Loss before income taxes	(44,179)	(28,716)
Provision for income taxes	(36)	(32)
Net loss	$ (44,215)	$ (28,748)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.60)	$ (1.16)
Weighted average common shares outstanding, basic and diluted	27,616,839	24,702,764

The accompanying notes are an integral part of these consolidated financial statements.

TRANSMEDICS GROUP, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)

	Year Ended December 31,	
	2021	2020
Net loss	$ (44,215)	$ (28,748)
Other comprehensive loss:		
Foreign currency translation adjustment	(46)	(49)
Unrealized losses on marketable securities, net of tax of $0	(47)	(44)
Total other comprehensive loss	(93)	(93)
Comprehensive loss	$ (44,308)	$ (28,841)

The accompanying notes are an integral part of these consolidated financial statements.

TRANSMEDICS GROUP, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(In thousands, except share amounts)

	Common Stock		Accumulated Other Comprehen-sive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balances at December 28, 2019	21,184,524	$ 424,134	$ (2)	$ (369,483)	$ 54,649
Issuance of common stock upon the exercise of common stock options	218,084	227	—	—	227
Issuance of common stock in connection with employee stock purchase plan	22,697	357	—	—	357
Issuance of common stock in public offering, net of discounts and issuance costs of $585	5,750,000	75,085	—	—	75,085
Stock-based compensation expense	—	2,414	—	—	2,414
Foreign currency translation adjustment	—	—	(49)	—	(49)
Unrealized losses on marketable securities	—	—	(44)	—	(44)
Net loss	—	—	—	(28,748)	(28,748)
Balances at December 31, 2020	27,175,305	502,217	(95)	(398,231)	103,891
Issuance of common stock upon the exercise of common stock options	588,461	974	—	—	974
Issuance of common stock in connection with employee stock purchase plan	27,849	419	—	—	419
Stock-based compensation expense	—	6,878	—	—	6,878
Foreign currency translation adjustment	—	—	(46)	—	(46)
Unrealized losses on marketable securities	—	—	(47)	—	(47)
Net loss	—	—	—	(44,215)	(44,215)
Balances at December 31, 2021	27,791,615	$ 510,488	$ (188)	$ (442,446)	$ 67,854

The accompanying notes are an integral part of these consolidated financial statements.

TRANSMEDICS GROUP, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Year Ended December 31,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (44,215)	$ (28,748)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	1,817	1,577
Stock-based compensation expense	6,878	2,414
Non-cash interest and end of term accretion expense	540	511
Non-cash lease expense	829	—
Net amortization of premiums on marketable securities	1,356	634
Unrealized foreign currency transaction (gains) losses	928	(1,065)
Changes in operating assets and liabilities:		
Accounts receivable	840	(218)
Inventory	(4,894)	(1,740)
Prepaid expenses and other current assets	(3,151)	(769)
Accounts payable	5,090	(5,802)
Accrued expenses and other current liabilities	4,875	1,948
Deferred revenue	7	60
Operating lease liabilities	236	—
Deferred rent	—	933
Net cash used in operating activities	(28,864)	(30,265)
Cash flows from investing activities:		
Purchases of property and equipment	(3,519)	(455)
Purchases of marketable securities	(72,024)	(121,793)
Proceeds from sales and maturities of marketable securities	104,810	80,650
Net cash provided by (used) in investing activities	29,267	(41,598)
Cash flows from financing activities:		
Proceeds from issuance of common stock in public offering, net of underwriting discounts and commissions	—	75,670
Payments of public offering and other financing costs	—	(705)
Proceeds from issuance of common stock upon exercise of stock options	974	227
Proceeds from issuance of common stock in connection with employee stock purchase plan	419	357
Proceeds from Paycheck Protection Program loan	—	2,249
Repayment of Paycheck Protection Program loan	—	(2,249)
Net cash provided by financing activities	1,393	75,549
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(797)	803
Net increase in cash, cash equivalents and restricted cash	999	4,489
Cash, cash equivalents and restricted cash, beginning of period	25,081	20,592
Cash, cash equivalents and restricted cash, end of period	$ 26,080	$ 25,081
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 3,334	$ 3,475
Supplemental disclosure of non-cash investing and financing activities:		
Transfers of inventory to property and equipment	$ 1,823	$ 1,191
Purchases of property and equipment included in accounts payable and accrued expenses	$ 1,200	$ —
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$ 25,580	$ 24,581
Restricted cash	500	500
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	$ 26,080	$ 25,081

The accompanying notes are an integral part of these consolidated financial statements.

1. Nature of the Business and Basis of Presentation

TransMedics Group, Inc. ("TransMedics Group" and together with its consolidated subsidiaries, the "Company") was incorporated in the Commonwealth of Massachusetts in October 2018. TransMedics, Inc. ("TransMedics"), an operating company and wholly owned subsidiary of TransMedics Group 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 accompanying consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the ordinary course of business. The Company has incurred recurring losses since inception, including net losses of $44.2 million and $28.7 million for the years ended December 31, 2021 and 2020, respectively. As of December 31, 2021, the Company had an accumulated deficit of $442.4 million. The Company expects to continue to generate operating losses in the foreseeable future.

The Company believes that its existing cash, cash equivalents, and marketable securities of $92.5 million as of December 31, 2021 will be sufficient to fund its operations, capital expenditures, and debt service payments for at least the next 12 months following the filing of this Annual Report on Form 10-K. The Company may need to seek additional funding through 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 shareholders. 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.

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. Potential risks and uncertainties also include, without limitation, uncertainties regarding the duration and magnitude of the impact of the COVID-19 pandemic on the Company's business and the economy generally. 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. The Company's research and development may not be successfully completed, adequate protection for the Company's technology may not be obtained, the Company may not obtain necessary government regulatory approval on its expected timeline or at all, and approved products may not prove commercially viable. The Company operates in an environment of rapid change in technology and competition.

The impact of the COVID-19 pandemic has been and may continue to be extensive in many aspects of society, which has resulted in and may continue to result in significant disruptions to the global economy, as well as businesses and capital markets around the world. Impacts to the Company's business as a result of COVID-19 have included the temporary disruption of transplant procedures at many of the organ transplant centers that purchase OCS products; customer delays or reductions in customer capital expenditures and operating budgets and the related impact on our product sales; disruptions to the Company's manufacturing operations and supply chain caused by facility closures, reductions in operating hours, staggered shifts and other social distancing efforts; labor shortages; decreased productivity and unavailability of materials or components; delays of reviews and approvals by the Food and Drug Administration ("FDA") and other health authorities; delays in the Company's clinical trial enrollment; limitations on its employees' and customers' ability to travel, and delays in product installations, trainings or shipments to and from other affected countries and within the United States.

In response to the pandemic, healthcare providers have, and may need to further, reallocate resources, such as physicians, staff, hospital beds and intensive care unit facilities, and these actions significantly delay the provision of other medical care such as organ transplantation and reduce the number of transplant procedures that are performed, which negatively impacts the Company's revenue and cash flows. While the Company maintains an inventory of finished products and raw materials used in its OCS products, a prolonged pandemic could lead to shortages in the raw materials necessary to manufacture its products. The COVID-19 pandemic also has impacted operations at the FDA and other health authorities, resulting in delays of reviews and approvals, and may affect other potential Pre-Market Approval ("PMA") applications.

