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 September 28, 2019

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 October 31, 2019, the registrant had 21,163,664 shares of common stock, no par value per share, outstanding.

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements, which reflect our current views with respect to, among other things, our operations and financial performance. All statements other than statements of historical facts contained in this 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. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy, short- and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in “Risk Factors.” Moreover, we operate in a very competitive and rapidly changing environment and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this 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 from our expectations include:

- our anticipation that we will continue to incur losses in the future;
- our potential need to raise additional funding;
- our existing and any future indebtedness, including our ability to comply with affirmative and negative covenants under the Credit Agreement to which we will remain subject to until maturity, 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 NOLs and research and development credit carryforwards;
- our dependence on the success of the OCS;
- the rate and degree of market acceptance of the OCS;
- our ability to educate patients, surgeons, transplant centers and private payors of benefits offered by the OCS;
- our ability to improve the OCS platform;
- our dependence 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 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;
- our expectations for the pricing of the OCS, as well as the reimbursement coverage for the OCS in the United States and internationally;

- regulatory developments in the United States, European Union and other jurisdictions;
- the extent and success of competing products that are or may become available;
- the impact of any product recalls or improper use of our products; and
- our use of proceeds from our IPO; and
- our estimates regarding revenues, expenses and needs for additional financing.

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. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Moreover, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this Quarterly Report on Form 10-Q to conform these statements to actual results or to changes in our expectations.

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)

	September 28, 2019	December 29, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 20,407	$ 20,241
Marketable securities	67,865	—
Accounts receivable, net of $0 allowance	6,465	3,438
Inventory	10,536	9,277
Prepaid expenses and other current assets	2,093	1,838
Total current assets	107,366	34,794
Property and equipment, net	4,746	3,474
Deferred offering costs	—	3,383
Restricted cash	500	500
Other long-term assets	6	6
Total assets	$ 112,618	$ 42,157
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 4,766	$ 4,720
Accrued expenses and other current liabilities	9,348	7,178
Deferred revenue	162	306
Current portion of deferred rent	365	349
Total current liabilities	14,641	12,553
Preferred stock warrant liability	—	898
Long-term debt, net of discount	34,023	33,670
Deferred rent, net of current portion	482	759
Total liabilities	49,146	47,880
Commitments and contingencies (Note 10)		
Convertible preferred stock (Series A-1, B, B-1, C, D, E and F) $0.0001 par value; no shares and 50,776,054 shares authorized at September 28, 2019 and December 29, 2018, respectively; and no shares and 50,404,140 shares issued and outstanding at September 28, 2019 and December 29, 2018, respectively	—	186,519
Stockholders' equity (deficit):		
Preferred stock, no par value; 25,000,000 shares and no shares authorized at September 28, 2019 and December 29, 2018, respectively; no shares issued and outstanding at September 28, 2019 and December 29, 2018	—	—
Common stock, no par value; 150,000,000 shares and no shares authorized at September 28, 2019 and December 29, 2018, respectively; 21,161,433 shares and no shares issued and outstanding at September 28, 2019 and December 29, 2018, respectively	423,758	—
Common stock, $0.0001 par value; no shares and 60,000,000 shares authorized at September 28, 2019 and December 29, 2018, respectively; no shares issued and 1,397,800 shares issued at September 28, 2019 and December 29, 2018, respectively; and no shares and 1,397,493 shares outstanding at September 28, 2019 and December 29, 2018, respectively	—	1
Additional paid-in capital	—	143,794
Accumulated other comprehensive income (loss)	20	(101)
Accumulated deficit	(360,306)	(335,936)
Total stockholders' equity (deficit)	63,472	(192,242)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 112,618	$ 42,157

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		Fiscal Nine Months Ended	
	September 28, 2019	September 29, 2018	September 28, 2019	September 29, 2018
Net revenue	$ 7,205	$ 4,039	$ 17,547	$ 9,473
Cost of revenue	2,989	1,907	7,425	5,238
Gross profit	4,216	2,132	10,122	4,235
Operating expenses:				
Research, development and clinical trials	4,939	3,272	13,608	10,170
Selling, general and administrative	6,519	2,799	17,423	7,941
Total operating expenses	11,458	6,071	31,031	18,111
Loss from operations	(7,242)	(3,939)	(20,909)	(13,876)
Other income (expense):				
Interest expense	(1,084)	(1,076)	(3,290)	(1,647)
Change in fair value of preferred stock warrant liability	—	(183)	(341)	(423)
Other income (expense), net	56	101	200	(152)
Total other expense, net	(1,028)	(1,158)	(3,431)	(2,222)
Loss before income taxes	(8,270)	(5,097)	(24,340)	(16,098)
Provision for income taxes	(10)	(8)	(30)	(23)
Net loss	$ (8,280)	$ (5,105)	$ (24,370)	$ (16,121)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.39)	$ (3.73)	$ (2.05)	$ (11.97)
Weighted average common shares outstanding, basic and diluted	21,131,618	1,368,260	11,882,626	1,346,942

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		Fiscal Nine Months Ended	
	September 28, 2019	September 29, 2018	September 28, 2019	September 29, 2018
Net loss	$ (8,280)	$ (5,105)	$ (24,370)	$ (16,121)
Other comprehensive income (loss):				
Foreign currency translation adjustment	56	12	69	4
Unrealized gains on marketable securities, net of tax of $0	22	—	52	7
Total other comprehensive income (loss)	78	12	121	11
Comprehensive loss	$ (8,202)	$ (5,093)	$ (24,249)	$ (16,110)

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 Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
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)
Conversion of convertible preferred stock into common stock upon initial public offering	(50,404,140)	(186,519)	13,119,424	186,519	—	—	—	186,519
Conversion of TransMedics' common stock into TransMedics Group's common stock upon Corporate Reorganization	—	—	—	143,859	(143,859)	—	—	—
Conversion of preferred stock warrants into common stock warrants upon initial public offering	—	—	—	1,239	—	—	—	1,239
Issuance of common stock in initial public offering, net of underwriting discounts and other offering costs of $5,966	—	—	6,543,500	91,401	—	—	—	91,401
Issuance of common stock upon the exercise of common stock options	—	—	8,771	6	—	—	—	6
Stock-based compensation expense	—	—	—	220	—	—	—	220
Foreign currency translation adjustment	—	—	—	—	—	(21)	—	(21)
Unrealized gains on marketable securities	—	—	—	—	—	30	—	30
Net loss	—	—	—	—	—	—	(9,195)	(9,195)
Balances at June 29, 2019	—	—	21,098,368	423,245	—	(58)	(352,026)	71,161
Issuance of common stock upon the exercise of common stock options	—	—	63,065	94	—	—	—	94
Settlement of accrued financing fee	—	—	—	124	—	—	—	124
Stock-based compensation expense	—	—	—	295	—	—	—	295
Foreign currency translation adjustment	—	—	—	—	—	56	—	56
Unrealized gains on marketable securities						22		22
Net loss	—	—	—	—	—	—	(8,280)	(8,280)
Balances at September 28, 2019	—	$ —	21,161,433	$ 423,758	$ —	$ 20	$ (360,306)	$ 63,472

