UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended March 31, 2022
OR
☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to _____
Commission File Number: 001-38891

TransMedics Group, Inc.

(Exact name of registrant as specified in its charter)

Massachusetts	**83-2181531**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
200 Minuteman Road Andover, Massachusetts	**01810**
(Address of principal executive offices)	**(Zip code)**

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

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

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

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

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

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

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

As of April 29, 2022, the registrant had 27,980,839 shares of common stock, no par value per share, outstanding.

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements with respect to, among other things, our operations and financial performance. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q, including statements regarding our future results of operations and financial position, business strategy and plans and our objectives for future operations, are forward-looking statements. The words “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “expect,” “should,” “could,” “target,” “predict,” “seek” and similar expressions are intended to identify forward-looking statements. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those referenced in the section titled “Risk Factors,” which could cause actual results to differ materially. Moreover, we operate in a very competitive and rapidly changing environment and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in or implied by any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this Quarterly Report on Form 10-Q may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

The forward-looking statements included in this Quarterly Report on Form 10-Q are made only as of the date of this report. You should not rely upon forward-looking statements as predictions of future events. We cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Moreover, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this Quarterly Report on Form 10-Q to conform these statements to actual results or reflect interim developments.

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

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

- our manufacturing, sales, marketing and clinical support capabilities and strategy;
- attacks against our information technology infrastructure;
- the economic, political and other risks associated with our foreign operations;
- the impact of the outbreak of the novel strain of coronavirus, or COVID-19, including variants of the virus and associated containment, remediation and vaccination efforts;
- our ability to protect, defend, maintain and enforce our intellectual property rights relating to the OCS and avoid allegations that our products infringe, misappropriate or otherwise violate the intellectual property rights of third parties;
- the pricing of the OCS, as well as the reimbursement coverage for the OCS in the United States and internationally;
- regulatory developments in the United States, European Union and other jurisdictions;
- the extent and success of competing products that are or may become available;
- the impact of any product recalls or improper use of our products; and
- our estimates regarding revenue, expenses and needs for additional financing.

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 amounts)
(Unaudited)

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 17,897	$ 25,580
Marketable securities	54,104	66,872
Accounts receivable	11,724	5,934
Inventory	16,714	14,859
Prepaid expenses and other current assets	5,356	5,460
Total current assets	105,795	118,705
Property and equipment, net	12,044	9,841
Restricted cash	500	500
Operating lease right-of-use assets	5,669	5,847
Total assets	$ 124,008	$ 134,893
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,934	$ 6,651
Accrued expenses and other current liabilities	15,738	16,337
Deferred revenue	247	250
Operating lease liabilities	1,337	—
Total current liabilities	20,256	23,238
Long-term debt, net of discount and current portion	35,334	35,197
Operating lease liabilities, net of current portion	8,508	8,604
Total liabilities	64,098	67,039
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, no par value; 25,000,000 shares authorized; no shares issued or outstanding	—	—
Common stock, no par value; 150,000,000 shares authorized; 27,968,583 shares and 27,791,615 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	513,203	510,488
Accumulated other comprehensive loss	(285)	(188)
Accumulated deficit	(453,008)	(442,446)
Total stockholders' equity	59,910	67,854
Total liabilities and stockholders' equity	$ 124,008	$ 134,893

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)

	Three Months Ended March 31,	
	2022	**2021**
Net revenue	$ 15,880	$ 7,053
Cost of revenue	3,776	2,242
Gross profit	12,104	4,811
Operating expenses:		
Research, development and clinical trials	7,534	4,532
Selling, general and administrative	13,939	6,786
Total operating expenses	21,473	11,318
Loss from operations	(9,369)	(6,507)
Other income (expense):		
Interest expense	(960)	(952)
Other expense, net	(227)	(454)
Total other expense, net	(1,187)	(1,406)
Loss before income taxes	(10,556)	(7,913)
Provision for income taxes	(6)	(4)
Net loss	$ (10,562)	$ (7,917)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.38)	$ (0.29)
Weighted average common shares outstanding, basic and diluted	27,950,330	27,368,090

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

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

	Three Months Ended March 31,	
	2022	2021
Net loss	$ (10,562)	$ (7,917)
Other comprehensive income (loss):		
Foreign currency translation adjustment	(24)	(2)
Unrealized gains (losses) on marketable securities, net of tax of $0	(73)	8
Total other comprehensive income (loss)	(97)	6
Comprehensive loss	$ (10,659)	$ (7,911)

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

TRANSMEDICS GROUP, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands, except share amounts)
(Unaudited)

	Common Stock		Accumulated Other Comprehen-sive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balances at December 31, 2021	27,791,615	$ 510,488	$ (188)	$ (442,446)	$ 67,854
Issuance of common stock upon the exercise of common stock options	164,503	202	—	—	202
Issuance of common stock in connection with employee stock purchase plan	12,465	203	—	—	203
Stock-based compensation expense	—	2,310	—	—	2,310
Foreign currency translation adjustment	—	—	(24)	—	(24)
Unrealized losses on marketable securities	—	—	(73)	—	(73)
Net loss	—	—	—	(10,562)	(10,562)
Balances at March 31, 2022	27,968,583	$ 513,203	$ (285)	$ (453,008)	$ 59,910