The Company's consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB"). 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.

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 and the valuation of stock-based awards. 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. The full extent to which the COVID-19 pandemic will directly or indirectly impact the Company's business, results of operations and financial condition, including sales, expenses, reserves and allowances, manufacturing, clinical trials, research and development costs and employee-related amounts, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain it or treat COVID-19, as well as the economic impact on local, regional, national and international customers and markets. The Company has made estimates of the impact of COVID-19 within its financial statements and there may be changes to those estimates in future periods. As of the date of issuance of these consolidated financial statements, the Company is not aware of any specific event or circumstance that would require the Company to update estimates, judgments or revise the carrying value of any assets or liabilities. Actual results may differ from those estimates or assumptions.

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, cash equivalents, marketable securities and accounts receivable. 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.

Significant customers are those that accounted for 10% or more of the Company's net revenue or accounts receivable. For the year ended December 31, 2021, one customer accounted for 11% of net revenue. For the year ended December 31, 2020, two customers accounted for 14% and 10% of net revenue, respectively. As of December 31, 2021, two customers accounted for 21% and 15% of accounts receivable, respectively. As of December 31, 2020, one customer accounted for 30% of accounts receivable.

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 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, 2021 and 2020, 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, 2021 and 2020. The Company's cash, cash equivalents and restricted cash was $26.1 million and $25.1 million for the years ended December 31, 2021 and 2020, respectively.

Accounts Receivable

Accounts receivable are presented net of an allowance for credit losses, which is an estimate of amounts that may not be collectible. The Company performs ongoing credit evaluations of its customers and monitors economic conditions to identify facts and circumstances that may indicate its receivables are at risk of collection. The Company provides reserves against accounts receivable for estimated credit losses, if any, that may result from a customer's inability to pay based on the composition of its accounts receivable, current economic conditions and historical credit loss activity. Amounts deemed uncollectible are charged or written-off against the reserve. As of December 31, 2021 and 2020, the Company had no allowance for credit losses. During the years ended December 31, 2021 and 2020, the Company did not record any provisions for credit losses 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 term 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.

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 and right-of-use assets. 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. The Company did not record any impairment losses on long-lived assets during the years ended December 31, 2021 and 2020.

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 years ended December 31, 2021 and 2020.

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 statements 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 any loss provision for future-period remaining purchase commitments for the year ended December 31, 2021.

Leases

Prior to January 1, 2021, the Company accounted for leases under ASC 840, Leases ("ASC 840"). Effective January 1, 2021, the Company accounts for leases under ASC 842, Leases ("ASC 842"). Therefore, as of and for the year ended December 31, 2020, the Company's consolidated financial statements continue to be presented in accordance with ASC 840, the accounting standard originally in effect for such period. As of and for the year ended December 31, 2021, the Company's consolidated financial statements are presented in accordance with ASC 842.

In accordance with ASC 842, the Company accounts for a contract as a lease when it has the right to control the asset for a period of time while obtaining substantially all of the asset's economic benefits. The Company determines if an arrangement is a lease or contains an embedded lease at inception. For arrangements that meet the definition of a lease, the Company determines the initial classification and measurement of its right-of-use asset and lease liability at the lease commencement date and thereafter if modified. The lease term includes any renewal options that the Company is reasonably assured to exercise. The present value of lease payments is determined by using the interest rate implicit in the lease, if that rate is readily determinable; otherwise, the Company uses its estimated secured incremental borrowing rate for that lease term. The Company's policy is to not record leases with an original term of twelve months or less on its consolidated balance sheets and recognizes those lease payments in the income statement on a straight-line basis over the lease term. The Company's existing leases are for office, laboratory and manufacturing space.

In addition to rent, the leases may require the Company to pay additional costs, such as utilities, maintenance and other operating costs, which are generally referred to as non-lease components. The Company has elected to not separate lease and non-lease components. Only the fixed costs for lease components and their associated non-lease components are accounted for as a single lease component and recognized as part of a right-of-use asset and lease liability. Rent expense for operating leases is recognized on a straight-line basis over the reasonably assured lease term based on the total lease payments and is included in operating expense in the consolidated statements of operations.

Revenue from leasing arrangements is not subject to the revenue standard for contracts with customers and remains separately accounted for under ASC 842. In accordance with ASC 842, lessors should classify and account for a lease with variable lease payments that do not depend on a reference index or a rate as an operating lease if the lease would have been classified as a sales-type lease or a direct financing lease and the lessor would have otherwise recognized a day-one loss. The Company's OCS Console implied rental agreements qualify as sales-type leases with

certain variable payments that meet specified criteria such that a day-one loss would be recognized under ASC 842. Therefore, in accordance with ASC 842, such leases are accounted for as operating leases and the Company does not derecognize the leased asset (the OCS Console) at the time of the sale but depreciates the leased asset over the useful life of the asset.

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 are carried at fair value, determined according to the fair value hierarchy described above (see Note 4). 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 (a level 2 measurement) at each balance sheet date due to its variable interest rate, which approximates a market interest rate.

Marketable Securities

The Company's marketable securities (non-equity instruments) 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. Realized gains and losses are based on the specific identification method and are included as a component of other income (expense), net in the consolidated statements of operations.

When the fair value is below the amortized cost of a marketable security, an estimate of expected credit losses is made. The credit-related impairment amount is recognized in the consolidated statements of operations. Credit losses are recognized through the use of an allowance for credit losses account in the consolidated balance sheet and subsequent improvements in expected credit losses are recognized as a reversal of an amount in the allowance account. If the Company has the intent to sell the security or it is more likely than not that the Company will be required to sell the security prior to recovery of its amortized cost basis, then the allowance for the credit loss is written-off and the excess of the amortized cost basis of the asset over its fair value is recorded in the consolidated statements of operations. There were no credit losses recorded during the years ended December 31, 2021 and 2020.

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, 2021 and 2020, the warranty accrual was less than $0.1 million.

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 OCS disposable set for use on the customer's existing organ-specific OCS Console.

The Company recognizes revenue from sales to customers applying the following five steps: (1) identification of the contract, or contracts, with a customer, (2) identification of the performance obligations in the contract, (3) determination of the transaction price, (4) allocation of the transaction price to the performance obligations in the contract, and (5) recognition of revenue when, or as, performance obligations are satisfied.

Substantially all of the Company's customer contracts have multiple-performance obligations that contain deliverables consisting of OCS Perfusion Sets and OCS Solutions. In some of those customer contracts, the deliverables also include an OCS Console, whether sold or loaned to the customer. The Company evaluates each promise within a multiple-performance obligation arrangement to determine whether it represents a distinct performance obligation. The primary performance obligations in the Company's customer arrangements from which it derives revenue are the OCS Perfusion Sets, the OCS Solutions and the OCS Console. Revenue for each OCS Perfusion Set and OCS Solutions is recognized at the point in time at which control is transferred to the customer, which is when title transfers to the customer, typically upon arrival at the customer site.

