UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2020

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 Number)**
200 Minuteman Road Andover, Massachusetts	**01810**
(Address of principal executive offices)	**(Zip code)**

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

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**

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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of April 30, 2020, the registrant had 21,361,513 shares of common stock, no par value per share, outstanding.

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements with respect to, among other things, our operations and financial performance. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q, 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. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those referenced in the section titled “Risk Factors,” which could cause actual results to differ materially. 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 or implied by any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this Quarterly Report on Form 10-Q may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

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

- 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 to until maturity, and our ability to obtain additional financing on favorable terms or at all;
- 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;
- the rate and degree of market acceptance of the OCS;
- our ability to educate patients, surgeons, transplant centers and private payors of benefits offered by the OCS;
- the impact of the outbreak of the novel strain of coronavirus and associated containment and remediation efforts;
- our ability to improve the OCS platform;
- our dependence on a limited number of customers for a significant portion of our net revenue;
- the timing of and our ability to obtain and maintain regulatory approvals or clearances 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 performance of our third-party suppliers and manufacturers;
- the timing or results of clinical trials for the OCS;
- our manufacturing, sales, marketing and clinical support capabilities and strategy;
- attacks against our information technology infrastructure;
- the economic, political and other risks associated with our foreign operations;
- our ability to attract and retain key personnel;
- our ability to protect, defend, maintain and enforce our intellectual property rights relating to the OCS and avoid allegations that our products infringe, misappropriate or otherwise violate the intellectual property rights of third parties;
- our ability to obtain and maintain regulatory approvals or clearance for our OCS products;
- the pricing of the OCS, as well as the reimbursement coverage for the OCS in the United States and internationally;

The forward-looking statements included in this Quarterly Report on Form 10-Q are made only as of the date of this report. You should not rely upon forward-looking statements as predictions of future events. 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 Quarterly Report on Form 10-Q to conform these statements to actual results or reflect interim developments.

TransMedics Group, Inc.
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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)

TRANSMEDICS GROUP, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share amounts)
(Unaudited)

	March 31, 2020	December 28, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 24,738	$ 20,092
Marketable securities	47,816	60,596
Accounts receivable	6,133	6,559
Inventory	11,361	11,216
Prepaid expenses and other current assets	1,656	1,538
Total current assets	91,704	100,001
Property and equipment, net	4,713	4,792
Restricted cash	500	500
Other long-term assets	6	6
Total assets	$ 96,923	$ 105,299
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,860	$ 7,247
Accrued expenses and other current liabilities	9,926	8,332
Deferred revenue	164	166
Current portion of deferred rent	89	370
Total current liabilities	15,039	16,115
Long-term debt, net of discount and current portion	34,269	34,146
Deferred rent, net of current portion	932	389
Total liabilities	50,240	50,650
Commitments and contingencies (Note 10)		
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; 21,343,480 shares and 21,184,524 shares issued and outstanding at March 31, 2020 and December 28, 2019, respectively	424,791	424,134
Accumulated other comprehensive income (loss)	227	(2)
Accumulated deficit	(378,335)	(369,483)
Total stockholders' equity	46,683	54,649
Total liabilities and stockholders' equity	$ 96,923	$ 105,299

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)
(Unaudited)

	Fiscal Three Months Ended	
	March 31, 2020	March 30, 2019
Net revenue	$ 7,530	$ 4,676
Cost of revenue	2,670	2,103
Gross profit	4,860	2,573
Operating expenses:		
Research, development and clinical trials	6,225	3,882
Selling, general and administrative	6,652	4,653
Total operating expenses	12,877	8,535
Loss from operations	(8,017)	(5,962)
Other income (expense):		
Interest expense	(1,042)	(1,093)
Change in fair value of preferred stock warrant liability	—	273
Other income (expense), net	217	(103)
Total other expense, net	(825)	(923)
Loss before income taxes	(8,842)	(6,885)
Provision for income taxes	(10)	(10)
Net loss	$ (8,852)	$ (6,895)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.42)	$ (4.86)
Weighted average common shares outstanding, basic and diluted	21,221,385	1,418,353

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

TRANSMEDICS GROUP, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(In thousands)
(Unaudited)

	Fiscal Three Months Ended	
	March 31, 2020	March 30, 2019
Net loss	$ (8,852)	$ (6,895)
Other comprehensive income:		
Foreign currency translation adjustment	16	34
Unrealized gains on marketable securities, net of tax of $0	213	—
Total other comprehensive income	229	34
Comprehensive loss	$ (8,623)	$ (6,861)

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

TRANSMEDICS GROUP, INC.
CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(in thousands, except share amounts)
(Unaudited)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehen-sive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Par Value				
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	—	—	146,793	75	—	—	—	75
Issuance of common stock in connection with employee stock purchase plan	—	—	12,163	197	—	—	—	197
Stock-based compensation expense	—	—	—	385	—	—	—	385
Foreign currency translation adjustment	—	—	—	—	—	16	—	16
Unrealized gains on marketable securities	—	—	—	—	—	213	—	213
Net loss	—	—	—	—	—	—	(8,852)	(8,852)
Balances at March 31, 2020	—	$ —	21,343,480	$424,791	$ —	$ 227	$ (378,335)	$ 46,683

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehen-sive Income (Loss)	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Par Value				
Balances at December 29, 2018	50,404,140	$ 186,519	1,397,493	$ 1	$143,794	$ (101)	$ (335,936)	$ (192,242)
Issuance of common stock upon the exercise of common stock options	—	—	29,180	—	8	—	—	8
Stock-based compensation expense	—	—	—	—	57	—	—	57
Foreign currency translation adjustment	—	—	—	—	—	34	—	34
Net loss	—	—	—	—	—	—	(6,895)	(6,895)
Balances at March 30, 2019	50,404,140	$ 186,519	1,426,673	$ 1	$143,859	$ (67)	$ (342,831)	$ (199,038)

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

TRANSMEDICS GROUP, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)
(Unaudited)

	Fiscal Three Months Ended	
	March 31, 2020	March 30, 2019
Cash flows from operating activities:		
Net loss	$ (8,852)	$ (6,895)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	371	245
Stock-based compensation expense	385	57
Change in fair value of preferred stock warrant liability	—	(273)
Non-cash interest expense and end of term accretion expense	123	115
Net amortization of premiums on marketable securities	1	—
Unrealized foreign currency transaction losses	78	160
Changes in operating assets and liabilities:		
Accounts receivable	422	(1,746)
Inventory	(241)	(2,468)
Prepaid expenses and other current assets	(120)	417
Accounts payable	(2,411)	758
Accrued expenses and other current liabilities	1,806	2,394
Deferred revenue	—	57
Deferred rent	262	(87)
Net cash used in operating activities	(8,176)	(7,266)
Cash flows from investing activities:		
Purchases of property and equipment	(277)	(3)
Purchases of marketable securities	(4,168)	—
Proceeds from sales and maturities of marketable securities	17,160	—
Net cash provided by (used in) investing activities	12,715	(3)
Cash flows from financing activities:		
Payments of initial public offering costs and other financing costs	(120)	(705)
Proceeds from issuance of common stock upon exercise of stock options	75	8
Proceeds from issuance of common stock in connection with employee stock purchase plan	197	—
Net cash provided by (used in) financing activities	152	(697)
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(45)	(60)
Net increase (decrease) in cash, cash equivalents and restricted cash	4,646	(8,026)
Cash, cash equivalents and restricted cash, beginning of period	20,592	20,741
Cash, cash equivalents and restricted cash, end of period	$ 25,238	$ 12,715
Supplemental disclosure of non-cash investing and financing activities:		
Transfers of inventory to property and equipment	$ 78	$ 407
Purchases of property and equipment included in accounts payable	$ 112	$ 129
Offering costs included in accounts payable and accrued expenses	$ —	$ 1,134
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$ 24,738	$ 12,215
Restricted cash	500	500
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	$ 25,238	$ 12,715

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

TRANSMEDICS GROUP, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

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.

On May 6, 2019, immediately prior to the closing of the Company's initial public offering (the "IPO"), the Company completed a corporate reorganization whereby TransMedics, the direct parent of TransMedics Group prior to the corporate reorganization, became a direct, wholly-owned subsidiary of TransMedics Group pursuant to the merger of TMDX, Inc., a direct, wholly-owned subsidiary of TransMedics Group prior to the corporate reorganization, with and into TransMedics, with TransMedics as the surviving corporation. Pursuant to the terms of an agreement and plan of merger and reorganization, as a result of the merger, each outstanding share of common stock of TransMedics was converted into shares of common stock of TransMedics Group on a 3.5-for-one basis, each outstanding share of convertible preferred stock of TransMedics was converted into shares of common stock of TransMedics Group based on the conversion ratio of each individual series of preferred stock, as defined in the certificate of incorporation of TransMedics prior to the conversion, and the 3.5-for-one ratio on which shares of common stock of TransMedics were converted into common stock of TransMedics Group; each outstanding option to purchase shares of common stock of TransMedics was converted into an outstanding option to purchase shares of common stock of TransMedics Group adjusted on a 3.5-for-one basis, with a corresponding adjustment to the exercise price; and each outstanding warrant to purchase shares of preferred stock of TransMedics was converted into a warrant to purchase shares of common stock of TransMedics Group adjusted on a 3.5-for-one basis, with a corresponding adjustment to the exercise price. This is referred to as the "Corporate Reorganization."

All share and per share amounts for all periods presented in the accompanying consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect the 3.5-for-one conversion ratio applied to common stock in the Corporate Reorganization.