	Common Stock		Accumulated Other Comprehen-sive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balances at December 31, 2020	27,175,305	$ 502,217	$ (95)	$ (398,231)	$ 103,891
Issuance of common stock upon the exercise of common stock options	287,705	372	—	—	372
Issuance of common stock in connection with employee stock purchase plan	14,951	211	—	—	211
Stock-based compensation expense	—	1,112	—	—	1,112
Foreign currency translation adjustment	—	—	(2)	—	(2)
Unrealized gains on marketable securities	—	—	8	—	8
Net loss	—	—	—	(7,917)	(7,917)
Balances at March 31, 2021	27,477,961	$ 503,912	$ (89)	$ (406,148)	$ 97,675

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

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

	Three Months Ended March 31,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (10,562)	$ (7,917)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	507	445
Stock-based compensation expense	2,310	1,112
Non-cash interest expense and end of term accretion expense	137	130
Non-cash lease expense	178	—
Net amortization of premiums on marketable securities	228	391
Unrealized foreign currency transaction losses	214	484
Changes in operating assets and liabilities:		
Accounts receivable	(5,804)	(583)
Inventory	(2,926)	(381)
Prepaid expenses and other current assets	88	(908)
Accounts payable	(4,013)	(82)
Accrued expenses and other current liabilities	(4)	(180)
Deferred revenue	—	182
Operating lease liabilities	1,241	—
Deferred rent	—	(23)
Net cash used in operating activities	(18,406)	(7,330)
Cash flows from investing activities:		
Purchases of property and equipment	(1,953)	(20)
Purchases of marketable securities	(2,033)	(11,708)
Proceeds from sales and maturities of marketable securities	14,500	21,000
Net cash provided by investing activities	10,514	9,272
Cash flows from financing activities:		
Proceeds from issuance of common stock upon exercise of stock options	202	372
Proceeds from issuance of common stock in connection with employee stock purchase plan	203	211
Net cash provided by financing activities	405	583
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(196)	(379)
Net increase (decrease) in cash, cash equivalents and restricted cash	(7,683)	2,146
Cash, cash equivalents and restricted cash, beginning of period	26,080	25,081
Cash, cash equivalents and restricted cash, end of period	$ 18,397	$ 27,227
Supplemental disclosure of non-cash investing and financing activities:		
Transfers of inventory to property and equipment	$ 1,030	$ 429
Purchases of property and equipment included in accounts payable and accrued expenses	$ 939	$ 7
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$ 17,897	$ 26,727
Restricted cash	500	500
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	$ 18,397	$ 27,227

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

1. Nature of the Business and Basis of Presentation

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

The accompanying consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the ordinary course of business. The Company has incurred recurring losses since inception, including net losses of $10.6 million for the three months ended March 31, 2022 and $44.2 million for the year ended December 31, 2021. As of March 31, 2022, the Company had an accumulated deficit of $453.0 million. The Company expects to continue to generate operating losses in the foreseeable future.

The Company believes that its existing cash, cash equivalents, and marketable securities of $72.0 million as of March 31, 2022 will be sufficient to fund its operations, capital expenditures, and debt service payments for at least the next 12 months following the filing of this Quarterly Report on Form 10-Q. The Company may need to seek additional funding through equity financings, debt financings or strategic alliances. The Company may not be able to obtain financing on acceptable terms, or at all, and the terms of any financing may adversely affect the holdings or the rights of the Company's shareholders. If the Company is unable to obtain funding, the Company will be required to delay, reduce or eliminate some or all of its research and development programs, product expansion or commercialization efforts, or the Company may be unable to continue operations.

The Company is subject to risks and uncertainties common to companies in the medical device industry and of similar size, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, uncertainty of market acceptance of products, and the need to obtain additional financing to fund operations. Potential risks and uncertainties also include, without limitation, uncertainties regarding the duration and magnitude of the impact of the COVID-19 pandemic on the Company's business and the economy generally. Products currently under development will require additional research and development efforts, including additional clinical testing and regulatory approval, prior to commercialization. These efforts require additional capital, adequate personnel, infrastructure and extensive compliance-reporting capabilities. The Company's research and development may not be successfully completed, adequate protection for the Company's technology may not be obtained, the Company may not obtain necessary government regulatory approval on its expected timeline or at all, and approved products may not prove commercially viable. The Company operates in an environment of rapid change in technology and competition.

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

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

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

2. Summary of Significant Accounting Policies

Unaudited Interim Financial Information

The accompanying unaudited interim financial statements and related notes have been prepared by the Company pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC") for interim financial statements. Certain information and footnote disclosures normally included in the financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. These consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and the notes thereto for the year ended December 31, 2021 included in the Company's Annual Report on Form 10-K filed with the SEC. In the opinion of management, all adjustments, consisting only of normal recurring adjustments necessary for a fair statement of the Company's financial position as of March 31, 2022 and results of operations for the three months ended March 31, 2022 and 2021 and cash flows for the three months ended March 31, 2022 and 2021 have been made. The Company's results of operations for the three months ended March 31, 2022 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2022.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenue and expenses during the reporting periods. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, revenue recognition, the valuation of inventory and the valuation of stock-based awards. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates as there are changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. The full extent to which the COVID-19 pandemic will directly or indirectly impact the Company's business, results of operations and financial condition, including sales, expenses, reserves and allowances, manufacturing, clinical trials, research and development costs and employee-related amounts, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain or treat COVID-19, as well as the economic impact on local, regional, national and international customers and markets. The Company has made estimates of the impact of COVID-19 within its financial statements and there may be changes to those estimates in future periods. As of the date of issuance of these unaudited consolidated financial statements, the Company is not aware of any specific event or circumstance that would require the Company to update estimates, judgments or revise the carrying value of any assets or liabilities. Actual results may differ from those estimates or assumptions.