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 Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balances at December 30, 2017	50,404,140	$ 186,519	1,330,693	$ 1	$ 143,604	$ (149)	$ (312,180)	$ (168,724)
Issuance of common stock upon the exercise of common stock options	—	—	5,357	—	12	—	—	12
Abandonment of shares of common stock by stockholders	—	—	(307)	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	27	—	—	27
Foreign currency translation adjustment	—	—	—	—	—	(6)	—	(6)
Unrealized gains on marketable securities	—	—	—	—	—	4	—	4
Net loss	—	—	—	—	—	—	(4,901)	(4,901)
Balances at March 31, 2018	50,404,140	186,519	1,335,743	1	143,643	(151)	(317,081)	(173,588)
Issuance of common stock upon the exercise of common stock options	—	—	23,019	—	9	—	—	9
Stock-based compensation expense	—	—	—	—	34	—	—	34
Foreign currency translation adjustment	—	—	—	—	—	(2)	—	(2)
Unrealized gains on marketable securities	—	—	—	—	—	3	—	3
Net loss	—	—	—	—	—	—	(6,115)	(6,115)
Balances at June 30, 2018	50,404,140	186,519	1,358,762	1	143,686	(150)	(323,196)	(179,659)
Issuance of common stock upon the exercise of common stock options	—	—	34,731	—	24	—	—	24
Stock-based compensation expense	—	—	—	—	31	—	—	31
Foreign currency translation adjustment	—	—	—	—	—	12	—	12
Net loss	—	—	—	—	—	—	(5,105)	(5,105)
Balances at September 29, 2018	50,404,140	$ 186,519	1,393,493	$ 1	$ 143,741	$ (138)	$ (328,301)	$ (184,697)

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

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

	Fiscal Nine Months Ended	
	September 28, 2019	**September 29, 2018**
Cash flows from operating activities:		
Net loss	$ (24,370)	$ (16,121)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	866	550
Stock-based compensation expense	572	92
Change in fair value of preferred stock warrant liability	341	423
Non-cash interest expense	352	116
Net amortization (accretion) of premiums (discounts) on marketable securities	(136)	9
Loss on extinguishment of debt	—	305
Unrealized foreign currency transaction (gains) losses	392	(10)
Changes in operating assets and liabilities:		
Accounts receivable	(3,098)	(2,979)
Inventory	(3,238)	(2,818)
Prepaid expenses and other current assets	(314)	(183)
Accounts payable	1,054	(753)
Accrued expenses and other current liabilities	2,954	1,805
Deferred revenue	(136)	(54)
Deferred rent	(261)	(246)
Net cash used in operating activities	(25,022)	(19,864)
Cash flows from investing activities:		
Purchases of property and equipment	(184)	(284)
Purchases of marketable securities	(67,677)	—
Proceeds from sales and maturities of marketable securities	—	12,725
Net cash provided by (used in) investing activities	(67,861)	12,441
Cash flows from financing activities:		
Repayments of long-term debt	—	(9,076)
Proceeds from issuance of long-term debt, net of issuance costs	—	33,436
Proceeds from issuance of common stock in initial public offering, net of underwriting discounts and commissions	97,367	—
Payments of initial public offering and other financing costs	(4,506)	(61)
Proceeds from issuance of common stock upon exercise of stock options	108	45
Net cash provided by financing activities	92,969	24,344
Effect of exchange rate changes on cash, cash equivalents and restricted cash	80	33
Net increase in cash, cash equivalents and restricted cash	166	16,954
Cash, cash equivalents and restricted cash, beginning of period	20,741	12,436
Cash, cash equivalents and restricted cash, end of period	$ 20,907	$ 29,390
Supplemental disclosure of non-cash investing and financing activities:		
Conversion of convertible preferred stock to common stock upon initial public offering	$ 186,519	—
Reclassification of warrant liability to equity upon initial public offering	$ 1,239	$ —
Transfers of inventory to property and equipment	$ 1,904	$ 1,168
Purchases of property and equipment included in accounts payable	$ 90	$ —
Settlement of accrued financing fee	$ 124	$ —
Offering costs included in accounts payable and accrued expenses	$ 120	$ 1,407

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

1. Nature of the Business and Basis of Presentation

TransMedics Group, Inc. ("TransMedics Group" and, together with its consolidated subsidiaries, the "Company") was incorporated in the Commonwealth of Massachusetts in October 2018. TransMedics, Inc. ("TransMedics"), an operating company and wholly-owned subsidiary of TransMedics Group, was incorporated in the State of Delaware in August 1998. The Company is a commercial-stage medical technology company transforming organ transplant therapy for end-stage organ failure patients across multiple disease states. The Company developed the Organ Care System ("OCS") to replace a decades-old standard of care. The OCS represents a paradigm shift that transforms organ preservation for transplantation from a static state to a dynamic environment that enables new capabilities, including organ optimization and assessment. The Company's OCS technology replicates many aspects of the organ's natural living and functioning environment outside of the human body.

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 $24.4 million for the fiscal nine months ended September 28, 2019 and $23.8 million for the fiscal year ended December 29, 2018. As of September 28, 2019, the Company had an accumulated deficit of $360.3 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 $88.3 million as of September 28, 2019 will be sufficient to fund operations, capital expenditures, and debt service payments for at least the next twelve months following the filing of this Quarterly Report on Form 10-Q.

The Company is subject to risks and uncertainties common to companies in the medical device industry and of similar size, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, uncertainty of market acceptance of products, and the need to obtain additional financing to fund operations. Products currently under development will require additional research and development efforts, including additional clinical testing and regulatory approval, prior to commercialization. These efforts require additional capital, adequate personnel, infrastructure and extensive compliance-reporting capabilities. There can be no assurance that the Company's research and development will be successfully completed, that adequate protection for the Company's technology will be obtained, that any products will obtain necessary government regulatory approval or that any approved products will be commercially viable. The Company operates in an environment of rapid change in technology and competition from other medical device companies.

The Company's fiscal year ends on the last Saturday in December, and the Company reports fiscal years using a 52/53-week convention. Under this convention, certain fiscal years contain 53 weeks. Each fiscal year is typically composed of four 13-week fiscal quarters, but in years with 53 weeks, the fourth quarter is a 14-week period. The fiscal year ended December 29, 2018 included 52 weeks and the fiscal year ending December 28, 2019 includes 52 weeks. The fiscal year ended December 29, 2018 is referred to as "fiscal 2018" and the fiscal year ended December 28, 2019 is referred to as "fiscal 2019."

The Company's consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

Revision

Subsequent to the filing of its Form 10-Q for the quarterly period ended June 29, 2019, the Company discovered an error in the calculation of basic and diluted net loss per share attributable to common stockholders for the three and six months ended June 30, 2018. The calculation of the weighted average number of common shares outstanding (basic and diluted) as originally reported had not appropriately reflected the 3.5-for-one conversion ratio applied to common stock in the Corporate Reorganization. The correction of this error decreased the weighted average number of common shares outstanding (basic and diluted) for the three and six months ended June 30, 2018 from 4,686,080 and 4,676,991, respectively, (as reported) to 1,338,880 and 1,336,283, respectively, (as revised). As a result, basic and diluted net loss per share attributable to common stockholders for the three and six months ended June 30, 2018 increased from $1.30 and $2.36, respectively, (as reported) to $4.57 and $8.24, respectively, (as revised). Management of the Company has concluded that these revisions of basic and diluted net loss per share attributable to common stockholders are not material to the previously issued interim financial statements.

2. Summary of Significant Accounting Policies

Unaudited Interim Financial Information

The consolidated balance sheet at December 29, 2018 was derived from audited financial statements but does not include all disclosures required by GAAP. The accompanying unaudited consolidated financial statements as of September 28, 2019 and for the fiscal three and nine months ended September 28, 2019 and September 29, 2018 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 TransMedics' audited consolidated financial statements and the notes thereto for the fiscal year ended December 29, 2018 included in the Company's Registration Statement on Form S-1, as amended, File No. 333-230736 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 September 28, 2019 and results of operations for the fiscal three and nine months ended September 28, 2019 and September 29, 2018 and cash flows for the fiscal nine months ended September 28, 2019 and September 29, 2018 have been made. The Company's results of operations for the fiscal three and nine months ended September 28, 2019 are not necessarily indicative of the results of operations that may be expected for the fiscal year ending December 28, 2019.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenue and expenses during the reporting periods. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, revenue recognition, the valuation of inventory, the valuation of common stock, the valuation of stock-based awards and the valuation of the preferred stock warrant liability. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates as there are changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results may differ from those estimates or assumptions.

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 total revenue or accounts receivable (see Note 13).