When a customer order includes an OCS Console, the Company has determined that customer training and the equipment set-up of the OCS Console, each performed by the Company, are not distinct 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. In addition, the Company has determined that the OCS Console itself is not distinct because the customer cannot benefit from the OCS Console without the training and equipment set-up having been completed. As a result, when the order includes an OCS Console, the Company has concluded that training, OCS Console equipment set-up, and the OCS Console itself are highly interdependent and represent a single, combined performance obligation. The Company recognizes revenue from the single, combined performance obligation only once the OCS Console has arrived at the customer site and the training and equipment set-up have been completed by the Company.

Customer orders may include the loan of an OCS Console as well as OCS disposable sets. 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 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 of OCS 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. Therefore, the Company allocates the arrangement consideration between the lease deliverables (i.e., the OCS Console) and non-lease deliverables (i.e., the OCS disposable sets) based on the relative estimated standalone selling price of each distinct performance obligation. To date, the amounts allocated to lease deliverables have been insignificant.

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

Revenue is recognized when control of the OCS product or products is transferred to the customer in an amount that reflects the consideration the Company expects to be entitled to in exchange for the product or products.

Payments Made to Customers

Under the Company's customer arrangements that include a customer clinical trial agreement, the Company makes payments to that customer for reimbursements of clinical trial costs, materials, and for specified clinical documentation related to the customer's use of its OCS products. The Company also makes payments to customers involved in post-approval studies for information related to the transplant procedures performed. The Company determines the appropriate accounting treatments for these payments depending on the nature of the payment and whether they are for distinct goods or services.

Contract Assets and Liabilities

The Company recognizes a receivable at the point in time at which it has an unconditional right to payment. Such receivables are not contract assets. Contract assets arise from unbilled amounts in customer arrangements when revenue recognized exceeds the amount billed to the customer and the Company's right to payment is not just subject to the passage of time. The Company had no contract assets as of December 31, 2021 and 2020.

Contract liabilities represent the Company's obligation to transfer goods or services to a customer for which it has received consideration (or the amount is due) from the customer. The Company has determined that its only contract liabilities are deferred revenue, which consists of amounts that have been invoiced but that have not been recognized as revenue.

The Company generally satisfies performance obligations within one year of the contract inception date. As of December 31, 2021, the Company's wholly- or partially unsatisfied performance obligations totaled $1.4 million and are expected to be completed within the next year.

Other Revenue Considerations

Revenue is reported net of taxes. The Company does not consider shipping to be a contract performance obligation, therefore shipping costs incurred and billed to customers are recorded as revenue and cost of revenue.

The Company only includes estimated variable amounts in the transaction price to the extent it is probable that a significant reversal of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is resolved. The Company does not assess whether promised goods or services are performance obligations if they are deemed immaterial in the context of the contract with the customer. Additionally, the Company does not assess whether a contract has a significant financing component if the expectation at contract inception is that the period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less.

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.

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.

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.

The Company also incurs transaction gains and losses resulting from intercompany transactions 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. Realized and unrealized foreign currency transaction gains (losses) are included in the consolidated statements of operations as a component of other income (expense) and totaled ($1.0) million and $1.0 million for the years ended December 31, 2021 and 2020, respectively.

Stock-Based Compensation

The Company measures stock-based option awards granted to employees, non-employees and directors based on their fair value on the date of grant using the Black-Scholes option-pricing model. Generally, the Company issues awards with only service-based vesting conditions. Compensation expense for those awards is recognized over the vesting period of the respective award using the straight-line method. The Company accounts for forfeitures as they occur and records compensation cost assuming all option holders will complete the requisite service period. When the unvested portion of an award is forfeited, the Company reverses compensation expense previously recognized in the period of the forfeiture.

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 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 gains (losses) on the consolidated balance sheets consists primarily of foreign currency translation adjustments. Accumulated other comprehensive loss attributable to unrealized losses on marketable securities has not been significant.

Net Income (Loss) per Share

Basic net income (loss) per common share is computed by dividing the net income (loss) by the weighted average number of shares of common stock outstanding for the period. Diluted net income (loss) per common share is computed by dividing net income (loss) by the weighted average number of shares of common stock outstanding for the period, including potential dilutive common shares assuming the dilutive effect of outstanding stock awards. For periods in which the Company reports a net loss, diluted net loss per common share is the same as basic net loss per common share, 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 each of the years ended December 31, 2021 and 2020.

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. 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 above because including them would have had an anti-dilutive effect:

	As of December 31,	
	2021	2020
Warrants to purchase common stock	64,440	64,440
Options to purchase common stock	2,797,550	2,261,234
Employee stock purchase plan	12,465	14,951
	2,874,455	2,340,625

Income Taxes

The Company accounts for income taxes under 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 financial statements or in the Company's tax returns. Deferred taxes are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect in the years 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 realized 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 analyzing carryback capacity in periods with taxable income, reversal of existing taxable temporary differences and estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty in income taxes recognized in the 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 financial statements. The amount of 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

The Company adopted ASU No. 2016-02, Leases (Topic 842), inclusive of ASU 2021-05 Leases (Topic 842): Lessors – Certain Leases with Variable Lease Payments, effective January 1, 2021, using the modified retrospective method under ASU No. 2018-11, Leases (Topic 842): Targeted Improvements. Since the Company ceased to be an emerging growth company as of December 31, 2021, the Company adopted the standard during the fourth quarter of 2021 effective as of January 1, 2021. The modified retrospective transition method allows entities to apply the transition requirements at the effective date rather than at the beginning of the earliest comparative period presented. The Company's reporting for comparative periods was not recast and is presented in accordance with ASC 840. Adoption of the new standard resulted in the recording of right-of-use assets and lease liabilities of $6.7 million and $8.4 million, respectively. The adoption of the standard did not have a material impact on the Company's results of operations or cash flows. The Company elected to use the transition package of three practical expedients, which among other things, allowed the Company to carry forward the historical lease classification. The Company has also elected to use its incremental borrowing rate on the date of adoption using the remaining lease term as of the date of adoption. The underlying assets of the Company's leases as of the adoption date consisted of office, laboratory and manufacturing space.

The Company assessed the implied rentals of OCS consoles loaned to customers at no charge. In accordance with ASC 842, lessors should classify and account for a lease with variable lease payments that do not depend on a reference index or a rate as an operating lease if the lease would have been classified as a sales-type lease or a direct financing lease and the lessor would have otherwise recognized a day-one loss. The Company's implied rentals of OCS consoles meet such criteria to continue to account for the lease as an operating lease as the lease would have been classified as a sales-type lease and a day-one loss would have otherwise been recognized. Therefore, the adoption of the standard had no impact on the consolidated financial statements and related disclosures in accordance with ASU 2021-05 Leases (Topic 842): Lessors – Certain Leases with Variable Lease Payments.

The Company adopted ASU No. 2016-13, Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments for the year ended December 31, 2021. The new standard adjusts the accounting for assets held at amortized costs basis, including marketable securities accounted for as available for sale, and trade receivables. The standard eliminates the probable initial recognition threshold and requires an entity to reflect its current estimate of all expected credit losses. The allowance for credit losses is a valuation account that is deducted from the amortized cost basis of the financial assets to present the net amount expected to be collected. The adoption of this standard did not have a material impact on the consolidated financial statements and related disclosures.