Risk of Concentrations of Credit, Significant Customers and Significant Suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash, cash equivalents, marketable securities, and accounts receivable. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships. As of March 31, 2022 and December 31, 2021, the Company had no allowance for credit losses.

Significant customers are those that accounted for 10% or more of the Company's net revenue or accounts receivable. For the three months ended March 31, 2022, three customers accounted for 16%, 15% and 12% of net revenue, respectively.

For the three months ended March 31, 2021, two customers each accounted for 12% of net revenue. As of March 31, 2022, four customers accounted for 14%, 12%, 12% and 10% of accounts receivable, respectively. As of December 31, 2021, two customers accounted for 21% and 15% of accounts receivable, respectively.

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

Fair Value Measurements

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

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

The Company's cash equivalents and marketable securities are carried at fair value, determined according to the fair value hierarchy described above (see Note 4). The carrying values of the Company's accounts receivable, accounts payable and accrued expenses approximate their fair values due to the short-term nature of these assets and liabilities. The carrying value of the Company's long-term debt approximates its fair value (a level 2 measurement) at each balance sheet date due to its variable interest rate, which approximates a market interest rate.

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

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 three months ended March 31, 2022 and 2021.

The Company's potential dilutive securities have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to common stockholders for the periods indicated above because including them would have had an anti-dilutive effect:

	As of March 31,	
	2022	2021
Warrants to purchase common stock	64,440	64,440
Options to purchase common stock	3,484,914	2,764,876
Employee stock purchase plan	5,794	5,882
	3,555,148	2,835,198

3. Marketable Securities

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

	March 31, 2022			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury securities (due within one year)	$ 51,212	$ —	$ (102)	$ 51,110
U.S. government agency bonds (due within one year)	3,001	—	(7)	2,994
	$ 54,213	$ —	$ (109)	$ 54,104

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

4. Fair Value of Financial Assets and Liabilities

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

	Fair Value Measurements at March 31, 2022 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 2,847	$ —	$ —	$ 2,847
Marketable securities:				
U.S. Treasury securities	—	51,110	—	51,110
U.S. government agency bonds	—	2,994	—	2,994
	$ 2,847	$ 54,104	$ —	$ 56,951

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

Money market funds were valued by the Company based on quoted market prices, which represent a Level 1 measurement within the fair value hierarchy. U.S. Treasury securities and U.S. government agency bonds were valued by the Company using quoted prices in active markets for similar securities, which represent a Level 2 measurement within the fair value hierarchy.

5. Inventory

Inventory consisted of the following (in thousands):

	March 31, 2022	December 31, 2021
Raw materials	$ 8,322	$ 7,274
Work-in-process	2,501	1,932
Finished goods	5,891	5,653
	$ 16,714	$ 14,859

During the three months ended March 31, 2022 and 2021, the Company made non-cash transfers of OCS Consoles from inventory to property and equipment (OCS Consoles loaned to customers) of $1.0 million and $0.4 million, respectively.

6. Accrued Expenses and Other Current Liabilities

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

	March 31, 2022	December 31, 2021
Accrued research, development and clinical trials expenses	$ 4,532	$ 4,567
Accrued payroll and related expenses	5,819	5,173
Accrued professional fees	857	1,973
Accrued other	4,530	4,624
	$ 15,738	$ 16,337

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. Long-term debt consisted of the following (in thousands):

	March 31, 2022	December 31, 2021
Principal amount of long-term debt	$ 35,000	$ 35,000
Less: Current portion of long-term debt	—	—
Long-term debt, net of current portion	35,000	35,000
Debt discount, net of accretion	(428)	(511)
Accrued end-of-term payment	762	708
Long-term debt, net of discount and current portion	$ 35,334	$ 35,197

Borrowings under the Credit Agreement bear interest at an annual rate equal to the London Interbank Offered Rate ("LIBOR"), subject to a minimum of 1.0% and a maximum of 4.0%, plus 8.5% (the "Applicable Margin"), subject in the aggregate to a maximum interest rate of 11.5%. In addition, borrowings under the Credit Agreement bear paid-in-kind ("PIK") interest at an annual rate equal to the amount by which LIBOR plus the Applicable Margin exceeds 11.5%, but not to exceed 12.5%. The PIK interest is added to the principal amount of the borrowings outstanding at the end of each quarter until the maturity date of the Credit Agreement in June 2023. Borrowings under the Credit Agreement are repayable in quarterly interest-only payments until the maturity date, at which time all principal and accrued interest is due and payable. At its option, the company may prepay outstanding borrowings under the Credit Agreement. The Company is required to make a final payment in an amount equal to 3.0% of the principal amount of any prepayment or repayment. The final payment and debt discount amounts are being accreted to interest expense over the term of the Credit Agreement using the effective interest method.