Immediately following the Corporate Reorganization, (i) TransMedics Group became a holding company with no material assets other than 100% of the equity interests in TransMedics, (ii) the holders of capital stock in TransMedics became shareholders of TransMedics Group and (iii) the historical consolidated financial statements of TransMedics became the historical consolidated financial statements of TransMedics Group because the Corporate Reorganization was accounted for as a reorganization of entities under common control. Prior to the Corporate Reorganization, TransMedics Group had not conducted any activities other than in connection with its formation and in preparation for the IPO and had no material assets other than 100% of the equity interests in TMDX, Inc.

On May 6, 2019, the Company completed its IPO, pursuant to which it issued and sold 6,543,500 shares of common stock, inclusive of 853,500 shares sold by the Company pursuant to the full exercise of the underwriters' option to purchase additional shares. The aggregate net proceeds received by the Company from the IPO were $91.4 million, after deducting underwriting discounts and commissions as well as other offering costs of $6.0 million.

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 attributable to the Company of $8.9 million for the fiscal three months ended March 31, 2020 and $33.5 million for the fiscal year ended December 28, 2019. As of March 31, 2020, the Company had an accumulated deficit of $378.3 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 $72.6 million as of March 31, 2020 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 Quarterly Report on Form 10-Q. 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, and approved products may not prove commercially viable. The Company operates in an environment of rapid change in technology and competition.

In December 2019, a novel strain of coronavirus (COVID-19) emerged in Wuhan, Hubei Province, China. Less than four months later, in March 2020, the World Health Organization declared COVID-19 a pandemic, and the virus has now spread to many other countries and regions and every state within the United States, including Massachusetts, where the Company's primary offices and manufacturing facilities are located. The impact of this pandemic has been and will likely continue to be extensive in many aspects of society, which has resulted in and will likely 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 include the temporary disruption of transplant procedures at many of the organ transplant centers who purchase OCS products; 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; restrictions on or delays of the Company's clinical trials and studies; limitations on its employees' and customers' ability to travel, and delays in product installations, trainings or shipments to and from 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 clinical trial activities. The Company's sales and clinical adoption team is also operating at reduced capacity and restricted in visiting many transplant centers in person. In addition, the Company has temporarily reduced the manufacturing and distribution of its OCS products at its facility in Andover, Massachusetts, and, while it 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 has impacted regulatory timelines, including with respect to the Company's OCS Heart Pre-Market Approval ("PMA") application, and may affect other potential PMA applications.

While the COVID-19 pandemic did not significantly impact the Company's business or results of operations during the first quarter of 2020, the Company anticipates a negative impact to OCS product sales for the remainder of 2020; however, the length and extent of the pandemic, its consequences, and containment efforts will determine the future impact on the Company's operations and financial condition.

Prior to 2020, the Company's fiscal year ended on the last Saturday in December, and the Company reported fiscal years using a 52/53-week convention. Under this convention, certain fiscal years contained 53 weeks. Each fiscal year was typically composed of four 13-week fiscal quarters, but in years with 53 weeks, the fourth quarter was a 14-week period. The fiscal year ended December 28, 2019 included 52 weeks. In February 2020, the Company changed the end of its fiscal year end from the last Saturday in December to December 31. As a result of this change, the Company's current fiscal year will end on December 31, 2020 and its current and each subsequent fiscal quarter will end on March 31, June 30 and September 30.

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

Unaudited Interim Financial Information

The accompanying unaudited interim financial statements and related notes have been prepared by the Company pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC") for interim financial statements. Certain information and footnote disclosures normally included in the financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. These consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and the notes thereto for the fiscal year ended December 28, 2019 included in the Company's Annual Report on Form 10-K on file with the SEC. In the opinion of management, all adjustments, consisting only of normal recurring adjustments necessary for a fair statement of the Company's financial position as of March 31, 2020 and results of operations for the fiscal three months ended March 31, 2020 and March 30, 2019 and cash flows for the fiscal three months ended in the same periods have been made. The Company's results of operations for the fiscal three months ended March 31, 2020 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2020.

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 unaudited 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 fiscal three months ended March 31, 2020, one customer represented 17% of net revenue. For the fiscal three months ended March 30, 2019, two customers represented 13% and 11% of net revenue. As of March 31, 2020, one customer accounted for 17% of accounts receivable. As of December 28, 2019, no customer accounted for 10% or more 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.

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 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 (deficit). Realized gains and losses and declines in value determined to be other than temporary are based on the specific identification method and are included as a component of other income (expense), net in the consolidated statements of operations.

The Company evaluates its marketable securities with unrealized losses for other-than-temporary impairment. When assessing marketable securities for other-than-temporary declines in value, the Company considers such factors as, among other things, how significant the decline in value is as a percentage of the original cost, how long the market value of the investment has been less than its original cost, the Company's ability and intent to retain the investment for a period of time sufficient to allow for any anticipated recovery in fair value and market conditions in general. If any adjustment to fair value reflects a decline in the value of the investment that the Company considers to be "other than temporary," the Company reduces the investment to fair value through a charge recorded in the consolidated statements of operations. No such adjustments were necessary during the periods presented.

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. 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.

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. A performance obligation is distinct if (1) the product or service is separately identifiable from other promises in the contract and (2) the customer can benefit from the product or service on its own or with other resources that are readily available to the customer.

When a customer order includes an OCS Console, whether sold or loaned, the Company has determined that customer training and the equipment set-up of the OCS Console, each performed by the Company, 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. Consequently, the Company does not recognize any revenue from any component of a customer order that includes an OCS Console, whether sold or loaned, until the OCS Console has arrived at the customer site and the training and equipment set-up have been completed by the Company. The Company has concluded that "transfer of control" of an OCS Console occurs only after the console has arrived at the customer site and the training and equipment set-up have been completed by the Company.

Some of the Company's revenue has been generated from products sold in conjunction with the clinical trials conducted for the Company's OCS products, under arrangements referred to as customer clinical trial agreements. Under most of these customer clinical trial agreements, the Company places an organ-specific OCS Console at the customer site for its use free of charge for the duration of the clinical trial, and the customer separately purchases from the Company the OCS disposable sets used in each transplant procedure during the clinical trial. When the Company loans the OCS Console to the customer, it retains title to the console at all times and does not require minimum purchase commitments from the customer related to any OCS products. In such cases, the Company invoices the customer for OCS disposable sets based on customer orders received for each new transplant procedure and the prices set forth in the customer agreement. Over time, the Company typically recovers the cost of the loaned OCS Console through the customer's continued purchasing and use of additional 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.

When the Company's customer arrangements have multiple-performance obligations that contain a loan of an OCS Console for the customer's use at its customer site as well as OCS disposable sets that are delivered simultaneously, the Company allocates the arrangement consideration between the lease deliverables (i.e., the OCS Console) and non-lease deliverables (i.e., the OCS disposable sets) based on the relative estimated standalone selling price ("SSP") of each distinct performance obligation. To date, the amounts allocated to lease deliverables have been insignificant. In determining SSP, the Company maximizes observable inputs and consider a number of data points, including: (1) the pricing of standalone sales (in instances where available), (2) the pricing established by management when setting prices for deliverables that are intended to be sold on a standalone basis, (3) contractually stated prices for deliverables that are intended to be sold on a standalone basis, and (4) other pricing factors, such as the geographical region in which the products are sold and expected discounts based on the customer size and type.

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.

Performance Obligations

The primary performance obligations in the Company's customer arrangements from which it derives revenue are as follows:

- *OCS Console* — The OCS Console is a medical device that houses and controls the function of the OCS. The performance obligation of the OCS Console includes customer training and equipment set-up. Revenue for each OCS Console is recognized at the point in time at which control is transferred to the customer, which is typically only after the console has arrived at the customer site and the training and equipment set-up have been completed by the Company because the customer cannot benefit from the OCS Console without the training and equipment set-up having been completed. At that time, the Company believes that the customer has the significant risks and rewards of ownership.
- *OCS Perfusion Set* — The OCS Perfusion Set is a single-use disposable set that stores the organ and circulates blood. Revenue for each OCS Perfusion Set is recognized at the point in time at which control is transferred to the customer, which is when title transfers to the customer in connection with delivery. In most of the Company's customer arrangements, title to the OCS Perfusion Set transfers when the OCS Perfusion Set arrives at the customer site. In limited instances, title transfers upon shipment to the customer by the Company.
- *OCS Solutions* — The OCS Solutions are a set of nutrient-enriched solutions to optimize the organ's condition outside the human body. Revenue for each OCS Solution is recognized at the point in time at which control is transferred to the customer, which is when title transfers to the customer in connection with delivery. In most of the Company's customer arrangements, title to the OCS Solutions transfers when the OCS Solutions arrive at the customer site. In limited instances, title transfers upon shipment to the customer by the Company.

Payments Made to Customers

Under the Company's customer arrangements that include a customer clinical trial agreement, the Company receives payments from sales to the customer of its OCS products and also makes payments to that customer for reimbursements of clinical trial 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.

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 Company recorded the reimbursable clinical costs as a reduction of revenue of $0.7 million and $0.6 million, for the fiscal three months ended March 31, 2020 and March 30, 2019, respectively, as presented below in disaggregated revenue.

The Company has also 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) do 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 represents the fair value of the distinct good or service received by the Company. As a result, these payments made to the customers for information related to post-approval studies or standard-of-care protocols are recorded as research, development, and clinical trials expenses. The Company recorded payments made to customers related to post-approval studies and for documentation related to existing standard-of-care protocols of $0.4 million and $0.2 million for the fiscal three months ended March 31, 2020 and March 30, 2019, respectively, as research, development, and clinical trials expenses.

Variable Consideration

Revenue is reported net of any taxes assessed by a governmental authority that are directly imposed on a revenue-producing transaction (e.g., sales, use, and value added taxes). 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.

Revenue from reimbursements of out-of-pocket expenses, including travel, lodging, and meals, is accounted for as variable consideration.