The Company adopted ASU No. 2019-12, Income Taxes – Simplifying the Accounting for Income Taxes (Topic 740) for the year ended December 31, 2021. The amendments in this update simplify the accounting for income taxes by removing certain exceptions to the general principles as well as clarifying and amending existing guidance to improve consistent application. The adoption of this standard did not have a material impact on the consolidated financial statements and related disclosures.

3. Marketable Securities

Marketable securities by security type consisted of the following (in thousands):

	December 31, 2021			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury securities (due within one year)	$ 63,907	$ —	$ (33)	$ 63,874
U.S. government agency bonds (due within one year)	3,001	—	(3)	2,998
	$ 66,908	$ —	$ (36)	$ 66,872

	December 31, 2020			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury securities (due within one year)	$ 74,066	$ 10	$ (3)	$ 74,073
U.S. government agency bonds (due within one year)	26,984	4	—	26,988
	$ 101,050	$ 14	$ (3)	$ 101,061

4. Fair Value of Financial Assets

The following tables present the Company’s fair value hierarchy for its assets that are measured at fair value on a recurring basis (in thousands):

	Fair Value Measurements at December 31, 2021 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 11,169	$ —	$ —	$ 11,169
Marketable securities:				
U.S. Treasury securities	—	63,874	—	63,874
U.S. government agency bonds	—	2,998	—	2,998
	$ 11,169	$ 66,872	$ —	$ 78,041

	Fair Value Measurements at December 31, 2020 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 13,829	$ —	$ —	$ 13,829
Marketable securities:				
U.S. Treasury securities	—	74,073	—	74,073
U.S. government agency bonds	—	26,988	—	26,988
	$ 13,829	$ 101,061	$ —	$ 114,890

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.

5. Inventory

Inventory consisted of the following (in thousands):

	December 31,	
	2021	2020
Raw materials	$ 7,274	$ 6,770
Work-in-process	1,932	1,102
Finished goods	5,653	4,062
	$ 14,859	$ 11,934

During the years ended December 31, 2021 and 2020, the Company made non-cash transfers of OCS Consoles from inventory to property and equipment (OCS Consoles loaned to customers) of $1.8 million and $1.2 million, respectively.

6. Property and Equipment, Net

Property and equipment, net consisted of the following (in thousands):

	December 31,	
	2021	2020
Manufacturing equipment	$ 1,769	$ 1,725
OCS Consoles loaned to customers	8,865	7,196
Computer equipment and software	1,511	1,338
Laboratory equipment	668	617
Office and trade show equipment	177	177
Leasehold improvements	1,319	1,319
Construction-in-progress	5,267	409
	19,576	12,781
Less: Accumulated depreciation and amortization	(9,735)	(8,027)
	$ 9,841	$ 4,754

During the years ended December 31, 2021 and 2020, total depreciation and amortization expense was $1.8 million and $1.6 million, respectively. Of those amounts, $1.4 million and $1.3 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, 2021 and 2020 was primarily related to leasehold improvements and in-process construction of manufacturing equipment, respectively.

7. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	December 31,	
	2021	2020
Accrued research, development and clinical trial expenses	$ 4,567	$ 4,426
Accrued payroll and related expenses	5,173	4,030
Accrued professional fees	1,973	344
Accrued other	4,624	1,610
	$ 16,337	$ 10,410

8. Long-Term Debt

TransMedics has a credit agreement (the "Credit Agreement") with OrbiMed Royalty Opportunities II, LP ("OrbiMed"), entered into in June 2018, pursuant to which TransMedics borrowed $35.0 million. Long-term debt consisted of the following (in thousands):

	December 31,	
	2021	2020
Principal amount of long-term debt	$ 35,000	$ 35,000
Less: Current portion of long-term debt	—	—
Long-term debt, net of current portion	35,000	35,000
Debt discount, net of accretion	(511)	(834)
Accrued end-of-term payments	708	491
Long-term debt, net of discount and current portion	$ 35,197	$ 34,657

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. 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 and debt discount amounts are 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 financial covenants include maintaining a minimum liquidity amount of $3.0 million; the requirement, on an annual basis, to deliver to OrbiMed annual audited financial statements with an unqualified audit opinion from the Company's independent registered public accounting firm; 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. As of December 31, 2021, the Company was in compliance with the financial covenants under the Credit Agreement.

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), failure to comply with certain covenants, including the minimum liquidity and unqualified audit opinion covenants, 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.

As of December 31, 2021 and 2020, the interest rate applicable to borrowings under the Credit Agreement was 9.5%. During each of the years ended December 31, 2021 and 2020, the weighted average effective interest rate on outstanding borrowings under the Credit Agreement was approximately 11.2%.

Paycheck Protection Program Loan

On April 20, 2020, TransMedics issued a Promissory Note to Bank of America, NA, pursuant to which it received loan proceeds of $2.2 million (the "Loan") provided under the Paycheck Protection Program established under the Coronavirus Aid, Relief, and Economic Security Act and guaranteed by the U.S. Small Business Administration (the "Paycheck Protection Program"). However, based on updated guidance related to this program, the Company decided to repay the full amount of the Loan, and repaid the Loan on May 1, 2020. The Loan was unsecured, was scheduled to mature on April 20, 2022, had a fixed interest rate of 1.0% per annum and was subject to the standard terms and conditions applicable to loans administered under the Paycheck Protection Program.

9. Equity

Preferred Stock

As of December 31, 2021, the Company's articles of organization authorized the Company to issue up to 25,000,000 shares of preferred stock, no par value per share, all of which is undesignated. The preferred stock will have such rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, as shall be determined by the Company's boards of directors upon issuance.

Common Stock

As of December 31, 2021, the Company's articles of organization authorized the Company to issue up to 150,000,000 shares of common stock, no par value per share. 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 are entitled to receive dividends, if any, as may be declared by the board of directors, as described above. Through December 31, 2021, no dividends had been declared or paid.

Warrants

As of December 31, 2021, the Company had outstanding warrants to purchase 50,000 shares of common stock at an exercise price of $8.75 per share with an expiration date of November 7, 2022 and warrants to purchase 14,440 shares of common stock at an exercise price of $17.47 per share with an expiration date of May 6, 2024.

10. Stock-Based Compensation

2019 Stock Incentive Plan and Option Grants

The 2019 Stock Incentive Plan (the "2019 Plan") provides for the grant of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock, restricted stock units, unrestricted stock, unrestricted stock units, and other stock-based awards to employees, directors, and consultants of the Company and its subsidiaries. The number of shares of common stock of TransMedics Group initially available for issuance under the 2019 Plan was 3,428,571 shares, plus the number of shares underlying awards under the previously outstanding 2014 Stock Incentive Plan (the "2014 Plan"), not to exceed 1,595,189 shares, that expire or are terminated, surrendered, or cancelled without the delivery of shares, are forfeited to or repurchased by TransMedics Group or otherwise become available again for grant. Since the effectiveness of the Company's 2019 Plan in April 2019, no future awards will be made under the 2014 Plan.