All obligations under the Credit Agreement are guaranteed by the Company and each of its material subsidiaries. All obligations of the Company and each guarantor are secured by substantially all of the Company's and each guarantor's assets, including their intellectual property, subject to certain exceptions, including a perfected security interest in substantially all tangible and intangible assets of the Company and each guarantor. Under the Credit Agreement, the Company has agreed to certain affirmative and negative covenants to which it will remain subject until maturity. The financial covenants include maintaining a minimum liquidity amount of $3.0 million; the requirement, on an annual basis, to deliver to OrbiMed annual audited financial statements with an unqualified audit opinion from the Company's independent registered public accounting firm; and restrictions on the Company's activities, including limitations on dispositions, mergers or acquisitions; encumbering its intellectual property; incurring indebtedness or liens; paying dividends; making certain investments; and engaging in certain other business transactions. As of March 31, 2022, the Company was in compliance with the financial covenants under the Credit Agreement.

The obligations under the Credit Agreement are subject to acceleration upon the occurrence of specified events of default, including payment default, change in control, bankruptcy, insolvency, certain defaults under other material debt, certain events with respect to governmental approvals (if such events could cause a material adverse change in the Company's business), failure to comply with certain covenants, including the minimum liquidity and unqualified audit opinion covenants, and a material adverse change in the Company's business, operations or other financial condition.

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

As of March 31, 2022, the interest rate applicable to borrowings under the Credit Agreement was 9.5%. During the three months ended March 31, 2022, the weighted average effective interest rate on outstanding borrowings under the Credit Agreement was approximately 11.2%.

8. Stock-Based Compensation

2019 Stock Incentive Plan

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

Shares withheld in payment of the exercise or purchase price of an award or in satisfaction of tax withholding requirements, and the shares covered by a stock appreciation right for which any portion is settled in stock, will reduce the number of shares available for issuance under the 2019 Plan. In addition, the number of shares available for issuance under the 2019 Plan (i) will not be increased by any shares delivered under the 2019 Plan that are subsequently repurchased using proceeds directly attributable to stock option exercises and (ii) will not be reduced by any awards that are settled in cash or that expire, become unexercisable, terminate or are forfeited to or repurchased by TransMedics Group without the issuance of stock under the 2019 Plan. As of March 31, 2022, 890,558 shares of common stock were available for issuance under the 2019 Plan.

2019 Employee Stock Purchase Plan

Pursuant to the Company's 2019 Employee Stock Purchase Plan (the "2019 ESPP"), certain employees of the Company are eligible to purchase common stock of the Company at a reduced price during offering periods. The 2019 ESPP permits participants to purchase common stock using funds contributed through payroll deductions, subject to the limitations set forth in the Internal Revenue Code, at a purchase price of 85% of the lower of the closing price of the Company's common stock on the first trading day of the offering period or the closing price on the applicable purchase date, which is the final trading day of the applicable offering period. A total of 371,142 shares of the Company's common stock are reserved for issuance under the 2019 ESPP. During the three months ended March 31, 2022, 12,465 shares of common stock were issued under the 2019 ESPP and as of March 31, 2022, 308,131 shares of common stock remained available for issuance.

2021 Inducement Plan

In August 2021, the Company's board of directors approved the TransMedics Group, Inc. Inducement Plan (the "Inducement Plan"). Pursuant to the terms of the Inducement Plan, the Company may grant nonstatutory stock options, stock appreciation rights, restricted stock, unrestricted stock, restricted stock unit awards and performance awards to individuals who were not previously employees or directors of the Company or individuals returning to employment after a bona fide period of non-employment with the Company. A total of 1,000,000 shares of the Company's common stock were initially available for issuance under the Inducement Plan. As of March 31, 2022, 580,200 shares of common stock were available for issuance under the Inducement Plan.

Stock-Based Compensation

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

	Three Months Ended March 31,	
	2022	2021
Cost of revenue	$ 25	$ 13
Research, development and clinical trials expenses	321	197
Selling, general and administrative expenses	1,964	902
	$ 2,310	$ 1,112

During the three months ended March 31, 2022, the Company granted options to its employees and directors with service-based vesting for the purchase of an aggregate of 880,910 shares of common stock with a weighted average grant-date fair value of $7.11 per share. As of March 31, 2022, total unrecognized compensation cost related to unvested share-based awards was $24.6 million, which is expected to be recognized over a weighted average period of 3.1 years.

9. Commitments and Contingencies

Operating Leases

The Company leases office, laboratory and manufacturing space under two non-cancelable operating leases. There have been no material changes to the Company's leases during the three months ended March 31, 2022. For additional information, please read Note 12 *Leases,* to the consolidated financial statements in the Company's Form 10-K for the year ended December 31, 2021.