The Company does not consider shipping to be a contract performance obligation. The Company records shipping costs billed to customers as revenue and records the associated costs incurred by the Company for those items as cost of revenue.

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. Payment terms for customer orders, including for each of the Company's primary performance obligations, are typically 30 days for customers in the United States and 30 to 90 days for customers in non-U.S. markets, and such payments do not include payments that are variable, dependent on specified factors or events.

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 March 31, 2020 and December 28, 2019.

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 each of March 31, 2020, and December 28, 2019, the Company's wholly- or partially-unsatisfied performance obligations totaled $0.7 million.

Disaggregated Revenue

In determining total net revenue under the revenue recognition guidance applicable to both periods presented, the Company reduces revenue by the amount of certain payments made to customers (see "Payments Made to Customers" above). The reconciliation of gross revenue to net revenue for these certain payments is shown below (in thousands):

	Fiscal Three Months Ended	
	March 31, 2020	March 30, 2019
Gross revenue from sales to customers	$ 8,243	$ 5,290
Less: clinical trial payments reducing revenue	713	614
Total net revenue	$ 7,530	$ 4,676

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):

	Fiscal Three Months Ended	
	March 31, 2020	March 30, 2019
Net revenue by OCS product:		
OCS Lung net revenue	$ 2,008	$ 1,412
OCS Heart net revenue	4,131	1,922
OCS Liver net revenue	1,391	1,342
Total net revenue	$ 7,530	$ 4,676

	Fiscal Three Months Ended	
	March 31, 2020	March 30, 2019
Net revenue by country:		
United States	$ 5,208	$ 2,953
United Kingdom	1,112	569
All other countries	1,210	1,154
Total net revenue	$ 7,530	$ 4,676

Other Revenue Considerations

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. The Company does not consider shipping to be a contract performance obligation.

Distributors

The Company markets and sells its products primarily through its direct sales force, which sells its products to end customers globally. A small portion of the Company's revenue is generated by sales to a limited number of distributors in Europe and Asia-Pacific. When the Company transacts with a distributor, its contractual arrangement is with the distributor and not with the end customer. Whether the Company transacts business with and receives the order from a distributor or directly from an end customer, its revenue recognition policy and resulting pattern of revenue recognition for the order are the same.

In its business with distributors, the Company enters into a distributor agreement under which the distributor places orders to the Company for its products in connection with the distributor's own sales to identified end customers, and the Company confirms the identification of the end customer prior to accepting each order. The Company's distributors do not stock OCS Consoles purchased from the Company and stock only minimal quantities of OCS disposable sets. Under these contractual arrangements, the Company invoices the distributor for the selling price (which reflects a distributor discount relative to typical end customer pricing) and payment to the Company from the distributor is not contingent upon the distributor's collection from the end customer. The Company records revenue based on the amount of the discounted selling price.

When a sale to a distributor includes an OCS Console, the Company performs the training and OCS Console equipment set-up for the end customer. The Company recognizes no revenue from a distributor order that includes an OCS Console until the OCS Console has arrived at the customer site and the training and equipment set-up have been completed by the Company.

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.

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.

Net Income (Loss) per Share

Prior to closing of the IPO, the Company followed the two-class method when computing net income (loss) per share, as TransMedics had issued shares that met the definition of participating securities. The two-class method determines net income (loss) per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed. The outstanding convertible preferred stock contractually entitled the holders of such shares to participate in dividends but did not contractually require the holders of such shares to participate in losses of the Company. Accordingly, in periods in which the Company reported a net loss, such losses were not allocated to such participating securities, and as a result, basic and diluted net loss per share were the same. The Company reported a net loss attributable to common stockholders for the fiscal three months ended March 30, 2019.

Under the two-class method, basic net income (loss) per share attributable to common stockholders is computed by dividing the net income (loss) attributable to common stockholders by the weighted average number of common shares outstanding for the period. Diluted net income (loss) attributable to common stockholders is computed by adjusting net income (loss) attributable to common stockholders to reallocate undistributed earnings based on the potential impact of dilutive securities. Diluted net income (loss) per share attributable to common stockholders is computed by dividing the diluted net income (loss) attributable to common stockholders by the weighted average number of common shares outstanding for the period, including potential dilutive common shares assuming the dilutive effect of common stock equivalents.

Subsequent to the closing of its IPO, the Company only has one class of shares outstanding and 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 the fiscal three months ended March 31, 2020.

Recently Issued Accounting Pronouncements

The Company qualifies as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 and has elected not to "opt out" of the extended transition related to complying with new or revised accounting standards, which means that when a standard is issued or revised and it has different application dates for public and nonpublic companies, the Company will adopt the new or revised standard at the time nonpublic companies adopt the new or revised standard and will do so until such time that the Company either (i) irrevocably elects to "opt out" of such extended transition period or (ii) no longer qualifies as an emerging growth company.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* ("ASU 2016-02"), which sets out the principles for the recognition, measurement, presentation, and disclosure of leases for both parties to a contract (i.e., lessees and lessors). The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or less may be accounted for similar to existing guidance for operating leases today. For public entities, the guidance has been effective for annual reporting periods beginning after December 15, 2018 and for interim periods within those fiscal years. ASU 2016-02 initially required adoption using a modified retrospective approach, under which all years presented in the financial statements would be prepared under the revised guidance. In July 2018, the FASB issued ASU No. 2018-11, *Leases (Topic 842)*, which added an optional transition method under which financial statements may be prepared under the revised guidance for the year of adoption, but not for prior years. Under the latter method, entities will recognize a cumulative catch-up adjustment to the opening balance of retained earnings in the period of adoption. In November 2019, the FASB issued ASU No. ASU 2019-10, which deferred the effective date for nonpublic entities to annual reporting periods beginning after December 15, 2020, and interim periods within fiscal years beginning after December 15, 2021. The Company is currently planning to adopt this guidance on January 1, 2021 in accordance with the nonpublic company requirements and is evaluating the method of adoption and the impact that the adoption of ASU 2016-02 will have on its consolidated financial statements.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments – Credit Losses (Topic 326)*. 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. For public entities except smaller reporting companies, the guidance is effective for annual reporting periods beginning after December 15, 2019 and for interim periods within those fiscal years. For non-public entities and smaller reporting companies, the guidance was effective for annual reporting periods beginning after December 15, 2021. Early adoption is permitted for all entities. In November 2019, the FASB issued ASU No. 2019-10, which deferred the effective date for non-public entities to annual reporting periods beginning after December 15, 2022, including interim periods within those fiscal years. Early application continues to be allowed. The Company is currently assessing the impact of the adoption of this guidance on its financial statements.

3. Marketable Securities

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

	March 31, 2020			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury securities (due within one year)	$ 24,803	$ 184	$ —	$24,987
U.S. government agency bonds (due within one year)	22,746	83	—	22,829
	$ 47,549	$ 267	$ —	$47,816

	December 28, 2019			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury securities (due within one year)	$ 23,318	$ 17	$ —	$23,335
U.S. government agency bonds (due within one year)	37,224	39	(2)	37,261
	$ 60,542	$ 56	$ (2)	$60,596

4. Fair Value of Financial Assets and Liabilities

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

	Fair Value Measurements at March 31, 2020 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 12,080	$ —	$ —	$ 12,080
Marketable securities:				
U.S. Treasury securities	—	24,987	—	24,987
U.S. government agency bonds	—	22,829	—	22,829
	$ 12,080	$ 47,816	$ —	$ 59,896

	Fair Value Measurements at December 28, 2019 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 11,760	$ —	$ —	$ 11,760
Marketable securities:				
U.S. Treasury securities	—	23,335	—	23,335
U.S. government agency bonds	—	37,261	—	37,261
	$ 11,760	$ 60,596	$ —	$ 72,356

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. During the fiscal three months ended March 31, 2020 and March 30, 2019, there were no transfers between Level 1, Level 2, and Level 3.

5. Inventory

As of March 31, 2020 and December 28, 2019, inventory consisted of the following (in thousands):

	March 31, 2020	December 28, 2019
Raw materials	$ 5,676	$ 4,881
Work-in-process	1,032	903
Finished goods	4,653	5,432
	$ 11,361	$ 11,216

During the fiscal three months ended March 31, 2020 and March 30, 2019, the Company made non-cash transfers of OCS Consoles from inventory to property and equipment (OCS Consoles loaned to customers) of $0.1 million and $0.4 million, respectively.

6. Accrued Expenses and Other Current Liabilities

As of March 31, 2020 and December 28, 2019, accrued expenses and other current liabilities consisted of the following (in thousands):

	March 31, 2020	December 28, 2019
Accrued research, development and clinical trials expenses	$ 3,751	$ 3,144
Accrued payroll and related expenses	4,513	3,604
Accrued other	1,662	1,584
	$ 9,926	$ 8,332

7. 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. As of March 31, 2020 and December 28, 2019, long-term debt consisted of the following (in thousands):

	March 31, 2020	December 28, 2019
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	(1,065)	(1,139)
Accrued end-of-term payment	334	285
Long-term debt, net of discount and current portion	$ 34,269	$ 34,146

Borrowings under the Credit Agreement bear interest at an annual rate equal to the London Interbank Offered Rate ("LIBOR"), subject to a minimum of 1.0% and a maximum of 4.0%, plus 8.5% (the "Applicable Margin"), subject in the aggregate to a maximum interest rate of 11.5%. In addition, borrowings under the Credit Agreement bear paid-in-kind ("PIK") interest at an annual rate equal to the amount by which LIBOR plus the Applicable Margin exceeds 11.5%, but not to exceed 12.5%. The PIK interest is added to the principal amount of the borrowings outstanding at the end of each quarter until the maturity date of the Credit Agreement in June 2023. Borrowings under the Credit Agreement are repayable in quarterly interest-only payments until the maturity date, at which time all principal and accrued interest is due and payable. At its option, the Company may prepay outstanding borrowings under the Credit Agreement, subject to a prepayment premium of 9.0% of the principal amount of any prepayment within the first three years, which percentage decreases annually until it reaches zero at the end of three years. The Company is also required to make a final payment in an amount equal to 3.0% of the principal amount of any prepayment or repayment. The final payment 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 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 March 31, 2020, the Company was in compliance with the 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 March 31, 2020, the interest rate applicable to borrowings under the Credit Agreement was 10.5%. During the fiscal three months ended March 31, 2020, the weighted average effective interest rate on outstanding borrowings under the Credit Agreement was approximately 12.2%.