Shares withheld in payment of the exercise or purchase price of an award or in satisfaction of tax withholding requirements, and the shares covered by a stock appreciation right for which any portion is settled in stock, will reduce the number of shares available for issuance under the 2019 Plan. In addition, the number of shares available for issuance under the 2019 Plan (i) will not be increased by any shares delivered under the 2019 Plan that are subsequently repurchased using proceeds directly attributable to stock option exercises and (ii) will not be reduced by any awards that are settled in cash or that expire, become unexercisable, terminate or are forfeited to or repurchased by TransMedics Group without the issuance of stock under the 2019 Plan. As of December 31, 2021, 1,583,925 shares of common stock were available for issuance under the 2019 Plan.

2019 Employee Stock Purchase Plan

Pursuant to the Company's 2019 Employee Stock Purchase Plan (the "2019 ESPP"), certain employees of the Company are eligible to purchase common stock of the Company at a reduced price during offering periods. The 2019 ESPP permits participants to purchase common stock using funds contributed through payroll deductions, subject to the limitations set forth in the Internal Revenue Code, at a purchase price of 85% of the lower of the closing price of the Company's common stock on the first trading day of the offering period or the closing price on the applicable purchase date, which is the final trading day of the applicable offering period. A total of 371,142 shares of common stock of TransMedics Group are reserved for issuance under the 2019 ESPP as of December 31, 2021. During the year ended December 31, 2021, 27,849 shares were issued under the 2019 ESPP and as of December 31, 2021, 320,596 shares remained available for issuance.

2021 Inducement Plan

In August 2021, the Company's board of directors approved the TransMedics Group, Inc. Inducement Plan (the "Inducement Plan"). Pursuant to the terms of the Inducement Plan, the Company may grant nonstatutory stock options, stock appreciation rights, restricted stock, unrestricted stock, restricted stock unit awards and performance awards to individuals who were not previously employees or directors of the Company or individuals returning to employment after a bona fide period of non-employment with the Company. A total of 1,000,000 shares of the Company's common stock were initially available for issuance under the Inducement Plan. As of December 31, 2021, 738,700 shares of common stock were available for issuance under the Inducement Plan.

Stock Option Valuation

The fair value of stock option grants is estimated using the Black-Scholes option-pricing model. Prior to the IPO, the Company was 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:

	Year Ended December 31,	
	2021	2020
Risk-free interest rate	0.90%	0.91%
Expected term (in years)	6.03	5.97
Expected volatility	58%	54%
Expected dividend yield	0%	0%

The following table summarizes the Company's option activity since December 31, 2020:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Contractual Term	Aggregate Intrinsic Value
			(in years)	(in thousands)
Outstanding as of December 31, 2020	2,261,234	$ 8.17	6.22	$ 26,671
Granted	1,326,675	34.60		
Exercised	(588,461)	1.65		
Forfeited	(200,060)	28.10		
Expired	(1,838)	31.76		
Outstanding as of December 31, 2021	2,797,550	$ 20.64	7.54	$ 14,625
Vested and expected to vest as of December 31, 2021	2,797,550	$ 20.64	7.54	$ 14,625
Options exercisable as of December 31, 2021	1,371,048	$ 11.80	6.11	$ 13,143

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 years ended December 31, 2021 and 2020, was $16.3 million and $2.9 million, respectively. The weighted average grant-date fair value of stock options granted during the years ended December 31, 2021 and 2020 was $18.63 per share and $7.91 per share, respectively.

The Company has not granted to employees any stock-based awards with performance-based vesting conditions.

Stock-Based Compensation

The Company recorded stock-based compensation expense in the following expense categories of its consolidated statements of operations (in thousands):

	Year Ended December 31,	
	2021	2020
Cost of revenue	$ 72	$ 27
Research, development and clinical trials expenses	1,114	396
Selling, general and administrative expenses	5,692	1,991
	$ 6,878	$ 2,414

As of December 31, 2021, total unrecognized compensation cost related to unvested share-based awards was $20.9 million, which is expected to be recognized over a weighted average period of 2.7 years.

11. Income Taxes

Tax Provision Components

During the years ended December 31, 2021 and 2020, 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 the uncertainty regarding the realizability of these respective deferred tax assets. The Company generated income in the Netherlands for the years ended December 31, 2021 and 2020 and, accordingly, recorded a foreign income tax provision of less than $ 0.1 million for each of the years ended December 31, 2021 and 2020, respectively.

Income Before Taxes

The domestic and foreign components of loss before income taxes were as follows (in thousands):

	Year Ended December 31,	
	2021	2020
United States	$ (44,321)	$ (28,803)
Foreign	142	87
	$ (44,179)	$ (28,716)

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate is as follows:

	Year Ended December 31,	
	2021	2020
Federal statutory income tax rate	(21.0)%	(21.0)%
State taxes, net of federal benefit	(6.9)%	(5.7)%
Federal and state research and development tax credits	(2.4)%	(3.6)%
Nondeductible items	(3.2)%	(0.2)%
Deferred tax effect of change in state blended rate	(1.7)%	7.8%
Return to provision	1.1%	1.7%
Other	(0.2)%	0.0%
Change in deferred tax asset valuation allowance	34.3%	20.9%
Effective income tax rate	0.0%	(0.1)%

Net deferred tax assets consisted of the following (in thousands):

	December 31,	
	2021	2020
Deferred tax assets:		
Net operating loss carryforwards	$ 94,672	$ 81,390
Capitalized research and development expense	4,291	6,136
Research and development tax credit carryforwards	12,186	11,541
Accrued expenses	2,528	1,390
Stock-based compensation expense	2,254	791
Deferred rent	—	79
Lease liability	2,299	—
Other	170	132
Total deferred tax assets	118,400	101,459
Deferred tax liabilities:		
Other	(674)	(218)
Right-of-use assets	(1,562)	—
Unrealized gain (loss)	—	(212)
Total deferred tax liabilities	(2,236)	(430)
Valuation allowance	(116,164)	(101,029)
Net deferred tax assets	$ —	$ —

As of December 31, 2021, the Company had U.S. federal and state net operating loss carryforwards of $368.1 million and $304.0 million, respectively, which may be available to offset future taxable income and begin to expire in 2022 and 2030, respectively. The Company's federal net operating loss carryforwards include $156.4 million that can be carried forward indefinitely. As of December 31, 2021, the Company also had U.S. federal and state research and development tax credit carryforwards of $8.0 million and $5.3 million, respectively, which may be available to offset future tax liabilities and begin to expire in 2022 and 2024, respectively. As of December 31, 2021, the Company had no foreign net operating loss carryforwards.

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.

As required by Accounting Standard Codification 740, management of the Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets, which are comprised principally of net operating loss carryforwards. Management has determined that it is more likely than not that the Company will not recognize the benefits of federal and state deferred tax assets and, as a result, a valuation allowance of approximately $116.2 million has been recorded. During 2021, the Company recorded a net increase to its valuation allowance in the amount of $15.1 million primarily attributable to the current year operating loss and research credit generation for which the Company cannot provide a tax benefit.