Certain of the components and subassemblies included in the Company's products are obtained from a sole source, a single source or a limited group of suppliers. Although the Company seeks to reduce dependence on those limited sources of suppliers and manufacturers, the partial or complete loss of certain of these sources could have a material adverse effect on the Company's operating results, financial condition and cash flows and damage its customer relationships.

Deferred Offering Costs

The Company capitalizes certain legal, accounting and other third-party fees that are directly associated with equity financings as deferred offering costs until such financings are consummated. After consummation of an equity financing, these costs are recorded in stockholders' equity (deficit) as a reduction of common stock generated as a result of the offering. Should an in-process equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the consolidated statements of operations. The Company recorded deferred offering costs of $3.4 million as of December 29, 2018. Upon closing of the IPO on May 6, 2019, these deferred offering costs were included in the $6.0 million issuance costs classified to stockholders' equity (deficit) and recorded against the proceeds from the offering.

Fair Value Measurements

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company's cash equivalents and marketable securities consisting of money market funds, U.S. Treasury securities, and U.S. government agency bonds and its preferred stock warrant liability are carried at fair value, determined according to the fair value hierarchy described above (see Note 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 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 statement 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.

In these cases, 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, the Company has determined that 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 $1.8 million, for the fiscal three and nine months ended September 28, 2019, respectively, and $0.7 million and $1.3 million for the fiscal three and nine months ended September 29, 2018, 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 $0.9 million for the fiscal three and nine months ended September 28, 2019, respectively, and $0.2 million and $0.3 million for the fiscal three and nine months ended September 29, 2018, 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 September 28, 2019 and December 29, 2018.

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 September 28, 2019, and December 29, 2018, the Company's wholly- or partially-unsatisfied performance obligations totaled $0.3 million and $1.5 million, respectively.

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		Fiscal Nine Months Ended	
	September 28, 2019	September 29, 2018	September 28, 2019	September 29, 2018
Gross revenue from sales to customers	$ 7,876	$ 4,755	$ 19,381	$ 10,776
Less: Clinical trial payments reducing revenue	671	716	1,834	1,303
Total net revenue	$ 7,205	$ 4,039	$ 17,547	$ 9,473

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		Fiscal Nine Months Ended	
	September 28, 2019	September 29, 2018	September 28, 2019	September 29, 2018
Net revenue by OCS product:				
OCS Lung net revenue	$ 2,114	$ 1,487	$ 5,744	$ 3,146
OCS Heart net revenue	3,739	1,639	8,305	4,860
OCS Liver net revenue	1,352	913	3,498	1,467
Total net revenue	$ 7,205	$ 4,039	$ 17,547	$ 9,473

	Fiscal Three Months Ended		Fiscal Nine Months Ended	
	September 28, 2019	September 29, 2018	September 28, 2019	September 29, 2018
Net revenue by geography:				
United States	$ 4,341	$ 2,244	$ 11,596	$ 4,391
Outside the U.S.	2,864	1,795	5,951	5,082
Total net revenue	$ 7,205	$ 4,039	$ 17,547	$ 9,473

Practical Expedients Used in Application of ASC 606

The Company has elected to apply the practical expedient for immaterial goods and services in the context of the contract. Accordingly, 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.

The Company has elected to apply the practical expedient for shipping. Accordingly, the Company does not consider shipping to be a contract performance obligation.

When applicable, the Company has elected to apply the practical expedient for considering the existence of a significant financing component. Accordingly, the Company does not adjust the promised amount of arrangement consideration for the effects of a significant financing component if it expects, at contract inception, that the period of time between the Company's transfer of a promised good or service to a customer and the customer's payment for that good or service will be one year or less.

Distributors

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

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. Compensation expense for those awards is recognized over the requisite service period, which is generally the vesting period of the respective award. Generally, the Company issues awards with only service-based vesting conditions and records the expense for these awards using the straight-line method.

Prior to the adoption of Accounting Standards Update ("ASU") 2018-07 on December 30, 2018 discussed below, the Company measured the fair value of stock-based option awards granted to non-employee consultants on the date that the related service was complete, which was generally the vesting date. Prior to the service completion date, compensation expense was recognized over the period during which services were rendered by such non-employee consultants. At the end of each financial reporting period prior to completion of the service, the fair value of these awards was remeasured using the then-current fair value of the Company's common stock and updated assumption inputs in the Black-Scholes option-pricing model.

The Company classifies stock-based compensation expense in its consolidated statements of operations in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

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 meet the definition of participating securities. The two-class method determines net income (loss) per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed.

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

The 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 reports a net loss, such losses are not allocated to such participating securities. In periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive.

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 each of the fiscal three and nine months ended September 28, 2019 and September 29, 2018.

Recently Adopted Accounting Pronouncements

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606)* ("ASC 606"). ASC 606 outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry specific guidance. The new standards require entities to apportion consideration from contracts to performance obligations on a relative standalone selling price basis, based on a five-step model. Under ASC 606, revenue is recognized when a customer obtains control of a promised good or service and is recognized in an amount that reflects the consideration that the entity expects to receive in exchange for the good or service. In addition, ASC 606 provides guidance on accounting for certain revenue related costs, including costs associated with obtaining and fulfilling a contract. The Company adopted ASC 606 on December 30, 2018, applied using the modified retrospective method. Under this method, (i) the new guidance is applied to customer contracts that are not yet completed as of December 29, 2018, with the cumulative effect of initially applying the new guidance recorded as an adjustment to accumulated deficit on the effective date of adoption, and (ii) the Company's historical results for all periods prior to December 30, 2018, including for the fiscal three and nine months ended September 29, 2018, are not adjusted. The Company did not elect to apply any permitted practical expedients as part of its adoption.

The Company's adoption of ASC 606 did not substantially change the revenue recognition of its OCS products as applied under the prior revenue guidance, ASC 605, and, as a result, the adoption did not have a material impact on the Company's consolidated financial statements. Accordingly, transitional disclosures were not presented. The Company's revenue accounting policies related to ASC 605, which were applied in its reporting of amounts presented for all periods prior to December 30, 2018, were unchanged.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation – Stock Compensation (Topic 718), Improvements to Nonemployee Share-Based Payment Accounting* ("ASU 2018-07"). ASU 2018-07 is intended to simplify aspects of share-based compensation issued to non-employees by making the guidance consistent with the accounting for employee share-based compensation. For public entities, ASU 2018-07 was required to be adopted for annual periods beginning after December 15, 2018, including interim periods within those fiscal years. For nonpublic entities, ASU 2018-07 is effective for annual periods beginning after December 15, 2019. Early adoption is permitted for all entities but no earlier than the Company's adoption of ASU 2014-09. The Company early-adopted ASU 2018-07 on December 30, 2018 and the adoption did not have a material impact on the Company's financial statements.

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. For nonpublic entities, the guidance is effective for annual reporting periods beginning after December 15, 2019 and for interim periods within fiscal years beginning after December 15, 2020. Early adoption is permitted for all entities. ASU 2016-02 initially required adoption using a modified retrospective approach, under which all years presented in the financial statements would be prepared under the revised guidance. In July 2018, the FASB issued ASU No. 2018-11, *Leases (Topic 842)*, which added an optional transition method under which financial statements may be prepared under the revised guidance for the year of adoption, but not for prior years. Under the latter method, entities will recognize a cumulative catch-up adjustment to the opening balance of retained earnings in the period of adoption. In October 2019, the FASB formally approved the new effective date for ASC 842 for nonpublic entities. Accordingly, for nonpublic entities, the guidance is effective for annual reporting periods beginning after December 15, 2020 and for interim periods within fiscal years beginning after December 15, 2021. The Company will adopt ASU 2016-02 in its fiscal year 2021, which begins on December 27, 2020, in accordance with the nonpublic company requirements. The Company is currently evaluating the method of adoption of this guidance and the impact that the adoption of ASU 2016-02 will have on its consolidated financial statements.