8. Equity

Preferred Stock

As of March 31, 2020, 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.

Common Stock

As of March 31, 2020, 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 shareholders. The holders of common stock are entitled to receive dividends, if any, as may be declared by the board of directors. Through March 31, 2020, no dividends had been declared or paid.

Warrants

Immediately prior to the closing of the IPO on May 6, 2019, pursuant to the Corporate Reorganization, all of the outstanding preferred stock warrants of TransMedics were converted into warrants to purchase an aggregate of 64,440 shares of common stock. No warrants have been exercised. As a result, as of March 31, 2020, the Company has 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.

9. Stock-Based Compensation

2019 Stock Incentive Plan and Option Grants

On April 15, 2019, TransMedics Group's board of directors adopted and its sole stockholder approved the 2019 Stock Incentive Plan (the "2019 Plan"), which became effective on that same date. 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 March 31, 2020, 2,609,280 shares of common stock were available for issuance under the 2019 Plan.

During the fiscal three months ended March 31, 2020, the Company granted options to its employees and a director with service-based vesting for the purchase of an aggregate of 383,300 shares of common stock with a weighted average grant fair value of $8.11 per share.

2019 Employee Stock Purchase Plan

On April 15, 2019, TransMedics Group's board of directors adopted and its sole stockholder approved the 2019 Employee Stock Purchase Plan (the "2019 ESPP"), which became effective that same date. A total of 371,142 shares of common stock of TransMedics Group are reserved for issuance under the 2019 ESPP. During the fiscal three months ended March 31, 2020, 12,163 shares of common stock were issued under the 2019 ESPP and as of March 31, 2020, 358,979 shares of common stock remained available for issuance.

Stock-Based Compensation

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

	Fiscal Three Months Ended	
	March 31, 2020	March 30, 2019
Cost of revenue	$ 4	$ 3
Research, development and clinical trials expenses	54	16
Selling, general and administrative expenses	327	38
	$ 385	$ 57

As of March 31, 2020 total unrecognized compensation cost related to unvested share-based awards was $6.4 million which is expected to be recognized over a weighted average period of 3.06 years.

10. Commitments and Contingencies

Operating Leases

On January 9, 2020, the Company amended each of the lease agreements for its corporate headquarters (the "Amendment") to lease an additional 39,744 square feet for general office use and an additional 11,735 square feet for operational use. The Amendment also extended each of the existing lease terms from December 2021 to December 2026, with an option to extend for one additional period of five years. Under the Amendment, the landlord will contribute $3.4 million towards the Company's leasehold improvements. The Amendment provides for annual base rent for the premises of approximately $1.9 million for the first year of the lease. Thereafter, the annual base rent will increase at an average 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.

The Company's lease agreements, including as amended by the Amendment, include payment escalations, rent holidays, and other lease incentives, which are accrued or deferred as appropriate such that rent expense for each lease is recognized on a straight-line basis over the respective lease terms, recording deferred rent for rent expense incurred but not yet paid. The Company recorded rent expense of $0.5 million and $0.3 million in each of the fiscal three months ended March 31, 2020 and March 30, 2019, respectively.

Future minimum lease payments under operating leases as of March 31, 2020 are as follows (in thousands):

Year Ending:	
December 31, 2020 (remaining 9 months)	$ 1,615
December 31, 2021	1,899
December 31, 2022	1,947
December 31, 2023	1,996
December 31, 2024	2,046
Thereafter	4,268
	$13,771

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 has been granted an interim patent term extension for this patent until September 23, 2020. The Company has not received final approval of the patent extension beyond the interim patent term extension already granted. The maximum extension granted would be through May 2022; however, the length of the patent term extension will be determined by the United States Patent and Trademark Office. The license includes the right to grant sublicenses, subject to approval by the VA and other restrictions, and is subject to the U.S. government's right to practice the licensed patents on its own behalf without payment of a royalty and obligation to grant certain sublicenses as necessary to fulfill public health, welfare and safety needs. The license agreement also requires the Company to make its products covered by the licensed patents available to the public on reasonable terms and to provide the U.S. government such products at the lowest price.

As consideration for the licenses granted by the VA, the Company is obligated to pay tiered royalties ranging from a low single-digit to a mid single-digit percentage on net sales of each product covered by a licensed patent (subject to a minimum aggregate royalty payment of less than $0.1 million per year during each of the first five years after the first commercial sale, after which no minimum is required). Royalties will be paid by the Company on a licensed product-by-licensed product and country-by-country basis, beginning on the first commercial sale of such licensed product in such country until expiration of the last valid patent claim covering such licensed product in such country. The Company is also responsible for all costs related to the amendment, prosecution and maintenance of the licensed patent rights.

The 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. As of March 31, 2020 and December 28, 2019, 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 March 31, 2020 and December 28, 2019.

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.

11. Net Loss per Share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows (in thousands, except share and per share amounts):

	Fiscal Three Months Ended	
	March 31, 2020	March 30, 2019
Numerator:		
Net loss attributable to common stockholders	$ (8,852)	$ (6,895)
Denominator:		
Weighted average common shares outstanding, basic and diluted	21,221,385	1,418,353
Net loss per share attributable to common stockholders, basic and diluted	$ (0.42)	$ (4.86)

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:

	March 31, 2020	March 30, 2019
Convertible preferred stock (as converted to common stock)	—	13,119,424
Warrants to purchase convertible preferred stock (as converted to common stock)	—	64,440
Warrants to purchase common stock	64,440	—
Options to purchase common stock	2,178,215	1,595,150
Employee stock purchase plan	10,871	—
	2,253,526	14,779,014

12. 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):

	Fiscal Three Months Ended	
	March 31, 2020	March 30, 2019
Net revenue by country(1):		
United States	$ 5,208	$ 2,953
United Kingdom	1,112	569
All other countries	1,210	1,154
Total net revenue	$ 7,530	$ 4,676

	March 31, 2020	December 28, 2019
Long-lived assets by country(2):		
United States	$ 4,006	$ 4,007
All other countries	707	785
Total long-lived assets	$ 4,713	$ 4,792

(1) Net revenue by country is categorized based on the location of the end customer.
(2) The Company's only long-lived assets consist of property and equipment, net of depreciation, which are categorized based on their location of domicile.

13. 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 and Chief Executive Officer and a member of the Company's board of directors. The Company paid Dr. Amira Hassanein less than $0.1 million in total compensation for each of the fiscal three months ended March 31, 2020 and March 30, 2019 for her services as an employee.

14. Subsequent Events

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.

Amendment to Credit Agreement

On April 23, 2020, the Company entered into a Second Amendment to the Credit Agreement (the "Second Amendment").

The Second Amendment provides that TransMedics may incur unsecured indebtedness (a) incurred pursuant to the Paycheck Protection Program, (b) in an aggregate principal amount not to exceed $2.2 million at any one time, (c) in respect of which TransMedics will (i) promptly, and in any event within 90 days after incurring such indebtedness, apply for forgiveness of an aggregate principal amount of at least $2.0 million and (ii) obtain such forgiveness by October 31, 2020; provided, however, that if, through no fault of TransMedics, the U.S. Small Business Administration does not respond to TransMedics' application for forgiveness (X) by October 31, 2020, the deadline for obtaining such forgiveness shall be extended to November 30, 2020, and (Y) by November 30, 2020, the deadline shall be extended to December 31, 2020, and (d) in respect of which TransMedics will remain at all times in compliance with the terms and conditions thereof.

Item 2. 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 Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the fiscal year ended December 28, 2019, as filed with the SEC on March 17, 2020 ("2019 Form 10-K"). Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, 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 1.A. Risk Factors" section of this Quarterly Report on Form 10-Q and the "Item 1.A. Risk Factors" section of our 2019 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 our substantial body of clinical evidence has demonstrated the potential for the OCS to significantly increase the number of organ transplants and improve post-transplant outcomes.

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

We designed the OCS to be a platform that allows us to leverage core technologies across products for multiple organs. To date, we have developed three OCS products, one for each of lung, heart and liver transplantations, making the OCS the only multi-organ technology platform. Our OCS products have been used for over 1,500 human organ transplants. During our clinical trials, we established relationships with over 55 leading transplant programs worldwide. We have commercialized the OCS Lung and OCS Heart outside of the United States and received our first Pre-Market Approval ("PMA") from the FDA in March 2018 for the use in the United States of the OCS Lung for donor lungs currently utilized for transplantation and since May 2019, for donor lungs currently unutilized for transplantation.