License Agreement with the Department of Veterans Affairs

In 2002, the Company entered into a license agreement with the Department of Veterans Affairs (the "VA"), under which the Company was granted an exclusive, worldwide license under specified patents to make, use, sell and import certain technology used in the Company's products and a non-exclusive, worldwide license to make, use, sell and import solutions for use in or with those products. The rights under the license agreement continue until the expiration of the last to expire of the licensed patents. The majority of the licensed U.S. patents expired in 2017, and the foreign patents expired in September 2018. However, the Company has requested a patent term extension for one U.S. patent covered by the VA license agreement, U.S. Patent No. 6100082. The Company was granted an interim patent term extension for this patent until November 6, 2021. The Company has not received final approval of the patent extension beyond the interim patent term extension already granted. The maximum extension requested would be through May 2022; however, the length of the patent term extension will be determined by the United States Patent and Trademark Office ("USPTO") based on input from the FDA. On February 8, 2021, the FDA provided to the USPTO a determined regulatory review period for the OCS Lung. Under the FDA's analysis, the patent term extension of the '082 patent would be until November 6, 2021. The Company has not yet received communication from the USPTO but expects that the USPTO's determination of patent term extension for the '082 patent will maintain the November 6, 2021 expiration date. The final determination of the length of the patent extension is not expected to have a material impact on the Company's financial results. The license includes the right to grant sublicenses, subject to approval by the VA and other restrictions, and is subject to the U.S. government's right to practice the licensed patents on its own behalf without payment of a royalty and obligation to grant certain sublicenses as necessary to fulfill public health, welfare and safety needs. The license agreement also requires the Company to make its products covered by the licensed patents available to the public on reasonable terms and to provide the U.S. government such products at the lowest price.

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

The VA license agreement can be terminated by the Company or the VA only if the other party fails to cure its material breach within a specified period after receiving notice of such breach.

401(k) Savings Plan

The Company has a defined-contribution savings plan under Section 401(k) of the Internal Revenue Code. This plan covers substantially all employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. Company contributions to the plan may be made at the discretion of the board of directors. As of March 31, 2022 and December 31, 2021, the Company had not made any contributions to the plan.

Indemnification Agreements

In the ordinary course of business, the Company has agreed to defend and indemnify its customers against third-party claims asserting infringement of certain intellectual property rights, which may include patents, copyrights, trademarks, or trade secrets. The Company's exposure under these indemnification provisions is generally limited to the total amount paid

by the end-customer under the agreement. However, certain agreements include indemnification provisions that could potentially expose the Company to losses in excess of the amount received under the agreement. In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners, and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or services as directors or officers.

The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not currently aware of any indemnification claims and had not accrued any liabilities related to such obligations in its consolidated financial statements as of March 31, 2022 and December 31, 2021.

Unconditional Purchase Commitment

In January 2021, the Company entered into an unconditional $9.5 million purchase commitment, in the ordinary course of business, for goods with specified annual minimum quantities to be purchased through December 2029. The contract is not cancellable without penalty. The remaining purchase commitment as of March 31, 2022 was $8.0 million.

Legal Proceedings

The Company is not currently party to any material legal proceedings. At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company expenses as incurred the costs related to such legal proceedings.

10. Segment Reporting and Geographic Data

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

See Note 11 for revenue by country. Long-lived assets by geography are summarized as follows (in thousands):

	March 31, 2022	December 31, 2021
Long-lived assets by country(1):		
United States	$ 11,317	$ 9,085
All other countries	727	756
Total long-lived assets	$ 12,044	$ 9,841

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

11. Revenue

The Company has determined that the payments made to the customer for reimbursement of clinical trial materials and customer's costs incurred to execute specific clinical trial protocols related to the Company's OCS products do not provide the Company with a distinct good or service transferred by the customer, and therefore such payments are recorded as a reduction of revenue from the customer in the Company's consolidated statements of operations. Reductions of revenue related to such payments made to customers for reimbursements are recognized when the Company recognizes the revenue for the sale of its OCS disposable sets.

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

	Three Months Ended March 31,	
	2022	2021
Gross revenue from sales to customers	$ 15,880	$ 7,637
Less: clinical trial payments reducing revenue	—	584
Total net revenue	$ 15,880	$ 7,053

The Company determined that payments made to customers to obtain information related to post-approval studies or existing standard-of-care protocols (i.e., unrelated to the Company's OCS products) meet the criteria to be classified as a cost because the Company receives a distinct good or service transferred by the customer separate from the customer's purchase of the Company's OCS products and the consideration paid to the customer represents the fair value of the distinct good or service received. As a result, such payments made to the customers are recorded as operating expenses. The Company recorded payments made to customers related to post-approval studies and for documentation related to existing standard-of-care protocols of $0.5 million for each of the three months ended March 31, 2022 and 2021, as operating expenses.

Disaggregated Revenue

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

	Three Months Ended March 31,	
	2022	2021
Net revenue by OCS product:		
OCS Lung net revenue	$ 2,298	$ 2,430
OCS Heart net revenue	5,713	4,181
OCS Liver net revenue	7,869	442
Total net revenue	$ 15,880	$ 7,053

	Three Months Ended March 31,	
	2022	2021
Net revenue by country(1):		
United States	$ 13,561	$ 5,757
All other countries	2,319	1,296
Total net revenue	$ 15,880	$ 7,053

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

Contract Assets and Liabilities

The Company recognizes a receivable at the point in time at which it has an unconditional right to payment. Such receivables are not contract assets. Contract assets arise from unbilled amounts in customer arrangements when revenue recognized exceeds the amount billed to the customer and the Company's right to payment is not just subject to the passage of time. The Company had no contract assets as of March 31, 2022 and December 31, 2021.

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 March 31, 2022, the Company's wholly- or partially unsatisfied performance obligations totaled $2.1 million and are expected to be completed within the next year.