3. Marketable Securities

The Company invests its excess cash in fixed income instruments denominated and payable in U.S. dollars, including U.S. treasury securities and U.S. government agency bonds in accordance with the Company's investment policy that primarily seeks to maintain adequate liquidity and preserve capital.

The Company has designated investments as available-for-sale and therefore such investments are reported at fair value. Unrealized gains or losses on investments are recorded in accumulated other comprehensive income or loss, a component of stockholders' equity (deficit), on the Company's consolidated balance sheets.

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

	September 28, 2019			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury securities	$ 12,218	$ 3	$ —	$ 12,221
U.S. Government agency bonds	55,595	49	—	55,644
	$ 67,813	$ 52	$ —	$ 67,865

The Company's marketable securities are due within one year. The Company had no marketable securities as of December 29, 2018.

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 September 28, 2019 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 12,126	$ —	$ —	$ 12,126
Marketable securities:				
U.S Treasury securities	—	12,221	—	12,221
U.S. Government agency bonds	—	55,644	—	55,644
	$ 12,126	$ 67,865	$ —	$ 79,991

	Fair Value Measurements at Year Ended December 29, 2018 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 13,586	$ —	$ —	$ 13,586
	$ 13,586	$ —	$ —	$ 13,586
Liabilities:				
Preferred stock warrant liability	$ —	$ —	$ 898	$ 898

Money market funds were valued by the Company based on quoted market prices, which represent a Level 1 measurement within the fair value hierarchy. During the fiscal nine months ended September 28, 2019 and September 29, 2018, there were no transfers between Level 1, Level 2, and Level 3.

The preferred stock warrant liability in the table above consisted of the fair value of warrants to purchase Series D and Series F convertible preferred stock (see Note 8) and was based on significant inputs not observable in the market, which represented a Level 3 measurement within the fair value hierarchy. The Company's valuation of the preferred stock warrants utilized the Black-Scholes option-pricing model, which incorporated assumptions and estimates to value the preferred stock warrants. The Company assessed these assumptions and estimates on a quarterly basis as additional information impacting the assumptions was obtained. Changes in the fair value of the preferred stock warrants were recognized as other income (expense), net in the consolidated statement of operations. On May 6, 2019, immediately prior to the closing of the 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 the IPO, the Company no longer remeasures the fair value of the warrant liability at each reporting date.

The quantitative elements associated with the Company's Level 3 inputs impacting the fair value measurement of the preferred stock warrant liability included the fair value per share of the underlying Series D and Series F convertible preferred stock, the remaining contractual term of the warrants, risk-free interest rate, expected dividend yield and expected volatility of the price of the underlying preferred stock. The most significant assumption in the Black-Scholes option-pricing model that impacted the fair value of the preferred stock warrants was the fair value of the Company's convertible preferred stock as of each remeasurement date. The Company determined the fair value per share of the underlying preferred stock by taking into consideration the most recent sales of its convertible preferred stock, results obtained from third-party valuations and additional factors that the Company deemed relevant. As of December 29, 2018, the fair value of each share of Series D and Series F convertible preferred stock was $6.21 per share and $5.73 per share, respectively. Prior to its IPO, the Company historically had been a private company and lacked company-specific historical and implied volatility information of its stock. Therefore, it estimated its expected stock volatility based on the historical volatility of publicly traded peer companies for a term equal to the remaining contractual term of the warrants. The risk-free interest rate was determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the warrants. The Company had estimated a 0% dividend yield based on the expected dividend yield and the fact that the Company had never paid or declared dividends.

Based on the terms and conditions of the warrants and pursuant to the Corporate Reorganization, immediately prior to the closing of the Company's IPO on May 6, 2019, the preferred stock warrants converted to common stock warrants. On that date, the Company remeasured the warrants and reclassified the total carrying value to stockholders' equity (deficit). The Company performed the final measurement of the warrants using the fair value of the underlying common shares of $27.41 per share on May 6, 2019 and recorded the change in fair value in other income (expense), net in the consolidated statement of operations.

The following table provides a roll-forward of the aggregate fair values of the Company's preferred stock warrants for which fair value is determined by Level 3 inputs (in thousands):

	Preferred Stock Warrant Liability
Fair value at December 29, 2018	$ 898
Change in fair value	341
Reclassification of warrant liability to equity upon initial public offering	(1,239)
Fair value at September 28, 2019	$ —

5. Accrued Expenses and Other Current Liabilities

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

	September 28, 2019	December 29, 2018
Accrued research, development and clinical trials expenses	$ 3,072	$ 1,853
Accrued payroll and related expenses	3,515	1,729
Accrued financing fees (Note 10)	340	1,466
Accrued professional fees	837	549
Accrued premium for manufacturing contract	—	1,089
Accrued other	1,584	492
	$ 9,348	$ 7,178

6. Inventory

Inventory consisted of the following (in thousands):

	September 28, 2019	December 29, 2018
Raw materials	$ 4,665	$ 3,817
Work-in-process	924	882
Finished goods	4,947	4,578
	$ 10,536	$ 9,277

During the fiscal nine months ended September 28, 2019 and September 29, 2018, the Company made non-cash transfers of OCS Consoles from inventory to property and equipment (OCS Consoles loaned to customers) of $1.9 million and $1.2 million, respectively.

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 September 28, 2019, and December 29, 2018, long-term debt consisted of the following (in thousands):

	September 28, 2019	December 29, 2018
Principal amount of long-term debt	$ 35,000	$ 35,000
Debt discount, net of accretion	(1,213)	(1,424)
Accrued end-of-term payment	236	94
Long-term debt, net of discount	$ 34,023	$ 33,670

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. With respect to its consolidated financial statements for the fiscal year ended December 29, 2018, the Company received a waiver of the covenant requiring delivery to OrbiMed of audited financial statements with an unqualified audit opinion. As of September 28, 2019, the Company was in compliance with the minimum liquidity covenant of 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 September 28, 2019, the interest rate applicable to borrowings under the Credit Agreement was 11.3%. During the fiscal nine months ended September 28, 2019, the weighted average effective interest rate on outstanding borrowings under the Credit Agreement was approximately 12.9%.

8. Convertible Preferred Stock and Warrants to Purchase Preferred Stock

Convertible Preferred Stock

TransMedics issued Series A-1 convertible preferred stock (the "Series A-1 Preferred Stock"), Series B convertible preferred stock (the "Series B Preferred Stock"), Series B-1 convertible preferred stock (the "Series B-1 Preferred Stock"), Series C convertible preferred stock (the "Series C Preferred Stock"), Series D convertible preferred stock (the "Series D Preferred Stock"), Series E convertible preferred stock (the "Series E Preferred Stock") and Series F convertible preferred stock (the "Series F Preferred Stock").

As of December 29, 2018, preferred stock consisted of the following (in thousands, except share amounts):

	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A-1 Preferred Stock	13,332	13,332	$ 3,333	$ 33	984
Series B Preferred Stock	3,771,020	3,624,650	10,691	12,382	286,102
Series B-1 Preferred Stock	2,560,245	2,560,245	8,746	8,746	202,086
Series C Preferred Stock	6,198,057	6,198,057	14,970	15,495	1,770,873
Series D Preferred Stock	14,740,000	14,565,000	34,868	72,825	4,161,428
Series E Preferred Stock	6,562,232	6,562,232	29,865	29,966	1,874,923
Series F Preferred Stock	16,931,168	16,880,624	84,046	84,234	4,823,028
	50,776,054	50,404,140	$ 186,519	$ 223,681	13,119,424

Immediately prior to the closing of the IPO on May 6, 2019, pursuant to the Corporate Reorganization, all of the outstanding shares of convertible preferred stock of TransMedics were converted into an aggregate of 13,119,424 shares of common stock of TransMedics Group.