Since our inception, we have focused substantially all of our resources on designing, developing and building our proprietary OCS technology platform and organ-specific OCS products; obtaining clinical evidence for the safety and effectiveness of our OCS products through clinical trials; securing regulatory approval; organizing and staffing our company; planning our business; raising capital; and providing general and administrative support for these operations. To date, we have funded our operations primarily with proceeds from sales of preferred stock and borrowings under loan agreements, proceeds from the sale of common stock in our IPO 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 $7.5 million and incurred a net loss of $8.9 million for the fiscal three months ended March 31, 2020. We generated net revenue of $23.6 million and incurred a net loss of $33.5 million for the fiscal year ended December 28, 2019. As of March 31, 2020, we had an accumulated deficit of $378.3 million. We expect to continue to incur net losses for the foreseeable future as we focus on growing commercial sales of our products in both the U.S. and select non-U.S. markets, including growing our sales and clinical adoption team, which will pursue increasing commercial sales and clinical adoption of our OCS products; scaling our manufacturing operations; continuing research, development and clinical trial efforts; and seeking regulatory clearance for new products and product enhancements, including new indications, in both the U.S. and select non-U.S. markets. Further, following the closing of our IPO we have incurred and expect to continue to incur additional costs associated with operating as a public company. As a result, we will need substantial additional funding for expenses related to our operating activities, including selling, general and administrative expenses and research, development and clinical trials expenses.

On May 6, 2019, we completed our IPO, pursuant to which we issued and sold 6,543,500 shares of common stock, inclusive of 853,500 shares we sold pursuant to the full exercise of the underwriters' option to purchase additional shares. The aggregate net proceeds received by us from the IPO were $91.4 million, after deducting underwriting discounts and commissions as well as other offering costs of $6.0 million.

On May 6, 2019, immediately prior to the completion of our IPO, we completed a corporate reorganization whereby TransMedics, Inc., the direct parent of TransMedics Group prior to the corporate reorganization, became a direct, wholly-owned subsidiary of TransMedics Group pursuant to the merger of TMDX, Inc., a direct, wholly-owned subsidiary of TransMedics Group prior to the corporate reorganization, merged with and into TransMedics, Inc., with TransMedics, Inc. as the surviving corporation. As part of the transactions, each outstanding share of capital stock of TransMedics, Inc. was converted into shares of common stock of TransMedics Group, each outstanding option to purchase shares of common stock of TransMedics, Inc. was converted into an outstanding option to purchase shares of common stock of TransMedics Group and each outstanding warrant to purchase shares of preferred stock of TransMedics, Inc. was converted into a warrant to purchase shares of common stock of TransMedics Group.

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 existing 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 the next 12 months. 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

In December 2019, a novel strain of coronavirus (COVID-19) emerged in Wuhan, Hubei Province, China. Less than four months later, in March 2020, the World Health Organization declared COVID-19 a pandemic, and the virus has now spread to many other countries and regions and every state within the United States, including Massachusetts, where our primary offices and manufacturing facility are located. The impact of this pandemic has been and will likely continue to be extensive in many aspects of society, which has resulted in and will likely continue to result in significant disruptions to the global economy, as well as businesses and capital markets around the world.

Impacts to our business as a result of COVID-19 include the temporary disruption of transplant procedures at many of the organ transplant centers who purchase OCS products; 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; restrictions on or delays of our clinical trials and studies; limitations on our employees' and customers' ability to travel, and delays in product installations, trainings or shipments to and from 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 has a negative impact on our revenue and clinical trial activities. Our sales and clinical adoption team is also operating at reduced capacity and restricted in visiting many transplant centers in person. Customer delays or reductions in capital expenditures and operating budgets also have a negative impact on our product sales. The COVID-19 pandemic also has impacted operations at the FDA and other health authorities, resulting in delays of reviews and approvals, including with respect to our OCS Heart PMA application, and may affect other potential PMA applications. For example, although the FDA had scheduled an advisory committee of experts from outside the FDA to review and evaluate our OCS Heart PMA application in the second quarter of 2020, due to the COVID-19 pandemic the advisory committee meeting has been postponed and we currently anticipate that the FDA will convene this advisory committee meeting in the second half of 2020. In addition, we have temporarily reduced the manufacturing and distribution of our OCS products at our facility in Andover, Massachusetts though we maintain critical staff for product shipment and clinical support. While we maintain an inventory of finished products and raw materials used in our OCS products, a prolonged pandemic could lead to shortages in the raw materials necessary to manufacture our products. If we experience a prolonged disruption in our manufacturing, supply chains, clinical trial or commercial operations, or if demand for our products is significantly reduced as a result of the COVID-19 pandemic, we would expect to experience a material adverse impact on our business, financial condition, results of operations and prospects. While the COVID-19 pandemic did not significantly impact our business or results of operations during the first quarter of 2020, we anticipate more substantial negative impact to OCS product sales for the remainder of 2020.

In April 2020, we announced several steps to respond to the COVID-19 pandemic. These steps are intended to protect the health and safety of our employees, to establish a process to support the continuous supply of our OCS products at transplant centers globally and to maintain financial flexibility. These actions include transitioning most employees to a remote work environment, except for those who are deemed essential to product supply and reducing near-term expenses, such as reducing non-essential discretionary expenses and deferring a portion of executive and employee compensation. While the COVID-19 pandemic did not significantly impact our business or results of operations during the first quarter of 2020, we anticipate a negative impact to OCS product sales for the remainder of 2020; however, the length and extent of the pandemic, its consequences, and containment efforts will determine the future impact on our operations and financial condition. We continue to monitor developments regarding the COVID-19 pandemic and its impact on our business, financial condition, results of operations and prospects. However, we are unable to predict the extent of the impact with confidence due to the uncertainty of future developments, such as the duration of the pandemic, additional or modified government actions, new information which may emerge concerning the severity and incidence of COVID-19 and actions to contain the virus or treat its impact. In particular, the speed of the continued spread of COVID-19 globally, and the magnitude of interventions to contain the spread of the virus, such as government-imposed quarantines, including shelter-in-place mandates, sweeping restrictions on travel, mandatory shutdowns for non-essential businesses, requirements regarding social distancing, and other public health safety measures, will determine the impact of the pandemic on our business.

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

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

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

Under some of our customer clinical trial agreements, we make payments to our customers for reimbursements of clinical trial materials and for specified clinical documentation related to their use of our OCS products. Because some of these payments do not provide us with a separately identifiable benefit, we record such payments as a reduction of revenue from the customer, resulting in our net revenue presentation. We recorded reimbursable clinical trial costs as a reduction of revenue of $0.7 million and $0.6 million, for the fiscal three months ended March 31, 2020 and March 30, 2019, respectively.

In March 2018, we received our first FDA PMA for the OCS Lung, and we began commercial sales of this product in the United States during the fourth quarter of 2018. In May 2019, we received our second FDA PMA approval for the OCS Lung for additional clinical indications. Therefore, our net revenue in the United States for the OCS Lung is now derived primarily from commercial sales and consists of sales of OCS disposable sets and, to a much lesser extent, sales of OCS Consoles. In 2019, we also recorded revenue from clinical trial sales of the OCS Lung for our OCS Lung EXPAND II Trial, which stopped enrollment as of June 24, 2019 since we received FDA PMA approval for the OCS Lung EXPAND indication.

In the United States, we expect to continue to only have clinical trial sales for our OCS Heart and OCS Liver products until we receive similar FDA PMA approvals for those products. Our net revenue in the United States for OCS Heart and OCS Liver products fluctuates from period to period as a result of the timing of patient enrollment in our clinical trials. Historically, our net revenue during periods of patient enrollment has been higher due to the sale of OCS disposable sets for use during these clinical trials, as compared to periods during which our clinical trials were not actively enrolled. Our OCS Heart EXPAND Trial began patient enrollment in September 2015 and completed patient enrollment in March 2018. Our Liver PROTECT Trial began enrollment in January 2016 and completed enrollment in October 2019. Our OCS Heart EXPAND Continued Access Protocol (CAP) Trial and our OCS Heart DCD Trial began patient enrollment in May 2019 and December 2019, respectively, and are currently enrolling patients. Our OCS Liver PROTECT CAP Trial began patient enrollment in February 2020 and is currently enrolling patients. Our net revenue may continue to fluctuate from period to period as a result of the timing of ongoing clinical trials in which our OCS products are used.

Through March 31, 2020, all of our sales outside of the United States have been commercial sales (unrelated to any clinical trials) and our net revenue has been generated primarily from sales of OCS disposable sets and, to a much lesser extent, sales of OCS Consoles.

Commercial sales of OCS disposable sets generally have a higher average selling price than clinical trial sales of OCS disposable sets. We expect that our net revenue will increase over the long term as a result of receiving our first two FDA PMA approvals for the OCS Lung in the United States in March 2018 and May 2019 and any potential future FDA approvals in the United States for OCS Heart and OCS Liver. 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. We expect that net revenue will decrease in the short term as a result of the COVID-19 pandemic.

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

We expect that cost of revenue as a percentage of net revenue will decrease and gross margin and gross profit will increase over the long term as our sales and production volumes increase and our cost per unit of our OCS disposable sets decreases due to efficiencies of scale. We intend to use our design, engineering and manufacturing capabilities to further advance and improve the efficiency of our manufacturing processes, which we believe will reduce costs and increase our gross margin. As utilization by customers of our OCS products increases, we expect that a greater number of OCS disposable sets will be used per year on the same OCS Console, thereby driving overall gross margin improvement. Because we expect that the number of OCS disposable sets sold over time will be significantly greater than the number of OCS Consoles sold or loaned to customers over that same period, we expect that our gross margin improvement will not be significantly affected by the number of OCS Consoles that we sell or loan to customers. While we expect gross margin to increase over the long term, it will likely fluctuate from quarter to quarter. In addition, we expect gross margin to decrease in the short-term resulting from lower efficiencies of scale due to anticipated lower revenue as a result of the COVID-19 pandemic and potential idle capacity charges due to temporarily reducing the manufacturing of our OCS products at our facility in Andover, Massachusetts.

Operating Expenses

Research, Development and Clinical Trials Expenses

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

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

We expense research, development and clinical trials costs as incurred. In the future, we expect that research, development and clinical trials expenses will increase 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 to developing the next generation of our OCS technology platform.