The Company had no unrecognized tax benefits or related interest and penalties accrued for the years ended December 31, 2021 and 2020. The Company's policy is to record any interest or penalties related to income taxes as part of the income tax provision.

The Company generated research credits for the tax years ending after December 31, 2001 but has not conducted a study to document qualified activities. This study may result in an adjustment to the Company's research and development carryforwards; however, until a study is completed and any adjustment is known, no amounts are being presented as an unrecognized tax benefit for the year ended December 31, 2021. A full valuation allowance has been provided against the Company's research and development credits and, if an adjustment is required, this adjustment would be offset by an adjustment to the deferred tax asset established for the research credit carryforward and the valuation allowance.

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 federal or state tax examinations. The Company has open tax years subject to examination from fiscal year 2018 to present. To the extent that the Company has carryforward attributes, the tax years in which the attribute was generated may still be adjusted upon examination by federal, state or local tax authorities if they either have been or will be used in the future.

Changes in the valuation allowance for deferred tax assets during the years ended December 31, 2021 and 2020 related primarily to the increase in net operating loss carryforwards and research and development tax credit carryforwards in 2021 and 2020, and were as follows (in thousands):

	Year Ended December 31,	
	2021	2020
Valuation allowance as of beginning of year	$ (101,029)	$ (95,024)
Decreases recorded as benefit to income tax provision	—	—
Increases recorded to income tax provision	(15,135)	(6,005)
Valuation allowance as of end of year	$ (116,164)	$ (101,029)

As of December 31, 2021 and 2020, 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.

12. Leases

The Company leases its office, laboratory and manufacturing space under two noncancelable leases (the “Leases”) that expire in December 2027 and include a lease incentive, fixed payment escalations, and rent holidays. The Leases include an option to renew for an additional five years. The option to extend the lease term was not included in the right-of-use asset and the lease liability as it was not reasonably certain of being exercised. The Company classified the Leases as operating leases under ASC 842. Annual base rent increases at an average rate of 2.5% each year until the end of the term. The Company is also obligated to pay the landlord certain costs, taxes, and operating expenses, subject to certain exclusions. As these costs are generally variable in nature, they are not included in the measurement of the right-of-use asset and related lease liability.

Under the Leases, the landlord will contribute up to $3.4 million towards the Company’s leasehold improvements. The Company determined that it owns the leasehold improvements related to the Leases and, as such, reflected the $3.4 million

lease incentive as a reduction of rental payments used to measure the operating lease liability, and, in turn, the operating lease right-of-use asset upon adoption of ASC 842.

The components of the Company's lease expense under ASC 842 are as follows:

	Year Ended December 31, 2021
Operating lease cost	$ 1,353
Short-term lease cost	159
Variable lease cost	640
	$ 2,152

Supplemental disclosure of cash flow information related to the leases were as follows (in thousands):

	Year Ended December 31, 2021
Cash paid for amounts included in the measurement of operating lease liabilities	$ 1,901
Operating lease liabilities arising from obtaining right-of-use assets and leasehold improvements	$ —

The weighted-average remaining lease term as of December 31, 2021 was 6.0 years. The weighted-average discount rate as of December 31, 2021 was 6.7%. Because the interest rate implicit in the lease was not readily determinable, the Company's estimated incremental borrowing rate was used to calculate the present value of the Leases. In determining its incremental borrowing rate, the Company considered its credit quality and assessed interest rates available in the market for similar borrowings, adjusted for the impact of collateral over the term of the lease.

Future annual lease payments under the Company's Leases as of December 31, 2021 are as follows (in thousands):

Year Ending December 31,	
2022	$ 1,948
2023	1,997
2024	2,047
2025	2,098
2026	2,150
Thereafter	2,204
Total future minimum lease payments	12,444
Less: imputed interest	(2,273)
Less: estimated lease incentives	(1,567)
Total operating lease liabilities	$ 8,604

The following table represents lease liabilities on the consolidated balance sheet (in thousands):

	December 31, 2021
Current operating lease liabilities	$ —
Operating lease liabilities, net of current portion	8,604
Total operating lease liabilities	$ 8,604

Under prior lease guidance, minimum lease payments under operating leases were as follows as December 31, 2020 (in thousands):

Year Ending December 31,		
2021	$	1,900
2022		1,948
2023		1,997
2024		2,047
2025		2,098
Thereafter		4,354
	$	14,344

13. Commitments and Contingencies

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. 6100082. The Company was granted an interim patent term extension for this patent until November 6, 2021. The Company has not received final approval of the patent extension beyond the interim patent term extension already requested. 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 ("USPTO") based on input from the FDA. On February 8, 2021, the FDA provided to the USPTO a determined regulatory review period for the OCS Lung. Under the FDA's analysis, the patent term extension of the '082 patent would be until November 6, 2021. The Company has not yet received communication from the USPTO, but expects that the USPTO's determination of patent term extension for the '082 patent will maintain the November 6, 2021 expiration date. The final determination of the length of the patent extension is not expected to have a material impact on the Company's financial results. 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 $0.4 million and $0.3 million during of the years ended December 31, 2021 and 2020, respectively. The Company also accrued VA royalties of $0.2 million and $0.1 million as of December 31, 2021 and 2020, respectively.

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.

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. For the years ended December 31, 2021 and 2020, 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, 2021 and 2020.

Unconditional Purchase Commitment

In January 2021, the Company entered into an unconditional $9.5 million purchase commitment, in the ordinary course of business, for goods with specified annual minimum quantities to be purchased through December 2029. The contract is not cancellable without penalty. The remaining purchase commitment as of December 31, 2021 was $8.0 million.

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 expenses as incurred the costs related to such legal proceedings.

14. Segment Reporting and Geographic Data

The Company has determined that it operates in one segment (see Note 2).

Financial data by geographical area is summarized as follows (in thousands):

	Year Ended December 31,	
	2021	2020
Net revenue by country:		
United States	$ 21,861	$ 19,239
All other countries	8,401	6,400
Total net revenue	$ 30,262	$ 25,639

	December 31,	
	2021	2020
Long-lived assets by country(1):		
United States	$ 9,085	$ 4,114
All other countries	756	640
Total long-lived assets	$ 9,841	$ 4,754

(1) The Company's only long-lived assets consist of property and equipment, net of depreciation, which are categorized based on their location of domicile.

15. Revenue

The Company has determined that the payments made to the customer for reimbursement of clinical trial materials and customer's costs incurred to execute specific clinical trial protocols related to the Company's OCS products do not provide the Company with a distinct good or service transferred by the customer, 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.

The reconciliation of gross revenue to net revenue for these certain payments is shown below (in thousands):

	Year Ended December 31,	
	2021	2020
Gross revenue from sales to customers	$ 31,385	$ 28,356
Less: Clinical trial payments reducing revenue	1,123	2,717
Total net revenue	$ 30,262	$ 25,639

The Company determined that payments made to customers to obtain information related to post-approval studies or existing standard-of-care protocols (i.e., unrelated to the Company's OCS products) meet the criteria to be classified as a cost because the Company receives a distinct good or service transferred by the customer separate from the customer's purchase of the Company's OCS products and the consideration paid to the customer represents the fair value of the distinct good or service received. As a result, such payments made to the customers are recorded as operating expenses. The Company recorded payments made to customers related to post-approval studies and for documentation related to existing standard-of-care protocols of $2.1 million and $1.6 million for the years ended December 31, 2021 and 2020, respectively, as operating expenses.