Warrants to Purchase Preferred Stock

In connection with prior debt agreements and amendments to such agreements, TransMedics had outstanding warrants to purchase shares of Series D Preferred Stock and Series F Preferred Stock as of December 29, 2018. The Company classified all of its preferred stock warrants as a liability on its consolidated balance sheets because the warrants were freestanding financial instruments that could require TransMedics to transfer assets upon exercise. The liability associated with each of these warrants was initially recorded at fair value upon the issuance date of each warrant and subsequently remeasured to fair value at each reporting date. The fair value of these warrants was determined using the Black-Scholes option-pricing model (see Note 4), and the resulting change in fair value of the warrant liability was recorded in other income (expense) in the Company's consolidated statements of operations (see Note 4).

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 of TransMedics Group at a weighted average exercise price of $10.70 per share and an expiration date of May 6, 2024. Upon conversion, the fair value of the warrant liability at that time was reclassified to common stock. As a result, subsequent to the closing of the Company's IPO, the Company will no longer remeasure the fair value of the warrant liability at each reporting date.

9. Stock-Based Compensation

2014 Stock Incentive Plan

The Company's 2014 Stock Incentive Plan (the "2014 Plan") permitted the Company to sell or issue incentive stock options or nonqualified stock options, stock appreciation rights, restricted stock, restricted stock units, and other stock-based awards to employees, directors, and non-employee consultants of the Company. The 2014 Plan was administered by the board of directors or, at the discretion of the board of directors, by a committee of the board of directors. The exercise prices, vesting, and other restrictions were determined at the discretion of the board of directors, or its committee if so delegated.

Stock options granted under the 2014 Plan with service-based vesting conditions typically vest over three or four years and expire after ten years. Following the effectiveness of the Company's 2019 Stock Incentive Plan (the "2019 Stock Plan") in April 2019, no future awards will be made under the 2014 Plan. Additionally, shares underlying awards under the 2014 Plan that expire or are terminated, surrendered, or canceled without the delivery of shares will be available for future awards under the 2019 Stock Plan.

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 Plan, which became effective on that same date. The 2019 Stock 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 Stock Plan was 3,428,571 shares, plus the number of shares underlying awards under 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 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 Stock Plan. In addition, the number of shares available for issuance under the 2019 Stock Plan (i) will not be increased by any shares delivered under the 2019 Stock 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 Stock Plan. As of September 28, 2019, 2,987,866 shares of common stock were available for issuance under the 2019 Plan.

During the fiscal nine months ended September 28, 2019, the Company granted options to its employees and a director with service-based vesting for the purchase of an aggregate of 457,357 shares of common stock with a weighted average grant fair value of $8.54 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 as of September 28, 2019. As of September 28, 2019, no shares have been issued under the 2019 ESPP and 371,142 shares 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 and comprehensive loss (in thousands):

	Fiscal Three Months Ended		Fiscal Nine Months Ended	
	September 28, 2019	September 29, 2018	September 28, 2019	September 29, 2018
Cost of revenue	$ 6	$ 1	$ 14	$ 4
Research, development and clinical trials expenses	35	9	67	28
Selling, general and administrative expenses	254	21	491	60
	$ 295	$ 31	$ 572	$ 92

As of September 28, 2019, total unrecognized compensation cost related to unvested share-based awards was $4.0 million which is expected to be recognized over a weighted average period of 2.96 years.

10. Commitments and Contingencies

Operating Leases

The Company leases its office, laboratory, and manufacturing space under two noncancelable operating leases that expire in December 2021. The lease agreements include payment escalations, rent holidays, and other lease incentives, which are accrued or deferred as appropriate such that rent expense for each lease is recognized on a straight-line basis over the respective lease terms, recording deferred rent for rent expense incurred but not yet paid. The Company recorded rent expense of $0.3 million and $1.0 million in each of the fiscal three and nine months ended September 28, 2019 and September 29, 2018, respectively.

Future minimum lease payments under operating leases as of September 28, 2019 are as follows (in thousands):

Fiscal Year Ending:		
December 28, 2019 (remaining 3 months)	$	388
December 26, 2020		1,570
December 25, 2021		1,589
	$	3,547

License Agreement with the Department of Veterans Affairs

The Company has a license agreement with the Department of Veterans Affairs (the "VA"), entered into in 2002, under which the Company was granted an exclusive, worldwide license under specified patents to make, use, sell, and import certain technology used in the Company's products and a non-exclusive, worldwide license to make, use, sell, and import solutions for use in or with those products. The rights under the license agreement continue until the expiration of the last to expire of the licensed patents. The majority of the licensed U.S. patents expired in 2017, and the foreign patents expired in September 2018. However, the Company has requested a patent term extension for one U.S. patent covered by the VA license agreement, U.S. Patent No. 6,100,082. The Company has been granted an interim patent term extension for this patent. As of September 28, 2019, the Company had not received final approval of the patent extension beyond the interim patent term extension until September 23, 2020 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.

Accrued Financing Fees

In periods prior to 2016, the Company incurred financing fees of $1.5 million for amounts due to its former financial advisors related to the issuance of its Series B Preferred Stock and Series D Preferred Stock. These financing fees were contingently payable in cash only upon an IPO or certain alternative transactions, including a sale of the Company. As a result of the IPO in May 2019, the Company became obligated to pay those financing fees, of which $1.0 million was paid in the fiscal three months ended September 28, 2019 and $0.3 million was accrued as of September 28, 2019. The difference between the amount previously accrued of $1.5 million and the final payment $1.3 million were recorded to stockholders' equity (deficit) in the three and nine fiscal months ended September 28, 2019 (see Note 5).

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 September 28, 2019, and December 29, 2018, 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 September 28, 2019 or December 29, 2018.

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		Fiscal Nine Months Ended	
	September 28, 2019	September 29, 2018	September 28, 2019	September 29, 2018
Numerator:				
Net loss attributable to common stockholders	$ (8,280)	$ (5,105)	$ (24,370)	$ (16,121)
Denominator:				
Weighted average common shares outstanding, basic and diluted	21,131,618	1,368,260	11,882,626	1,346,942
Net loss per share attributable to common stockholders, basic and diluted	$ (0.39)	$ (3.73)	$ (2.05)	$ (11.97)

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:

	September 28, 2019	September 29, 2018
Convertible preferred stock (as converted to common stock)	—	13,119,424
Warrants to purchase common stock	64,440	64,440
Options to purchase common stock	1,969,392	1,538,619
	2,033,832	14,722,483

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		Fiscal Nine Months Ended	
	September 28, 2019	September 29, 2018	September 28, 2019	September 29, 2018
Net revenue(1):				
United States	$ 4,341	$ 2,244	$ 11,596	$ 4,391
United Kingdom	773	937	1,747	2,049
Germany	194	252	871	1,098
Australia	251	167	561	987
All other countries	1,646	439	2,772	948
Total net revenue	$ 7,205	$ 4,039	$ 17,547	$ 9,473

	September 28, 2019	December 29, 2018
Long-lived assets(2):		
United States	$ 3,906	$ 2,567
Netherlands	840	907
Total long-lived assets	$ 4,746	$ 3,474

(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. Significant Customer Concentrations

Significant customers are those that accounted for 10% or more of the Company's net revenue or accounts receivable, as set forth in the following tables for the periods presented:

Net revenue:

	Fiscal Three Months Ended		Fiscal Nine Months Ended	
	September 28, 2019	September 29, 2018	September 28, 2019	September 29, 2018
Company A	*	*	10%	*
Company B	*	*	*	11%
Company C	*	11%	*	*
Company D	*	10%	*	*

* Less than 10% of total

Accounts receivable:

	September 28, 2019	December 29, 2018
Company A	*	15%
Company B	*	13%

* Less than 10% of total

14. 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 and $0.2 million in total compensation for each of the fiscal three and nine months ended September 28, 2019 and September 29, 2018 for her services as an employee.