Selling, General and Administrative Expenses

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

We expect that our selling, general and administrative expenses will increase 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 incur increased accounting, audit, legal, regulatory, compliance and director and officer insurance costs as well as investor and public relations expenses associated with operating as a public company.

Other Income (Expense)

Interest Expense

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

Change in Fair Value of Preferred Stock Warrant Liability

Prior to our IPO in May 2019, we had outstanding warrants to purchase preferred stock. We classified these warrants as a liability on our consolidated balance sheet that we remeasured to fair value at each reporting date, and we recognized changes in the fair value of the warrant liability as a component of other income (expense) in our consolidated statements of operations. On May 6, 2019, immediately prior to the closing of our IPO, the warrants to purchase preferred stock were converted into warrants to purchase common stock, and the fair value of the warrant liability at that time was reclassified to common stock. As a result, subsequent to the closing of our IPO, we no longer remeasure the fair value of the warrant liability at each reporting date.

Other Income (Expense), Net

Other income (expense), net includes interest income, foreign currency transaction gains and losses and other non-operating income and expense items unrelated to our core operations. 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. In reporting periods subsequent to 2016, we have recorded provisions for foreign income taxes of an insignificant amount related to the operations of one of our foreign subsidiaries.

As of December 28, 2019, we had U.S. federal and state net operating loss carryforwards of $287.8 million and $217.8 million, respectively, which may be available to offset future taxable income and begin to expire in 2020 and 2030 respectively. Our federal net operating losses include $72.8 million, which can be carried forward indefinitely. As of December 28, 2019, we also had U.S. federal and state research and development tax credit carryforwards of $7.0 million and $4.7 million, respectively, which may be available to offset future tax liabilities and begin to expire in 2020 and 2024, respectively. As of December 28, 2019, 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.

Results of Operations

Prior to 2020, our fiscal year ended on the last Saturday in December, and we reported fiscal years using a 52/53-week convention. Under this convention, certain fiscal years contained 53 weeks. Each fiscal year was typically composed of four 13-week fiscal quarters, but in years with 53 weeks, the fourth quarter was a 14-week period. Our fiscal year ended December 28, 2019 included 52 weeks. In February 2020, we changed the end of our fiscal year end from the last Saturday in December to December 31. As a result of this change, our current fiscal year will end on December 31, 2020 and our current and each subsequent fiscal quarter will end on March 31, June 30 and September 30.

Comparison of the Fiscal Three Months Ended March 31, 2020 and March 30, 2019

The following table summarizes our results of operations for the fiscal three months ended March 31, 2020 and March 30, 2019

	Fiscal Three Months Ended		
	March 31, 2020	March 30, 2019	Change
	(in thousands)		
Net revenue	$ 7,530	$ 4,676	$ 2,854
Cost of revenue	2,670	2,103	567
Gross profit	4,860	2,573	2,287
Operating expenses:			
Research, development and clinical trials	6,225	3,882	2,343
Selling, general and administrative	6,652	4,653	1,999
Total operating expenses	12,877	8,535	4,342
Loss from operations	(8,017)	(5,962)	(2,055)
Other income (expense):			
Interest expense	(1,042)	(1,093)	51
Change in fair value of preferred stock warrant liability	—	273	(273)
Other income (expense), net	217	(103)	320
Total other expense, net	(825)	(923)	98
Loss before income taxes	(8,842)	(6,885)	(1,957)
Provision for income taxes	(10)	(10)	—
Net loss	$ (8,852)	$ (6,895)	$(1,957)

Net Revenue, Cost of Revenue and Gross Profit

	Fiscal Three Months Ended		
	March 31, 2020	March 30, 2019	Change
	(in thousands)		
Net revenue	$ 7,530	$ 4,676	$2,854
Cost of revenue	2,670	2,103	567
Gross profit	$ 4,860	$ 2,573	$2,287

Net Revenue

	Fiscal Three Months Ended		
	March 31, 2020	March 30, 2019	Change
	(in thousands)		
Net revenue by geography:			
United States	$ 5,208	$ 2,953	$2,255
Outside the U.S.	2,322	1,723	599
Total net revenue	$ 7,530	$ 4,676	$2,854
Net revenue by OCS product:			
OCS Lung net revenue	$ 2,008	$ 1,412	$ 596
OCS Heart net revenue	4,131	1,922	2,209
OCS Liver net revenue	1,391	1,342	49
Total net revenue	$ 7,530	$ 4,676	$2,854

Net revenue increased by $2.9 million in the fiscal three months ended March 31, 2020 compared to the fiscal three months ended March 30, 2019 primarily as a result of an increase in the number of OCS disposable sets sold to customers globally.

Net revenue from customers in the United States was $5.2 million in the fiscal three months ended March 31, 2020 and increased by $2.3 million in the fiscal three months ended March 31, 2020 compared to the fiscal three months ended March 30, 2019. The increase in net revenue from customers in the United States was primarily due to commercial sales of OCS Lung products, sales of OCS disposable sets for use in our OCS Heart EXPAND CAP Trial and OCS Heart DCD Trial and sales of OCS disposable sets to customers for use in our OCS Liver PROTECT CAP Trial. Net revenue from sales of OCS Lung products in the United States increased from $1.3 million in the fiscal three months ended March 30, 2019 to $1.9 million in the fiscal three months ended March 31, 2020. Net revenue from OCS Heart disposable sets sold to customers for use in our OCS Heart EXPAND CAP Trial and OCS Heart DCD Trial increased from $0.3 million in the fiscal three months ended March 30, 2019 to $1.9 million in the fiscal three months ended March 31, 2020. Net revenue from OCS Liver disposable sets sold to customers for use in our OCS Liver PROTECT CAP Trial increased from $1.3 million in the fiscal three months ended March 30, 2019 to $1.4 million in the fiscal three months ended March 31, 2020. In addition, the U.S. selling price of OCS disposable sets sold in the first quarter of 2020 was approximately 30% higher than the U.S. selling prices of OCS disposable sets sold in the same period in fiscal 2019, which accounted for $1.0 million of the overall $2.3 million increase in net revenue in the United States from the first quarter of fiscal 2019 to the same period in fiscal 2020. The higher average selling prices were a result of a shift to more commercial sales and the price of clinical trial disposables moving closer to commercial prices.

Net revenue from customers outside the U.S. was $2.3 million in the fiscal three months ended March 31, 2020 compared to $1.7 million in the fiscal three months ended March 30, 2019. The increase in net revenue from customers outside the United States was primarily due to sales of OCS disposable sets to existing customers in the quarter.

Cost of Revenue, Gross Profit and Gross Margin

Cost of revenue increased by $0.6 million in the fiscal three months ended March 31, 2020 compared to the fiscal three months ended March 30, 2019. Gross profit increased by $2.3 million in the fiscal three months ended March 31, 2020 compared to the fiscal three months ended March 30, 2019. Gross margin was 65% and 55% for the fiscal three months ended March 31, 2020 and March 30, 2019, respectively. Gross profit and gross margin increased primarily as a result of a higher average selling price of OCS disposable sets sold in the United States in the first quarter of 2020 relative to the average selling price of OCS disposable sets in the comparable period of fiscal 2019 and overall higher sales, which resulted in a reduction of the impact of fixed costs in our manufacturing operation.

Operating Expenses

Research, Development and Clinical Trials Expenses

	Fiscal Three Months Ended		
	March 31, 2020	March 30, 2019	Change
	(in thousands)		
Personnel related (including stock-based compensation expense)	$ 2,148	$ 1,412	$ 736
Clinical trials costs	1,986	1,003	983
Consulting and third-party testing	679	324	355
Laboratory supplies and research materials	624	524	100
Other	788	619	169
Total research, development and clinical trials expenses	$ 6,225	$ 3,882	$2,343

Total research, development and clinical trials expenses increased by $2.3 million from $3.9 million in the fiscal three months ended March 30, 2019 to $6.2 million in the fiscal three months ended March 31, 2020. Personnel related costs increased $0.7 million primarily due to additional resources supporting clinical trials and new product development. Clinical trials costs increased by $1.0 million, primarily due to clinical trial activity in our active clinical trials; the OCS Liver PROTECT Trial, the OCS Heart EXPAND CAP Trial and the OCS Heart DCD Trial. Consulting and third-party testing costs increased by $0.4 million primarily due to clinical trial activity and new product development.

Selling, General and Administrative Expenses

	Fiscal Three Months Ended		
	March 31, 2020	March 30, 2019	Change
	(in thousands)		
Personnel related (including stock-based compensation expense)	$ 3,072	$ 1,842	$1,230
Professional and consultant fees	1,612	1,256	356
Tradeshows and conferences	487	507	(20)
Other	1,481	1,048	433
Total selling, general and administrative expenses	$ 6,652	$ 4,653	$1,999

Total selling, general and administrative expenses increased by $2.0 million from $4.7 million in the fiscal three months ended March 30, 2019 to $6.7 million in the fiscal three months ended March 31, 2020 primarily due to increases in personnel related costs and professional and consultant fees as we hired additional resources and engaged consultants to support commercial sales of our OCS Lung product in the United States and to support our operation as a public company. Other costs also increased by $0.4 million primarily as a result of increased costs to operate as a public company.

Other Income (Expense)

Interest Expense

Interest expense was $1.0 million and $1.1 million for the fiscal three months ended March 31, 2020 and March 30, 2019, respectively.

Change in Fair Value of Preferred Stock Warrant Liability

The change in the fair value of our preferred stock warrant liability in the fiscal three months ended March 30, 2019 was due primarily to the changes in the fair value of our preferred stock during that period.

On May 6, 2019, immediately prior to the closing of our IPO, the warrants to purchase preferred stock were converted into warrants to purchase common stock, and the fair value of the warrant liability at that time was reclassified to common stock. As a result, subsequent to the closing of our IPO, we no longer remeasure the fair value of the warrant liability at each reporting date.