12. 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 approximately $0.1 million in total compensation for each of the three months ended March 31, 2022 and 2021 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 Annual Report on Form 10-K for the year ended December 31, 2021, as filed with the SEC on March 1, 2022 ("2021 Form 10-K"). Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Item 1A. Risk Factors" section of this Quarterly Report on Form 10-Q and the "Item 1A. Risk Factors" section of our 2021 Form 10-K, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a commercial-stage medical technology company transforming organ transplant therapy for end-stage organ failure patients across multiple disease states. We developed the OCS to replace a decades-old standard of care that we believe is significantly limiting access to life-saving transplant therapy for hundreds of thousands of patients worldwide. Our innovative OCS technology replicates many aspects of the organ's natural living and functioning environment outside of the human body. As such, the OCS represents a paradigm shift that transforms organ preservation for transplantation from a static state to a dynamic environment that enables new capabilities, including organ optimization and assessment. We believe the use of the OCS has the potential to significantly increase the number of organ transplants and improve post-transplant outcomes. We have developed our National OCS Program, a turnkey solution to provide outsourced organ retrieval and OCS organ management, to provide transplant programs with a more efficient process to procure donor organs with the OCS.

We designed the OCS to be a platform that allows us to leverage core technologies across products for multiple organs. To date, we have developed three OCS products, one for each of lung, heart and liver transplantations, making the OCS the only multi-organ technology platform. We have commercialized the OCS Lung and OCS Heart outside of the United States. All three of our products, OCS Lung, OCS Heart, and OCS Liver have received Pre-Market Approval, or PMA, from the Food and Drug Administration, or FDA, as follows:

- OCS Lung for the preservation of standard criteria donor lungs for double-lung transplantation;
- OCS Lung for the preservation of donor lungs initially deemed unsuitable due to limitations of cold storage for double-lung transplantation;
- OCS Heart for the preservation of DBD donor hearts deemed unsuitable due to limitations of cold storage (e.g. >4 hours of cross-clamp time);
- OCS Heart for the ex vivo reanimation, functional monitoring, and beating-heart preservation of DCD hearts (FDA approval received on April 28, 2022), and
- OCS Liver for the preservation of DBD and DCD donor livers $\leq$ 55 years old, macrosteatosis <15% and with $\leq$ 30 mins of warm ischemia time.

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

Since our inception, we have incurred significant operating losses. Our ability to generate net revenue sufficient to achieve profitability will depend on the successful further development and commercialization of our products. We generated net revenue of $15.9 million and incurred a net loss of $10.6 million for the three months ended March 31, 2022. We generated net revenue of $30.3 million and incurred a net loss of $44.2 million for the year ended December 31, 2021. As of March 31, 2022, we had an accumulated deficit of $453.0 million. We expect to continue to incur net losses for the foreseeable future as we focus on growing commercial sales of our products in both the United States and select non-U.S. markets, including growing our commercial team, which will pursue increasing commercial sales of our OCS products; scaling our manufacturing operations; building our commercial operations; continuing research, development and clinical trial efforts; seeking regulatory clearance for new products and product enhancements, including new indications, in both the

United States and select non-U.S. markets; and operating as a public company. As a result, we will need substantial additional funding for expenses related to our operating activities, including selling, general and administrative expenses and research, development and clinical trials expenses.

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

As of March 31, 2022, we had cash, cash equivalents and marketable securities of $72.0 million. Our credit facility of $35.0 million with OrbiMed matures on June 22, 2023. We believe that our cash, cash equivalents and marketable securities will be sufficient for us to fund our operating expenses, capital expenditure requirements and debt service payments for at least 12 months following the filing of our Quarterly Report on Form 10-Q. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See "— Liquidity and Capital Resources".

COVID-19

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

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

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

Recent Developments

On April 28, 2022, we received a PMA from the FDA for the use in the United States of the OCS Heart for use with organs from donors after circulatory death. The PMA for the OCS Heart was based on the results of the OCS DCD Heart Trial.

Components of Our Results of Operations

Net Revenue

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

All of our revenue has been generated by sales to transplant centers and Organ Procurement Organizations, not-for-profit organizations responsible for recovering organs from deceased donors for transplantation, in the United States, Europe and Asia-Pacific, or, in some cases, to distributors selling to transplant centers in select countries. Substantially all of our customer contracts have multiple-performance obligations that contain promises consisting of OCS Perfusion Sets and OCS Solutions. In some of those contracts, the promises also include an OCS Console, whether sold or loaned to the customer.

We have customer agreements under which we loan our OCS Consoles to the customer for the duration of the agreement. In such cases, we place an organ-specific OCS Console at the customer site for its use free of charge, and the customer separately purchases from us the OCS disposable sets used in each transplant procedure. When we loan the OCS Console to the customer, we retain title to the console at all times and do not require minimum purchase commitments from the customer related to any OCS products. In such cases, we invoice the customer for OCS disposable sets based on customer orders received for each new transplant procedure and the prices set forth in the customer agreement. Over time, we typically recover the cost of the loaned OCS Console through the customer's continued purchasing and use of additional OCS disposable sets. For these reasons, we have determined that part of the selling price for the disposable set is an implied rental payment for use of the OCS Console.