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 final prospectus for our IPO filed pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended (the "Securities Act"), with the SEC, on May 2, 2019 (the "Final Prospectus"). 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 under "Risk Factors" in the Final Prospectus, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis

Overview

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

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

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

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 $17.6 million and incurred a net loss of $24.4 million for the fiscal nine months ended September 28, 2019. We generated net revenue of $13.0 million and incurred a net loss of $23.8 million for the fiscal year ended December 29, 2018. As of September 28, 2019, we had an accumulated deficit of $360.3 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.”

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 statement 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 $1.8 million, for the fiscal three and nine months ended September 28, 2019, respectively, and $0.7 million and $1.3 million, for the fiscal three and nine months ended September 29, 2018, respectively.

Prior to the fourth quarter of 2018, all of our net revenue in the United States had been generated from sales of OCS disposable sets sold in conjunction with clinical trials conducted for our OCS products. In March 2018, we received our first FDA Post Market Approval ("PMA") for the OCS Lung, and we began commercial sales of this product in the United States during the fourth quarter of 2018. Therefore, commencing in the fourth quarter of 2018, our net revenue in the United States is derived from both clinical trial sales and commercial sales and consists primarily of sales of OCS disposable sets and, to a much lesser extent, sales of OCS Consoles. In May 2019, we received our second FDA PMA approval for the OCS Lung for additional clinical indications. We expect to continue to have U.S. clinical trial sales for our OCS Heart and OCS Liver products until we receive similar FDA PMA approvals for those products.

Historically, our net revenue in the United States fluctuated from period to period as a result of the timing of patient enrollment in our clinical trials. Our net revenue during periods of patient enrollment has been higher due to the sale of OCS disposable sets for use during these clinical trials, as compared to periods during which our clinical trials were not actively enrolled. Our OCS Lung EXPAND Trial began patient enrollment in January 2014 and completed patient enrollment in October 2016. Our OCS Heart EXPAND Trial began patient enrollment in September 2015 and completed patient enrollment in March 2018. Our Liver PROTECT Trial began enrollment in January 2016 and completed enrollment in October 2019. Our OCS Lung EXPAND II Trial began patient enrollment in March 2018 and has stopped enrollment as of June 24, 2019 since we received FDA PMA approval for the OCS Lung EXPAND indication. Our OCS Heart EXPAND Continued Access Protocol (CAP) trial began patient enrollment in May 2019 and is currently enrolling patients. Our net revenue may continue to fluctuate from period to period as a result of the timing of ongoing clinical trials in which our OCS products are used.

Through September 28, 2019, 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 in the future 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 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.

Our consolidated financial results for the fiscal three and nine months ended September 28, 2019 reflect our adoption of ASC 606, *Revenue from Contracts with Customers*, as of December 30, 2018, applied using the modified retrospective method. Under this method, (i) the new guidance was applied to customer contracts that were not yet completed as of December 29, 2018, with the cumulative effect of initially applying the new guidance being recorded as an adjustment to accumulated deficit on the effective date of adoption, and (ii) our historical results for all periods prior to December 30, 2018, including for the fiscal three and nine months ended September 29, 2018, are not adjusted. Our adoption of ASC 606 did not have a material impact on our consolidated financial statements, and the revenue recognition of our OCS products remained substantially unchanged. The impact of the adoption of ASC 606 on our consolidated financial statements is described in Note 2 to our consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

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. In each reported period through December 29, 2018, we did not meet our obligation to purchase minimum quantities annually from our supplier of OCS Lung Solution and we were obligated to pay a premium equal to the order shortfall multiplied by a specified price. We capitalized any estimated premium we expected to pay at the end of each year as an adjustment to the inventory cost of OCS Lung Solution ordered during that year. The capitalized inventory adjustment is recognized as a component of cost of revenue when related OCS disposable sets are sold.

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

Gross profit is the amount by which our net revenue exceeds our cost of revenue in each reporting period. We calculate gross margin as gross profit divided by net revenue. Our gross margin has been and will continue to be affected by a variety of factors, primarily production volumes, the cost of components and direct materials, manufacturing costs, headcount, the selling price of our OCS products and fluctuations in amounts paid by us to customers related to reimbursements of their clinical trial expenses, where such payments are not distinct.

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.

Operating Expenses

Research, Development and Clinical Trials Expenses

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

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

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

Selling, General and Administrative Expenses

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

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

Other Income (Expense)

Interest Expense

Interest expense consists of interest expense associated with outstanding borrowings under a prior loan agreement and our existing loan agreement as well as the amortization of debt discount associated with such agreements. We expect our interest expense for fiscal 2019 will increase compared to fiscal 2018 in connection with our credit agreement with OrbiMed, under which we borrowed $35.0 million in June 2018. At that time, we repaid the remaining $6.7 million of principal that had been outstanding under our prior loan and security agreement with Hercules Technology Growth Capital, or Hercules, thereby increasing our total debt by $28.3 million.

Change in Fair Value of Preferred Stock Warrant Liability

In connection with our prior loan and security agreement, as amended, with Hercules, we issued warrants to purchase 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 including the loss on extinguishment of debt that we recognized in June 2019 in connection with our repayment of borrowings under our loan and security agreement with Hercules.

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

Provision for Income Taxes

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

As of December 29, 2018, we had U.S. federal and state net operating loss carryforwards of $246.6 million and $179.1 million, respectively, which may be available to offset future taxable income, of which $215.2 million and $179.1 million begin to expire in 2019 and 2030, respectively, and of which $31.4 million related to U.S. federal income taxes do not expire. As of December 29, 2018, we also had U.S. federal and state research and development tax credit carryforwards of $6.4 million and $4.3 million, respectively, which may be available to offset future tax liabilities and begin to expire in 2020 and 2024, respectively. As of December 29, 2018, 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

Our fiscal year ends on the last Saturday in December, and we report fiscal years using a 52/53-week convention. Under this convention, certain fiscal years contain 53 weeks. Each fiscal year is typically composed of four 13-week fiscal quarters, but in years with 53 weeks, the fourth quarter is a 14-week period. Our fiscal year ended December 29, 2018 included 52 weeks and our fiscal year ending December 28, 2019 includes 52 weeks. The fiscal year ended December 29, 2018 is referred to as “fiscal 2018” and the fiscal year ended December 28, 2019 is referred to as “fiscal 2019”.

Comparison of the Fiscal Three Months Ended September 28, 2019 and September 29, 2018

The following table summarizes our results of operations for the fiscal three months ended September 28, 2019 and September 29, 2018:

	Fiscal Three Months Ended		
	September 28, 2019	September 29, 2018	Change
	(in thousands)		
Net revenue	$ 7,205	$ 4,039	$ 3,166
Cost of revenue	2,989	1,907	1,082
Gross profit	4,216	2,132	2,084
Operating expenses:			
Research, development and clinical trials	4,939	3,272	1,667
Selling, general and administrative	6,519	2,799	3,720
Total operating expenses	11,458	6,071	5,387
Loss from operations	(7,242)	(3,939)	(3,303)
Other income (expense):			
Interest expense	(1,084)	(1,076)	(8)
Change in fair value of preferred stock warrant liability	—	(183)	183
Other income (expense), net	56	101	(45)
Total other expense, net	(1,028)	(1,158)	130
Loss before income taxes	(8,270)	(5,097)	(3,173)
Provision for income taxes	(10)	(8)	(2)
Net loss	$ (8,280)	$ (5,105)	$ (3,175)

Net Revenue, Cost of Revenue and Gross Profit

	Fiscal Three Months Ended		
	September 28, 2019	September 29, 2018	Change
	(in thousands)		
Net revenue	$ 7,205	$ 4,039	$ 3,166
Cost of revenue	2,989	1,907	1,082
Gross profit	$ 4,216	$ 2,132	$ 2,084