Other Income (Expense), Net

Other income (expense), net for the fiscal three months ended March 31, 2020 and March 30, 2019 included interest income of $0.3 million and $0.1 million, respectively, resulting from interest earned on invested cash balances, and $0.1 million and $0.2 million of foreign currency transaction losses, respectively.

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 IPO and revenue from clinical trials and commercial sales of our OCS products. As of March 31, 2020, we had cash, cash equivalents, and marketable securities of $72.6 million.

On May 6, 2019, we completed our IPO, pursuant to which we issued and sold 6,543,500 shares of common stock, inclusive of 853,500 shares we sold pursuant to the full exercise of the underwriters' option to purchase additional shares. The aggregate net proceeds received by us from the IPO were $91.4 million, after deducting underwriting discounts and commissions as well as other offering costs of $6.0 million.

Cash Flows

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

	Fiscal Three Months Ended	
	March 31, 2020	March 30, 2019
	(in thousands)	
Cash used in operating activities	$ (8,176)	$ (7,266)
Cash provided by (used in) investing activities	12,715	(3)
Cash provided by (used in) financing activities	152	(697)
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(45)	(60)
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 4,646	$ (8,026)

Operating Activities

During the fiscal three months ended March 31, 2020, operating activities used $8.2 million of cash, primarily resulting from our net loss of $8.9 million and net cash used by changes in our operating assets and liabilities of $0.3 million, partially offset by net non-cash charges of $1.0 million. Net cash used by changes in our operating assets and liabilities for the fiscal three months ended March 31, 2020 consisted primarily of a $0.2 million increase in inventory and a $0.6 million decrease in accounts payable and accrued expenses and other current liabilities, both partially offset by a $0.4 million decrease in accounts receivable and a $0.3 million increase in deferred rent.

During the fiscal three months ended March 30, 2019, operating activities used $7.3 million of cash, primarily resulting from our net loss of $6.9 million and net cash used by changes in our operating assets and liabilities of $0.7 million, partially offset by net non-cash charges of $0.3 million. Net cash used by changes in our operating assets and liabilities for the fiscal three months ended March 30, 2019 consisted primarily of a $2.5 million increase in inventory and a $1.7 million increase in accounts receivable, both partially offset by a $3.2 million increase in accounts payable and accrued expenses and other current liabilities.

Changes in accounts receivable, inventory, accounts payable, and accrued expenses and other current liabilities in each reporting period are generally due to growth in our business, including the growth in sales, expenses and employee headcount.

Investing Activities

During the fiscal three months ended March 31, 2020, net cash provided by investing activities of $12.7 million consisted of proceeds from sales and maturities of marketable securities of $17.2 million, partially offset by $4.2 million in purchases of marketable securities and $0.3 million in purchases of property and equipment.

Financing Activities

During the fiscal three months ended March 31, 2020, net cash provided by financing activities of $0.2 million consisted of proceeds from the issuance of common stock in connection with the employee stock purchase plan of $0.2 million and proceeds from the issuance of common stock upon exercise of stock options of $0.1 million, partially offset by payments of offering costs related to our IPO of $0.1 million.

During the fiscal three months ended March 30, 2019, net cash used in financing activities of $0.7 million consisted of the payment of offering costs related to our IPO that closed in May 2019.

Long-Term Debt

In June 2018, TransMedics entered into the Credit Agreement with OrbiMed, pursuant to which it 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, subject to a prepayment premium of 9.0% of the principal amount of any prepayment within the first three years, which percentage decreases annually until it reaches zero at the end of three years. We are also required to make a final payment in an amount equal to 3.0% of the principal amount of any prepayment or repayment, which we are accreting to interest expense over the term of the Credit Agreement using the effective interest method.

All obligations under the Credit Agreement are guaranteed by us and each of our material subsidiaries. All obligations of us and each guarantor are secured by substantially all of our and each guarantor's assets, including their intellectual property, subject to certain exceptions, including a perfected security interest in substantially all tangible and intangible assets of us and each guarantor. Under the Credit Agreement, we have agreed to certain affirmative and negative covenants to which we will remain subject until maturity. The 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 March 31, 2020, 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.

Funding Requirements

As we continue to pursue and increase commercial sales of our OCS products, we expect our costs and expenses to increase in the future, particularly as we expand our sales and clinical adoption team, scale our manufacturing operation, continue research, development and clinical trial efforts, and seek regulatory 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 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.

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 this Quarterly Report on Form 10-Q.

We may need to raise additional funding, which might not be available on favorable terms or at all. See “Item 1.A. Risk Factors—Risks Related to Our Financial Position and Need for Additional Capital” in our 2019 Form 10-K.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of March 31, 2020 and the effects that such obligations are expected to have on our liquidity and cash flows in future periods:

	Payments Due by Period				
	Total	Less Than 1 Year	1 to 3 Years	4 to 5 Years	More than 5 Years
	(in thousands)				
Operating lease commitments(1)	$ 13,771	$ 2,090	$ 3,870	$ 4,066	$ 3,745
Debt obligations(2)	47,952	3,685	7,370	36,897	—
Total	$ 61,723	$ 5,775	$ 11,240	$ 40,963	$ 3,745

(1) Amounts in table reflect payments due for our leases of office and laboratory space in Andover, Massachusetts under two operating lease agreements. On January 9, 2020, the Company amended these lease agreements to, among other things, extended the expiration date of each lease to December 2026, increase the rentable square feet subject to each lease, and increase annual base rent for each lease. For more information, see “Note 10. Operating Leases” to the consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

(2) Amounts in table reflect the contractually required principal and interest payments payable under the Credit Agreement, under which borrowings bear interest at a variable rate. For purposes of this table, the interest due under the Credit Agreement was calculated using an assumed interest rate of 10.5% per annum, which was the interest rate in effect as of March 31, 2020. Because such interest rate is below the PIK interest threshold of 11.5%, we did not include PIK in our calculated payments.

Inflation Risk

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

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.

There have been no material changes to our critical accounting policies and estimates from those disclosed in our consolidated financial statements and the related notes and other financial information included in our 2019 Form 10-K.

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 Quarterly Report on Form 10-Q.

Emerging Growth Company Status

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

Item 3. 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, hold investments 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. There has been no material change in the foreign currency exchange risk or interest rate risk discussed in "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our 2019 Form 10-K.

Item 4. 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 March 31, 2020. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (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, 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 March 31, 2020, 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.

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 fiscal three months ended March 31, 2020 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We are not currently subject to any material legal proceedings.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. For a detailed discussion of the risks that affect our business, please refer to the section titled "Item 1A. Risk Factors" in our 2019 Form 10-K and the additional risks below. The COVID-19 pandemic may also have the effect of heightening many of the other risks described in the section titled "Item 1A. Risk Factors" in our 2019 Form 10-K, such as risks related to our need to raise additional funding, fluctuation of our quarterly financial results, our ability to continue to educate surgeons, transplant centers and private payors, our manufacturing facilities, our information technology infrastructure, our foreign operations, and our ability to obtain and maintain regulatory approvals and qualifications.

Risks Related to Our Business and Industry

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

In December 2019, a novel strain of coronavirus (COVID-19) emerged in Wuhan, Hubei Province, China. Less than four months later, in March 2020, the World Health Organization declared COVID-19 a pandemic. While initially the outbreak was largely concentrated in China and caused significant disruptions to its economy, the virus has now spread to many other countries and regions, and every state within the United States, including Massachusetts, where our primary offices and manufacturing facility are located.

The rapid spread of the virus has led to the implementation of various responses, including government-imposed quarantines, including shelter-in-place mandates, sweeping restrictions on travel, mandatory shutdowns for non-essential businesses, requirements regarding social distancing, and other public health safety measures, as well as reported adverse impacts on healthcare resources, facilities and providers across the United States and in other countries.

Impacts to our business as a result of COVID-19 include the temporary disruption of transplant procedures at many of the organ transplant centers who purchase OCS products; 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; restrictions on or delays of our clinical trials and studies; limitations on our employees' and customers' ability to travel; and delays in product installations, trainings or shipments to and from 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 and implement limitations on access to hospitals and other medical institutions due to concerns about the potential spread of COVID-19 in such settings. 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 clinical trial activities. These measures and challenges may continue for the duration of the COVID-19 pandemic, which is highly uncertain, and may significantly reduce our revenue and cash flows while the pandemic continues.

An adverse impact on the volume and availability of transplant procedures impacts our clinical trials and enrollment in our post-approval studies, and the COVID-19 pandemic has impacted operations at the FDA and other health authorities, resulting in delays of reviews and approvals, including with respect to our OCS Heart PMA application, and may affect other potential PMA applications.

Additionally, to protect the health of our employees and their families, and our communities, and in accordance with direction from state and local government authorities, we have restricted access to our facilities to personnel and third parties who must perform critical activities that must be completed on-site, limited the number of such personnel that can be present at our facilities at any one time, and requested that most of our personnel work remotely. As a result, our sales and clinical adoption team is operating at reduced capacity and restricted in visiting many transplant centers in person. Customer delays or reductions in capital expenditures and operating budgets also have a negative impact on our product sales. In addition, we have temporarily reduced the manufacturing and distribution of our OCS products at our facility in Andover, Massachusetts. In the event that governmental authorities were to further modify current 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 be faced with 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.

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 prolonged pandemic could lead to shortages in the raw materials necessary to manufacture our products.