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

Under some of our customer clinical trial agreements, we made payments to our customers for reimbursements of clinical trial materials and for specified clinical documentation related to their use of our OCS products. Because some of these payments did not provide us with a separately identifiable benefit, we recorded such payments as a reduction of revenue from the customer, resulting in our net revenue presentation. We did not record any reimbursable clinical trial costs as a reduction of revenue for the three months ended March 31, 2022. We recorded reimbursable clinical trial costs as a reduction of revenue of $0.6 million for the three months ended March 31, 2021.

Through March 31, 2022, all of our sales outside of the United States have been commercial sales (unrelated to any clinical trials). We expect that our net revenue will increase over the long term as a result of receiving PMAs for the OCS Lung, OCS Heart and OCS Liver in the United States. Additionally, commercial sales of OCS disposable sets generally have a higher average selling price than clinical trial sales of OCS disposable sets. We also expect that our net revenue will increase over the long term as a result of anticipated growth in non-U.S. sales if national healthcare systems begin to reimburse transplant centers for the use of the OCS, if transplant centers utilize the OCS in more transplant cases, and if more transplant centers adopt the OCS in their programs.

Cost of Revenue, Gross Profit and Gross Margin

Cost of revenue consists primarily of costs of components of our OCS Consoles and disposable sets, costs of direct materials, labor and the manufacturing overhead that directly supports production, and costs related to the depreciation of OCS Consoles loaned to customers. When we loan an OCS Console to a customer for its use free of charge, we capitalize as property and equipment the cost of our OCS Console and depreciate these assets over the five-year estimated useful life of the console. Included in the cost of OCS disposable sets are the costs of our OCS Lung, OCS Heart and OCS Liver Solutions. We expect that cost of revenue will increase or decrease in absolute dollars primarily as, and to the extent that, our net revenue increases or decreases.

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

We expect that cost of revenue as a percentage of net revenue will moderately decrease and gross margin and gross profit will moderately increase over the long term as our sales and production volumes increase and our cost per unit of our OCS disposable sets decreases due to economies of scale. We intend to use our design, engineering and manufacturing capabilities to further advance and improve the efficiency of our manufacturing processes, which we believe will reduce costs and increase our gross margin. While we expect gross margin to increase over the long term, it will likely fluctuate from quarter to quarter.

Operating Expenses

Research, Development and Clinical Trials Expenses

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

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

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

Selling, General and Administrative Expenses

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

We expect that our selling, general and administrative expenses will increase over the long term as we increase our headcount to support the expected continued sales growth of our OCS products.

Other Income (Expense)

Interest Expense

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

Other Income (Expense), Net

Other income (expense), net includes interest income, realized and unrealized foreign currency transaction gains and losses and other non-operating income and expense items unrelated to our core operations. Interest income consists of interest earned on our invested cash balances. Foreign currency transaction gains and losses result from intercompany transactions as well as transactions with customers or vendors denominated in currencies other than the functional currency of the legal entity in which the transaction is recorded.

Results of Operations

Comparison of the Three Months Ended March 31, 2022 and 2021

The following table summarizes our results of operations for the three months ended March 31, 2022 and 2021:

	Three Months Ended March 31,		
	2022	2021	Change
	(in thousands)		
Net revenue	$ 15,880	$ 7,053	$ 8,827
Cost of revenue	3,776	2,242	1,534
Gross profit	12,104	4,811	7,293
Operating expenses:			
Research, development and clinical trials	7,534	4,532	3,002
Selling, general and administrative	13,939	6,786	7,153
Total operating expenses	21,473	11,318	10,155
Loss from operations	(9,369)	(6,507)	(2,862)
Other income (expense):			
Interest expense	(960)	(952)	(8)
Other expense, net	(227)	(454)	227
Total other expense, net	(1,187)	(1,406)	219
Loss before income taxes	(10,556)	(7,913)	(2,643)
Provision for income taxes	(6)	(4)	(2)
Net loss	$ (10,562)	$ (7,917)	$ (2,645)

Net Revenue

	Three Months Ended March 31,		
	2022	2021	Change
	(in thousands)		
Net revenue by geography:			
United States	$ 13,561	$ 5,757	$ 7,804
Outside the U.S.	2,319	1,296	1,023
Total net revenue	$ 15,880	$ 7,053	$ 8,827
Net revenue by OCS product:			
OCS Lung net revenue	$ 2,298	$ 2,430	$ (132)
OCS Heart net revenue	5,713	4,181	1,532
OCS Liver net revenue	7,869	442	7,427
Total net revenue	$ 15,880	$ 7,053	$ 8,827

Net revenue from customers in the United States was $13.6 million in the three months ended March 31, 2022 and increased by $7.8 million compared to the three months ended March 31, 2021, primarily due to higher sales volumes of our OCS Liver and OCS Heart disposable sets as a result of the FDA approval for these two products in the third quarter of 2021. This increase was partially offset by lower sales volumes of our OCS Lung disposable sets. Net revenue from sales of OCS Liver disposable sets in the United States increased by $7.4 million due primarily to higher sales volumes of OCS Liver disposable sets resulting from the recent FDA approval of the OCS Liver product along with the expansion of our National OCS Program to provide a streamlined solution for transplant centers to use the OCS Liver. Net revenue from sales of OCS Heart disposable sets in the United States increased by $0.7 million also primarily as a result of the FDA approval of the OCS Heart in the third quarter of 2021. Both the OCS Heart and the OCS Liver were approved for commercial sale in September 2021, which has provided the opportunity for increased sales volumes and pricing. Net revenue from sales of OCS Lung disposable sets in the United States decreased by $0.4 million due to lower sales volumes of OCS Lung disposable sets, which were negatively impacted by the Omicron variant of COVID-19 in the early part of the first quarter of 2022.