Net Revenue

	Fiscal Three Months Ended		
	September 28, 2019	September 29, 2018	Change
	(in thousands)		
Net revenue by geography:			
United States	$ 4,341	$ 2,244	$ 2,097
Outside the U.S.	2,864	1,795	1,069
Total net revenue	$ 7,205	$ 4,039	$ 3,166
Net revenue by OCS product:			
OCS Lung net revenue	$ 2,114	$ 1,487	$ 627
OCS Heart net revenue	3,739	1,639	2,100
OCS Liver net revenue	1,352	913	439
Total net revenue	$ 7,205	$ 4,039	$ 3,166

Net revenue increased by $3.2 million in the fiscal three months ended September 28, 2019 compared to the fiscal three months ended September 29, 2018 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 $4.3 million in the fiscal three months ended September 28, 2019 and increased by $2.1 million in the fiscal three months ended September 28, 2019 compared to the fiscal three months ended September 29, 2018. 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 Trial. Net revenue from sales of OCS Lung products in the United States increased from $1.3 million in the fiscal three months ended September 29, 2018 to $1.9 million in the fiscal three months ended September 28, 2019. 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 $0.0 million in the fiscal three months ended September 29, 2018 to $1.1 million in the fiscal three months ended September 28, 2019. Net revenue from OCS Liver disposable sets sold to customers for use in our OCS Liver PROTECT Trial increased from $0.9 million in the fiscal three months ended September 29, 2018 to $1.4 million in the fiscal three months ended September 28, 2019. In addition, the U.S. selling price of OCS disposable sets sold in the third quarter of fiscal 2019 was approximately 25% higher than the U.S. selling prices of OCS disposable sets sold in the same period in fiscal 2018, which accounted for $0.8 million of the overall $2.1 million increase in net revenue in the United States from the third quarter of fiscal 2018 to the same period in fiscal 2019.

Net revenue from customers outside the U.S. was $2.9 million in the fiscal three months ended September 28, 2019 compared to $1.8 million in the fiscal three months ended September 29, 2018. The increase in net revenue from customers outside the United States was primarily due to sales of OCS disposable sets to existing customers along with the addition of several new customers in the quarter.

Cost of Revenue, Gross Profit and Gross Margin

Cost of revenue increased by $1.1 million in the fiscal three months ended September 29, 2019 compared to the fiscal three months ended September 28, 2018. Gross profit increased by $2.1 million in the fiscal three months ended September 28, 2019 compared to the fiscal three months ended September 29, 2018. Gross margin was 59% and 53% for the fiscal three months ended September 28, 2019 and September 29, 2018, 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 third quarter of fiscal 2019 relative to the average selling price of OCS disposable sets in the comparable period of fiscal 2018 and overall higher sales, as a result of a reduction of the impact of fixed costs in our manufacturing operation.

Operating Expenses

Research, Development and Clinical Trials Expenses

	Fiscal Three Months Ended		
	September 28, 2019	September 29, 2018	Change
	(in thousands)		
Personnel related (including stock-based compensation expense)	$ 1,765	$ 1,280	$ 485
Clinical trials costs	968	675	293
Consulting and third-party testing	1,073	441	632
Laboratory supplies and research materials	452	248	204
Facility related and other	681	628	53
Total research, development and clinical trials expenses	$ 4,939	$ 3,272	$ 1,667

Total research, development and clinical trials expenses increased by $1.7 million from $3.3 million in the fiscal three months ended September 29, 2018 to $4.9 million in the fiscal three months ended September 28, 2019. Consulting and third-party testing costs increased by $0.6 million primarily due to clinical trial activity and new product development. Personnel related costs increased $0.5 million primarily due to additional resources supporting clinical trials and new product development. Clinical trials costs increased by $0.3 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.

Selling, General and Administrative Expenses

	Fiscal Three Months Ended		
	September 28, 2019	September 29, 2018	Change
	(in thousands)		
Personnel related (including stock-based compensation expense)	$ 2,783	$ 1,326	$ 1,457
Professional and consultant fees	1,908	823	1,085
Tradeshows and conferences	327	95	232
Facility related and other	1,501	555	946
Total selling, general and administrative expenses	$ 6,519	$ 2,799	$ 3,720

Total selling, general and administrative expenses increased by $3.7 million from $2.8 million in the fiscal three months ended September 29, 2018 to $6.5 million in the fiscal three months ended September 28, 2019 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. Facility related and other costs also increased by $0.9 million primarily as a result of increased costs to operate as a public company.

Other Income (Expense)

Interest Expense

Interest expense remained relatively the same in the fiscal three months ended September 28, 2019 compared to the fiscal three months ended September 29, 2018 primarily as a result of a $28.3 million increase in our total outstanding borrowings in June 2018.

Change in Fair Value of Preferred Stock Warrant Liability

The change in the fair value of our preferred stock warrant liability in the fiscal three months ended September 29, 2018 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 September 28, 2019 and September 29, 2018 included interest income of $0.4 million and $0.1 million, respectively, resulting from interest earned on invested cash balances, as well as $0.4 million of foreign currency transaction losses and less than $0.1 million of foreign currency transaction gains, respectively.

Comparison of the Fiscal Nine months ended September 28, 2019 and September 29, 2018

The following table summarizes our results of operations for the fiscal nine months ended September 28, 2019 and September 29, 2018:

	Fiscal Nine Months Ended		
	September 28, 2019	September 29, 2018	Change
	(in thousands)		
Net revenue	$ 17,547	$ 9,473	$ 8,074
Cost of revenue	7,425	5,238	2,187
Gross profit	10,122	4,235	5,887
Operating expenses:			
Research, development and clinical trials	13,608	10,170	3,438
Selling, general and administrative	17,423	7,941	9,482
Total operating expenses	31,031	18,111	12,920
Loss from operations	(20,909)	(13,876)	(7,033)
Other income (expense):			
Interest expense	(3,290)	(1,647)	(1,643)
Change in fair value of preferred stock warrant liability	(341)	(423)	82
Other income (expense), net	200	(152)	352
Total other expense, net	(3,431)	(2,222)	(1,209)
Loss before income taxes	(24,340)	(16,098)	(8,242)
Provision for income taxes	(30)	(23)	(7)
Net loss	$ (24,370)	$ (16,121)	$ (8,249)

Net Revenue, Cost of Revenue and Gross Profit

	Fiscal Nine Months Ended		
	September 28, 2019	September 29, 2018	Change
	(in thousands)		
Net revenue	$ 17,547	$ 9,473	$ 8,074
Cost of revenue	7,425	5,238	2,187
Gross profit	$ 10,122	$ 4,235	$ 5,887

Net Revenue

	Fiscal Nine Months Ended		
	September 28, 2019	September 29, 2018	Change
	(in thousands)		
Net revenue by geography:			
United States	$ 11,596	$ 4,391	$ 7,205
Outside the U.S.	5,951	5,082	869
Total net revenue	$ 17,547	$ 9,473	$ 8,074
Net revenue by OCS product:			
OCS Lung net revenue	$ 5,744	$ 3,146	$ 2,598
OCS Heart net revenue	8,305	4,860	3,445
OCS Liver net revenue	3,498	1,467	2,031
Total net revenue	$ 17,547	$ 9,473	$ 8,074

Net revenue increased by $8.1 million in the fiscal nine months ended September 28, 2019 compared to the fiscal nine months ended September 29, 2018 primarily as a result of an increase in the number of OCS disposable sets sold to customers in the United States.

Net revenue from customers in the United States was $11.6 million in the fiscal nine months ended September 28, 2019 and increased by $7.2 million in the fiscal nine months ended September 28, 2019 compared to the fiscal nine months ended September 29, 2018. 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 Trial. Net revenue from sales of OCS Lung products in the United States increased from $2.8 million in the fiscal nine months ended September 29, 2018 to $5.3 million in the fiscal nine months ended September 28, 2019. Net revenue from sales of OCS Heart disposable sets increased from $0.1 million for use in our OCS Heart EXPAND Trial and OCS Heart DCD Trial in the fiscal nine months ended September 29, 2018 to $2.8 million for use in our OCS Heart EXPAND CAP Trial in the fiscal nine months ended September 28, 2019. Net revenue from OCS Liver disposable sets sold to customers for use in our OCS Liver PROTECT Trial increased from $1.5 million in the fiscal nine months ended September 29, 2018 to $3.5 million in the fiscal nine months ended September 28, 2019.