The extent to which COVID-19 impacts our operations and those of our third-party partners will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the pandemic, additional or modified government actions, new information which may emerge concerning the severity and incidence of COVID-19 and actions to contain the virus or treat its impact. In particular, the speed of the continued spread of COVID-19 globally, and the magnitude of interventions to contain the spread of the virus, such as government-imposed quarantines, including shelter-in-place mandates, sweeping restrictions on travel, mandatory shutdowns for non-essential businesses, requirements regarding social distancing, and other public safety measures, will determine the impact of the pandemic on our business, financial condition, operating results, cash flows and prospects. If we experience a prolonged disruption in our manufacturing, supply chains, clinical trial or commercial operations, or if demand for our products is significantly reduced as a result of the COVID-19 pandemic, we would expect to experience a material adverse impact on our business, financial condition, results of operations and prospects.

Additionally, the extent and duration of the impact of the COVID-19 pandemic on our stock price and on those of other companies in our industry is highly uncertain and may make us look less attractive to investors and, as a result, there may be a less active trading market for our common stock, our stock price may be more volatile, and our ability to raise capital could be impaired, which could in the future negatively affect our liquidity and financial position.

Risks Related to Government Regulation

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

The OCS products are medical devices subject to extensive regulation in the United States by the FDA and other federal, state and local authorities. The FDA regulates the design, development, testing, manufacturing, labeling, selling, promoting, distributing, importing, exporting and shipping of the OCS. We have obtained PMA approval for the OCS Lung for both the preservation of donor lungs currently utilized for transplantation and donor lungs that are currently unutilized for transplantation, but the OCS has not yet attained PMA approval for preservation of heart and liver donor organs. 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.

In the United States, before we can market the OCS products for each organ, we must first receive PMA approval from the FDA. This process can be expensive and lengthy and entail significant costs. The process of obtaining PMA approval requires significant clinical trial data. It generally takes one year, or even longer, from the time the PMA application is submitted to the FDA until an FDA action date. The COVID-19 pandemic time periods may result in extension of timelines. Despite the time, effort and cost involved in this process, the FDA might not approve the OCS products for use in preservation of donor hearts, livers, or other organs.

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

We are currently investigating the safety and effectiveness of the OCS in multiple investigational device exemption, or IDE, investigations. Specifically, we recently completed enrollment in a pivotal trial under IDEs that investigate the safety and effectiveness of the OCS Liver for the preservation of donor livers that are currently utilized and currently unutilized for transplantation. Further, we received IDE approval for the Continued Access Protocol for this trial. We also received IDE approval for a study of OCS Liver for certain donor livers that are donated after circulatory death that have extended warm ischemia time or older donor age. In addition, we completed an IDE pivotal trial of the OCS Heart for donor hearts that are currently unutilized for transplantation and received IDE approval for the Continued Access Protocol for this trial. We also received IDE approval for a study of OCS Heart for donor hearts that are donated after circulatory death. We intend to use data from the clinical trials we are conducting or have finished conducting under IDEs to support our applications for PMA approvals for the OCS Heart and OCS Liver.

As is typical to the PMA review process, during the course of its initial PMA review and in most cases within 90 calendar days of the company's PMA filing date, the FDA communicates issues that it has identified and views as deficiencies through a substantive interaction, which in most cases is a letter. That letter is technically referred to as a "major deficiency letter," and it provides the applicant with an opportunity to address the FDA's questions. After completing its review of a PMA application, the FDA will take one of the following actions: an approval, an approvable letter, a not approvable letter, or, in rare instances, a denial. We have received a "major deficiency letter" for each PMA application that we have submitted to the FDA and we believe our responses have been thorough and comprehensive. Regarding the OCS Heart PMA currently under review, the FDA has communicated that it will convene an advisory committee of experts from outside the FDA to review and evaluate our OCS Heart PMA application and provide recommendations to the FDA as to the safety, effectiveness, risk and benefit of the device. It is not uncommon for the FDA to seek advice from an outside expert panel when considering an application for a novel technology. The FDA ultimately decides whether to approve or disapprove the PMA application and may or may not follow the advisory committee's recommendation. Although the FDA had scheduled an advisory committee meeting regarding our OCS Heart PMA application in the second quarter of 2020, due to the COVID-19 pandemic the advisory committee meeting has been postponed and we currently anticipate that an advisory committee for our OCS Heart PMA application will be convened in the second half of 2020. The panel may provide unfavorable recommendations to the FDA with regard to the PMA application, and the FDA may follow such recommendations. Even if the panel recommendations are favorable, the FDA could determine that the data from our clinical trials does not support PMA approval or claims we wish to make, or the FDA could require us to gather significant additional clinical data or conduct additional non-clinical testing.

The approval process involving the OCS for each organ is subject to many of the same risks and uncertainties. If we are not able to obtain the necessary regulatory approvals for the OCS, or approvals or clearances for future products on a timely basis or at all, our financial condition and results of operations would suffer, possibly materially, and our business might fail. Even if the FDA grants PMA approval for the OCS Heart and OCS Liver for preservation of donor hearts and livers for transplantation, respectively, the claims approved by the FDA may be significantly narrower than those we are seeking.

We 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 after May 2021, we will have to meet the conditions set out in the transitional provisions in the Medical Devices Regulation (Regulation 2017/745), or the Medical Devices Regulation. Before expiry of these certificates, we will need to apply for their re-certification under the new Medical Devices Regulation. We might not be able to continue to use the CE Mark for any current use of the OCS. If:

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

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.

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:

- established a new Patient-Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical effectiveness research in an effort to coordinate and develop such research;
- implemented payment system reforms, including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models; and
- expanded the eligibility criteria for Medicaid programs.

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

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. The Budget Control Act of 2011, for example, reduced Medicare payments to providers by 2% per fiscal year, and will remain in effect through 2030 (except for the period from May 1, 2020 through December 31, 2020, when no reduction will occur) unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012 also reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA"), repealed the

formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates and a new system of incentive payments that are based on various performance measures and physicians' participation in alternative payment models such as accountable care organizations, which took effect in 2019. It is unclear what effect new quality and payment programs, such as MACRA, may have on our business, financial condition, results of operations or cash flows.

We expect additional state and federal healthcare policies and reform measures to be adopted in the future, including following the 2020 presidential election, any of which could limit reimbursement for healthcare products and services or otherwise result in reduced demand for the OCS or additional pricing pressure and have a material adverse effect on our industry generally and on our customers. Any changes of, or uncertainty with respect to, future reimbursement to hospitals and transplant centers could affect demand for the OCS, which in turn could have a material adverse effect on our business, financial condition and results of operations.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Use of Proceeds

On May 6, 2019, we completed the IPO of our common stock pursuant to which we issued and sold 6,543,500 shares of our common stock, inclusive of 853,500 shares we sold pursuant to the full exercise of the underwriters' option to purchase additional shares, at a price to the public of $16.00 per share. The aggregate offering price of the IPO was $104.7 million.

The offer and sale of all of the shares of our common stock in our IPO were registered under the Securities Act pursuant to a registration statement on Form S-1, as amended (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.

We received aggregate gross proceeds from our IPO of $104.7 million, or aggregate net proceeds of $91.4 million after deducting underwriting discounts and commissions as well as other offering costs of $6.0 million. None of the underwriting discounts and commissions or offering expenses were incurred or paid, directly or indirectly, to directors or officers of ours or their associates or to persons owning 10% or more of our common stock or to any of our affiliates.

As of March 31, 2020, we have used approximately $24.8 million of net offering proceeds primarily for commercialization of OCS Lung, 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.

Item 6. Exhibits.

Exhibit Number	Description
10.1	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 10.1 to the Registrant's Form 8-K (File No. 001-38891) filed with the SEC on January 15, 2020)
10.2	Amendment to Credit Agreement, dated as of February 27, 2020, by and among by and among TransMedics, Inc., TransMedics Group, Inc., TransMedics, B.V., and Orbimed Royalty Opportunities II, LP (incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K (File No. 001-38891) filed with the SEC on February 28, 2020)
10.3	Promissory Note, dated as of April 20, 2020 (incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K (File No. 001-38891) filed with the SEC on April 24, 2020)
10.4	Second Amendment to Credit Agreement, dated as of April 23, 2020, by and among by and among TransMedics, Inc., TransMedics Group, Inc., TransMedics, B.V., and Orbimed Royalty Opportunities II, LP (incorporated by reference to Exhibit 10.2 to the Registrant's Form 8-K (File No. 001-38891) filed with the SEC on April 24, 2020)
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of 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 Rule 13a-14(a) or Rule 15d-14(a) of 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	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Label Linkbase Document.
101.PRE	XBRL Taxonomy Presentation Linkbase Document.

* Filed herewith

† This certification will not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent specifically incorporated by reference into such filing.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: May 6, 2020

TRANSMEDICS GROUP, INC.

By: /s/ Waleed H. Hassanein, M.D.
Waleed H. Hassanein, M.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 6, 2020

By: /s/ Stephen Gordon
Stephen Gordon
Chief Financial Officer, Treasurer and Secretary
(Principal Financial and Accounting Officer)

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 Quarterly Report on Form 10-Q 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)) 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) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

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: May 6, 2020

/s/ Waleed H. Hassanein, M.D.

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 Quarterly Report on Form 10-Q 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)) 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) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

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: May 6, 2020

/s/ Stephen Gordon
Stephen Gordon
Chief Financial Officer, Treasurer and Secretary
(Principal Financial and Accounting Officer)

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 Quarterly Report on Form 10-Q of TransMedics Group, Inc. (the "Company") for the period ended March 31, 2020, 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 results of operations of the Company.

Date: May 6, 2020

By: /s/ Waleed H. Hassanein, M.D.
Waleed H. Hassanein, M.D.
President and Chief Executive Officer
(Principal 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 Quarterly Report on Form 10-Q of TransMedics Group, Inc. (the "Company") for the period ended March 31, 2020 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 results of operations of the Company.

Date: May 6, 2020

By: /s/ Stephen Gordon
Stephen Gordon
Chief Financial Officer, Treasurer and Secretary
(Principal Financial and Accounting Officer)