Disaggregated Revenue

The Company disaggregates revenue from contracts with customers by product type and geographical area as it believes this presentation best depicts how the nature, amount, timing and uncertainty of the Company's revenue and cash flows are affected by economic factors, as shown below (in thousands):

	Year Ended December 31,	
	2021	2020
Net revenue by OCS product:		
OCS Lung net revenue	$ 10,665	$ 6,194
OCS Heart net revenue	17,683	14,196
OCS Liver net revenue	1,914	5,249
Total net revenue	$ 30,262	$ 25,639

	Year Ended December 31,	
	2021	2020
Net revenue by country (1):		
United States	$ 21,861	$ 19,239
All other countries	8,401	6,400
Total net revenue	$ 30,262	$ 25,639

(1) Net revenue by country is categorized based on the location of the end customer.

16. 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 $0.4 million and $0.3 million in total compensation in the years ended December 31, 2021 and 2020, respectively, for her services as an employee.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our President and Chief Executive Officer and our Chief Financial Officer (our principal executive officer and principal financial and accounting officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2021. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2021, our President and Chief Executive Officer and our Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Internal Control Over Financial Reporting

Management's Annual Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) and 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our board of directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP.

Internal control over financial reporting includes policies and procedures that: (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect transactions and disposition of assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that receipts and expenditures are being made only in accordance with the authorization of its management and directors; and (3) provide reasonable assurance regarding the prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on its financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of the effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies and procedures included in such controls may deteriorate.

Our management conducted an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2021 based on the criteria described in "Internal Control-Integrated Framework" (2013) issued by the Committee of Sponsoring Organization of the Treadway Commission. Based on this assessment, management concluded that, as of December 31, 2021, our internal control over financial reporting was effective.

The effectiveness of our internal control over financial reporting as of December 31, 2021 has been audited by PricewaterhouseCoopers, LLP, an independent registered public accounting firm, as stated in their report which is included herein.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three months ended December 31, 2021 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None

Item 9C. Disclosures Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item 10 will be included in our Definitive Proxy Statement to be filed with the Securities and Exchange Commission, or SEC, with respect to our 2022 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 11. Executive Compensation.

The information required by this Item 11 will be included in our Definitive Proxy Statement to be filed with the Securities and Exchange Commission, or SEC, with respect to our 2022 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this Item 12 will be included in our Definitive Proxy Statement to be filed with the Securities and Exchange Commission, or SEC, with respect to our 2022 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this Item 13 will be included in our Definitive Proxy Statement to be filed with the Securities and Exchange Commission, or SEC, with respect to our 2022 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this Item 14 will be included in our Definitive Proxy Statement to be filed with the Securities and Exchange Commission, or SEC, with respect to our 2022 Annual Meeting of Stockholders and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(1) Financial Statements

The following documents are included on pages 76 through 103 attached hereto and are filed as part of this Annual Report on Form 10-K.

(2) Financial Statement Schedules:

All financial statement schedules have been omitted because they are not applicable, not required or the information required is shown in the financial statements or the notes thereto.

(3) Exhibits.

The following is a list of exhibits filed as part of this Annual Report on Form 10-K.

Exhibit Number	Description
3.1	Restated Articles of Organization (incorporated by reference to Exhibit 3.1 to the Registrant's Annual Report on Form 10-K (File No. 001-38891) filed with the SEC on March 17, 2020)
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.4 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 22, 2019)
4.1	Specimen stock certificate evidencing shares of common stock (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019).
4.2	Warrant Agreement to Purchase Preferred Stock, dated as of November 7, 2012, between the Registrant and Hercules Technology Growth Capital, Inc. (incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019).
4.3	Warrant Agreement to Purchase Preferred Stock, dated as of September 11, 2015, between the Registrant and Hercules Technology Growth Capital, Inc. (incorporated by reference to Exhibit 4.3 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)
4.4	Warrant Agreement to Purchase Preferred Stock, dated as of August 4, 2016, between the Registrant and Hercules Technology Growth Capital, Inc. (incorporated by reference to Exhibit 4.4 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)
4.5	Description of Registered Securities (incorporated by reference to Exhibit 4.5 to the Registrant's Annual Report on Form 10-K (File No. 001-38891) filed with the SEC on March 17, 2020)
10.1	Ninth Amended and Restated Investor Rights Agreement, dated as of May 6, 2019, by and among TransMedics Group, Inc., TransMedics, Inc. and the shareholders party thereto (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-38891) filed with the SEC on May 1, 2019)
10.2	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers (incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)

10.3#	Amended and Restated 2004 Stock Incentive Plan (incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)
10.4#	Form of Incentive Stock Option Agreement under 2004 Stock Incentive Plan (incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)
10.5#	Amended and Restated 2014 Stock Incentive Plan (incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)
10.6#	Form of Incentive Stock Option Agreement under 2014 Stock Incentive Plan (incorporated by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)
10.7#	Form of Non-Qualified Stock Option Agreement under 2014 Stock Incentive Plan (incorporated by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)
10.8#	Form of Restricted Stock Agreement under 2014 Stock Incentive Plan (incorporated by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)
10.9#	2019 Stock Incentive Plan (incorporated by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 22, 2019)
10.10#	Form of Incentive Stock Option Agreement under 2019 Stock Incentive Plan (incorporated by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 22, 2019)
10.11#	Form of Non-Statutory Stock Option Agreement under 2019 Stock Incentive Plan (incorporated by reference to Exhibit 10.11 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 22, 2019)
10.12#	2019 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 22, 2019)
10.13#	2019 Cash Incentive Plan (incorporated by reference to Exhibit 10.13 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 22, 2019)
10.14#	TransMedics Group, Inc. Inducement Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-38891) filed with the SEC on August 9, 2021)
10.15#	Executive Retention Agreement, dated as of November 15, 2007, by and among the Registrant and Waleed H. Hassanein, M.D. (incorporated by reference to Exhibit 10.14 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)
10.16#	Executive Retention Agreement, dated as of November 15, 2007, by and among the Registrant and Tamer I. Khayal, M.D. (incorporated by reference to Exhibit 10.15 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)
10.17#	Executive Retention Agreement, dated as of March 23, 2015, by and among the Registrant and Stephen Gordon (incorporated by reference to Exhibit 10.16 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)
10.18	Lease Agreement, dated as of June 25, 2004, between the Registrant and 200 Minuteman Limited Partnership (incorporated by reference to Exhibit 10.17 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)
10.19	First Amendment to Lease, dated as of September 28, 2004, between the Registrant and 200 Minuteman Limited Partnership (incorporated by reference to Exhibit 10.18 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)
10.20	Second Amendment to Lease, dated as of November 29, 2005, between the Registrant and 200 Minuteman Limited Partnership (incorporated by reference to Exhibit 10.19 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)