Net revenue from customers outside the U.S. was $6.0 and $5.1 million in the fiscal nine months ended September 28, 2019 and September 29, 2018, respectively, and was primarily generated from OCS Heart disposable sets in both periods.

Cost of Revenue, Gross Profit and Gross Margin

Cost of revenue increased by $2.2 million in the fiscal nine months ended September 28, 2019 compared to the fiscal nine months ended September 29, 2018. Gross profit increased by $5.9 million in the fiscal nine months ended September 28, 2019 compared to the fiscal nine months ended September 29, 2018. Gross margin was 58% and 45% for the fiscal nine months ended September 28, 2019 and September 29, 2018, respectively. Gross profit and gross margin increased primarily as a result of the transition of sales of U.S. OCS Lung disposable sets from clinical trial to commercial and overall higher sales, which improved efficiency in production and reduced the impact of fixed costs in our manufacturing operation.

Operating Expenses

Research, Development and Clinical Trials Expenses

	Fiscal Nine Months Ended		
	September 28, 2019	September 29, 2018	Change
	(in thousands)		
Personnel related (including stock-based compensation expense)	$ 4,415	$ 4,619	$ (204)
Clinical trials costs	3,071	1,568	1,503
Consulting and third-party testing	2,220	1,456	764
Laboratory supplies and research materials	1,692	797	895
Facility related and other	2,210	1,730	480
Total research, development and clinical trials Expenses	$ 13,608	$ 10,170	$ 3,438

Total research, development and clinical trials expenses increased by $3.4 million from $10.2 million in the fiscal nine months ended September 29, 2018 to $13.6 million in the fiscal nine months ended September 28, 2019. Clinical trials costs increased by $1.5 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. These increases were partially offset by lower costs in our clinical trials that have completed enrollment. Laboratory supplies and research materials costs increased by $0.9 million due primarily to the increased laboratory usage of OCS disposable sets. Consulting and third-party testing costs increased by $0.8 million primarily due to increased clinical trial activity and new product development.

Selling, General and Administrative Expenses

	Fiscal Nine Months Ended		
	September 28, 2019	September 29, 2018	Change
	(in thousands)		
Personnel related (including stock-based compensation expense)	$ 7,153	$ 3,358	$ 3,795
Professional and consultant fees	4,876	2,105	2,771
Tradeshows and conferences	1,475	793	682
Facility related and other	3,919	1,685	2,234
Total selling, general and administrative expenses	$ 17,423	$ 7,941	$ 9,482

Total selling, general and administrative expenses increased by $9.5 million from $7.9 million in the fiscal nine months ended September 29, 2018 to $17.4 million in the fiscal nine months ended September 28, 2019 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. Facility related and other costs also increased by $2.2 million primarily as a result of public company costs along with increased travel and recruiting costs.

Other Income (Expense)

Interest Expense

Interest expense increased by $1.6 million in the fiscal nine months ended September 28, 2019 compared to the fiscal nine months ended September 29, 2018 primarily as a result of a $28.3 million increase in our total outstanding borrowings in June 2018.

Change in Fair Value of Preferred Stock Warrant Liability

The change in the fair value of our preferred stock warrant liability in the fiscal nine months ended September 28, 2019 and September 29, 2018 was due primarily to the changes in the fair value of our preferred stock during those periods.

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 nine months ended September 28, 2019 and September 29, 2018 included interest income of $0.6 million and $0.2 million, respectively, resulting from interest earned on invested cash balances, as well as $0.4 million and less than $0.1 million of foreign currency transaction losses, respectively. Additionally, other income (expense), net for the fiscal nine months ended September 29, 2018 included a loss on extinguishment of debt of $0.3 million that we recognized in connection with the prepayment of our borrowings under our loan and security agreement with Hercules upon entering into our new credit agreement with OrbiMed.

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 September 28, 2019, we had cash, cash equivalents and marketable securities of $88.3 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 Nine Months Ended	
	September 28, 2019	September 29, 2018
	(in thousands)	
Cash used in operating activities	$ (25,022)	$ (19,864)
Cash (used in) provided by investing activities	(67,861)	12,441
Cash provided by financing activities	92,969	24,344
Effect of exchange rate changes on cash, cash equivalents and restricted cash	80	33
Net increase in cash, cash equivalents and restricted cash	$ 166	$ 16,954

Operating Activities

During the fiscal nine months ended September 28, 2019, operating activities used $25.0 million of cash, primarily resulting from our net loss of $24.4 million and net cash used by changes in our operating assets and liabilities of $3.0 million, partially offset by net non-cash charges of $2.4 million. Net cash used by changes in our operating assets and liabilities for the fiscal nine months ended September 28, 2019 consisted primarily of a $3.1 million increase in accounts receivable and $3.2 million increase in inventory, both partially offset by a $4.0 million increase in accounts payable and accrued expenses and other current liabilities.

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

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 nine months ended September 28, 2019, net cash used in investing activities of $67.9 million consisted of purchases of marketable securities.

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

Financing Activities

During the fiscal nine months ended September 28, 2019, net cash provided by financing activities of $93.0 million consisted of the proceeds from issuance of common stock in our IPO that closed in May 2019, partially offset by payment of offering costs related to our IPO.

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

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 London Interbank Offered Rate, or LIBOR, subject to a minimum of 1.0% and a maximum of 4.0%, plus 8.5%, which is 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. With respect to our consolidated financial statements for the fiscal year ended December 29, 2018, we received a waiver of the covenant requiring delivery to OrbiMed of audited financial statements with an unqualified audit opinion. As of September 28, 2019, 2018, we were in compliance with all of the other 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.

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

Funding Requirements

As we continue to pursue and increase commercial sales of our OCS products, we expect our costs and expenses to increase in the future, particularly as we expand our sales and clinical adoption team, scale our manufacturing operation, continue research, development and clinical trial efforts, and seek regulatory 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 twelve months following the filing of our 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 “Risk Factors—Risks Related to Our Financial Position and Need for Additional Capital” in the Final Prospectus.

Contractual Obligations and Commitments

During the fiscal nine months ended September 28, 2019, there were no material changes to our contractual obligations and commitments from those described under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Contractual Obligations and Commitments” in the Final Prospectus.

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. We believe that of our critical accounting policies described under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Significant Judgments and Estimates” in the Final Prospectus. The following involve the most judgment and complexity:

- revenue recognition;
- stock-based compensation;
- valuation of warrants to purchase preferred stock; and
- valuation of inventory.

Accordingly, we believe the policies set forth above are critical to fully understanding and evaluating our financial condition and results of operations. If actual results or events differ materially from the estimates, judgments and assumptions used by us in applying these policies, our reported financial condition and results of operations could be materially affected. Other than the adoption of ASC 606 on December 30, 2018 as described in more detail in Note 2 to our consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q, there have been no significant changes to our critical accounting policies from those described in the Final Prospectus.

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 and results of operations is disclosed in Note 2 to our consolidated financial statements appearing elsewhere in this Quarterly Report.

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 the Final Prospectus.

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 September 28, 2019. 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 September 28, 2019, 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 September 28, 2019 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 “Risk Factors” in the Final Prospectus. There have been no material changes to our risk factors as previously disclosed in the Final Prospectus.

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 $97.4 million after deducting underwriting discounts and commissions but before deducting other offering costs payable by us, which were $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 September 28, 2019, we have used approximately $9.1 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.

Item 6. Exhibits.

Exhibit Number	Description
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: November 8, 2019

TRANSMEDICS GROUP, INC.

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

Date: November 8, 2019

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: November 8, 2019

By: /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: November 8, 2019

By: /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 September 28, 2019, 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: November 8, 2019

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 September 28, 2019, 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: November 8, 2019

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