10.21	Third Amendment to Lease, dated as of June 12, 2006, between the Registrant and 200 Minuteman Limited Partnership (incorporated by reference to Exhibit 10.20 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)
10.22	Fourth Amendment to Lease, dated as of February 1, 2007, between the Registrant and 200 Minuteman Limited Partnership (incorporated by reference to Exhibit 10.21 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)
10.23	Fifth Amendment to Lease, dated as of April 30, 2010, between the Registrant and 200 Minuteman Limited Partnership (incorporated by reference to Exhibit 10.22 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)
10.24	Lease Agreement, dated as of June 25, 2004, between the Registrant and 30 Minuteman Limited Partnership (incorporated by reference to Exhibit 10.23 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)
10.25	Second Amendment to Lease, dated as of November 29, 2005, between the Registrant and 30 Minuteman Limited Partnership (incorporated by reference to Exhibit 10.24 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)
10.26	Third Amendment to Lease, dated as of April 30, 2010, between the Registrant and 30 Minuteman Limited Partnership (incorporated by reference to Exhibit 10.25 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)
10.27	Omnibus Amendment #1 to Lease Agreement, dated January 9, 2020, by and among the Company, Whetstone 200 Minuteman Park, LLC and Whetstone 30 Minuteman Park, LLC (incorporated by reference to Exhibit 10.26 to the Registrant's Annual Report on Form 10-K (File No. 001-38891) filed with the SEC on March 17, 2020)
10.28	Credit Agreement, dated as of June 22, 2018, by and between the Registrant and OrbiMed Royalty Opportunities II, LP (incorporated by reference to Exhibit 10.26 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)
10.29	Pledge and Security Agreement, dated as of June 22, 2018, by and between the Registrant and OrbiMed Royalty Opportunities II, LP (incorporated by reference to Exhibit 10.27 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)
10.30	Guarantee, dated as of June 22, 2018, made by TransMedics B.V. in favor of OrbiMed Royalty Opportunities II, LP (incorporated by reference to Exhibit 10.28 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)
10.31	Supplement to Guarantee, dated as of May 6, 2019, by TransMedics Group, Inc. in favor of OrbiMed Royalty Opportunities II, LP. (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 001-38891) filed with the SEC on May 1, 2019)
10.32	Supplement to Pledge and Security Agreement, dated as of May 6, 2019, by TransMedics Group, Inc. in favor of OrbiMed Royalty Opportunities II, LP. (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K (File No. 001-38891) filed with the SEC on May 1, 2019)
10.33	Third Waiver to Credit Agreement, dated as of March 29, 2019, by and among TransMedics, Inc., TransMedics B.V. and Orbimed Royalty Opportunities II, LP (incorporated by reference to Exhibit 10.35 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 22, 2019)
10.34+	License Agreement dated as of August 27, 2002 by and between the Registrant and The Department of Veterans Affairs (incorporated by reference to Exhibit 10.31 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)
10.35+	Development and Supply Agreement dated as of May 24, 2005 by and between the Registrant and Fresenius Kabi AB (incorporated by reference to Exhibit 10.32 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)
10.36+	Contract Manufacturing Agreement dated as of April 1, 2015 by and between the Registrant and Fresenius Kabi Austria GmbH (incorporated by reference to Exhibit 10.33 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)

10.37	Board Observer Agreement dated as of April 5, 2019 by and among the Registrant, Abrams Capital Partners I, L.P., Abrams Capital Partners II, L.P., Grant Hollow International, L.P., Riva Capital Partners III, L.P. and Whitecrest Partners, LP (incorporated by reference to Exhibit 10.34 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)
10.38+	Amendment to Executive Retention Agreement, be and between TransMedics, Inc. and Stephen Gordon, dated April 10, 2020 (incorporated by reference to the Registrant's Current Report on Form 8-K (File No. 001-38891) filed with the SEC on April 13, 2020).
10.39	Promissory Note, dated April 20, 2020 ((incorporated by reference to the Registrant's Current Report on Form 8-K (File No. 001-38891) filed with the SEC on April 24, 2020).
10.41	Second Amendment to Credit Agreement, dated as of April 23, 2020, by and among TransMedics, Inc., TransMedics Croup, Inc., TransMedics, B.V. and Orbimed Royalty Opportunities II, L.P. (incorporated by reference to the Registrant's Current Report on Form 8-K (File No. 001-38891) filed with the SEC on April 24, 2020).
10.42	Omnibus Amendment #2 to Lease, dated as of June 1, 2020, by and among the Company and Whetstone 200 Minuteman Park, LLC and Whetstone 30 Minuteman Park, LLC (incorporated by reference to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38891) filed with the SEC on August 7, 2020).
21.1	List of Subsidiaries (incorporated by reference to Exhibit 21.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019).
23.1*	Consent of PricewaterhouseCoopers LLP, independent registered public accounting firm.
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* Filed herewith.
\# Indicated a management or compensatory plan, contract or arrangement.
\+ Confidential treatment has been granted as to certain portions, which portions have been omitted and submitted separately to the SEC

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

Company Name

Date: March 1, 2022

By: /s/ Stephen Gordon

Stephen Gordon
Chief Financial Officer, Treasurer and Secretary

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Waleed H. Hassanein, M.D. **Waleed H. Hassanein**	President, Chief Executive Officer, Director	March 1, 2022
/s/ Stephen Gordon **Stephen Gordon**	Chief Financial Officer, Treasurer and Secretary	March 1, 2022
/s/ James R. Tobin **James R. Tobin**	Chairman of the Board of Directors	March 1, 2022
/s/ Edward M. Basile **Edward M. Basile**	Director	March 1, 2022
/s/ Thomas J. Gunderson **Thomas J. Gunderson**	Director	March 1, 2022
/s/ Edwin M. Kania, Jr. **Edwin M. Kania, Jr.**	Director	March 1, 2022
/s/ David Weill, M.D. **David Weill, M.D.**	Director	March 1, 2022
/s/ Merilee Raines **Merilee Raines**	Director	March 1, 2022

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-238052) and Form S-8 (No. 333-231243) of TransMedics Group, Inc. of our report dated March 1, 2022 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts
March 1, 2022

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Waleed Hassanein, M.D., certify that:

1. I have reviewed this Annual Report on Form 10-K of TransMedics Group, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 1, 2022

By: /s/ Waleed H. Hassanein

Waleed H. Hassanein, M.D.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Stephen Gordon, certify that:

1. I have reviewed this Annual Report on Form 10-K of TransMedics Group, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 1, 2022

By: /s/ Stephen Gordon

Stephen Gordon
Chief Financial Officer, Treasurer and Secretary

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of TransMedics Group, Inc. (the "Company") for the year ended December 31, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Waleed Hassanein, M.D., President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: March 1, 2022

By: /s/ Waleed H. Hassanein

Waleed H. Hassanein, M.D.
President and Chief Executive Officer

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of TransMedics Group, Inc. (the "Company") for the year ended December 31, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Stephen Gordon, Chief Financial Officer, Treasurer and Secretary of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: March 1, 2022

By: /s/ Stephen Gordon

Stephen Gordon
Chief Financial Officer, Treasurer and Secretary