Net revenue from customers outside the United States was $2.3 million in the three months ended March 31, 2022 compared to $1.3 million in the three months ended March 31, 2021. The increase in net revenue from customers outside the United States was primarily due to a progressive return to pre-COVID-19 volumes of transplant procedures in the European

market. Net revenue from sales of OCS Heart disposable sets outside the United States increased by $0.8 million due to increased sales volume of OCS Heart disposable sets. Net revenue from OCS Lung disposable sets increased by $0.2 million from the three months ended March 31, 2021 to the three months ended March 31, 2022 due to higher sales volumes of OCS Lung disposable sets.

Cost of Revenue, Gross Profit and Gross Margin

Cost of revenue increased by $1.5 million in the three months ended March 31, 2022 compared to the three months ended March 31, 2021. Gross profit increased by $7.3 million in the three months ended March 31, 2022 compared to the three months ended March 31, 2021. Gross margin was 76% and 68% for the three months ended March 31, 2022 and 2021, respectively. Gross margin increased primarily as a result economies of scale from higher sales volumes and an increase in pricing.

Operating Expenses

Research, Development and Clinical Trials Expenses

	Three Months Ended March 31,		
	2022	2021	Change
	(in thousands)		
Personnel related (including stock-based compensation expense)	$ 2,252	$ 2,130	$ 122
Clinical trials costs	563	977	(414)
Consulting and third-party testing	2,479	312	2,167
Laboratory supplies and research materials	1,137	410	727
Other	1,103	703	400
Total research, development and clinical trials expenses	$ 7,534	$ 4,532	$ 3,002

Total research, development and clinical trials expenses increased by $3.0 million from $4.5 million in the three months ended March 31, 2021 to $7.5 million in the three months ended March 31, 2022. Consulting and third-party testing, laboratory supplies and research materials and other costs increased by $2.2 million, $0.7 million and $0.4 million, respectively, due to increased activity in our next generation program and ongoing existing research activities. Clinical trial costs decreased by $0.4 million due to the completion of pre-market approval clinical trial enrollment activity following the approval of the OCS Heart and OCS Liver by the FDA in September 2021.

Selling, General and Administrative Expenses

	Three Months Ended March 31,		
	2022	2021	Change
	(in thousands)		
Personnel related (including stock-based compensation expense)	$ 8,387	$ 3,838	$ 4,549
Professional and consultant fees	2,088	1,402	686
Tradeshows and conferences	453	188	265
Other	3,011	1,358	1,653
Total selling, general and administrative expenses	$ 13,939	$ 6,786	$ 7,153

Total selling, general and administrative expenses increased by $7.2 million from $6.8 million in the three months ended March 31, 2021 to $13.9 million in the three months ended March 31, 2022 due to increases in personnel related costs, professional and consultant fees, tradeshows and conferences and other costs. Personnel related costs increased by $4.5 million primarily due to the continued expansion of our team to support the National OCS Program and commercial growth of our OCS Lung, OCS Heart and OCS Liver products in the United States, as well as an increase in stock-based compensation expense of $1.1 million due primarily to additional grants to new and existing employees. Professional and consultant fees increased by $0.7 million due to additional sales and administration costs related to the expansion of our National OCS Program. Tradeshows and conferences costs increased by $0.3 million as a result of an increase in activities as restrictions implemented in response to the COVID-19 pandemic were eased. Other costs increased by $1.7 million due to increased logistics costs related to the expansion of our National OCS Program.

Other Income (Expense)

Interest Expense

Interest expense was $1.0 million for each of the three months ended March 31, 2022 and 2021.

Other Expense, Net

Other expense, net for the three months ended March 31, 2022 and 2021 included interest income of less than $0.1 million in each period resulting from interest earned on invested cash balances, and $0.2 million and $0.5 million of realized and unrealized foreign currency transactions losses, respectively.

Liquidity and Capital Resources

Since our inception, we have incurred significant operating losses. To date, we have funded our operations primarily with proceeds from sales of preferred stock and borrowings under loan agreements, proceeds from the sale of common stock in our public offerings and revenue from clinical trials and commercial sales of our OCS products.

As of March 31, 2022, we had cash, cash equivalents, and marketable securities of $72.0 million.

Cash Flows

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

	Three Months Ended March 31,	
	2022	2021
	(in thousands)	
Net cash used in operating activities	$ (18,406)	$ (7,330)
Net cash provided by investing activities	10,514	9,272
Net cash provided by financing activities	405	583
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(196)	(379)
Net increase (decrease) in cash, cash equivalents and restricted cash	$ (7,683)	$ 2,146

Operating Activities

During the three months ended March 31, 2022, operating activities used $18.4 million of cash, primarily resulting from our net loss of $10.6 million and net cash used by changes in our operating assets and liabilities of $11.4 million, partially offset by net non-cash charges of $3.6 million. Net cash used by changes in our operating assets and liabilities for the three months ended March 31, 2022 consisted primarily of an increase in accounts receivable of $5.8 million, an increase in inventory of $2.9 million and a decrease in accounts payable and accrued expenses and other current liabilities of $4.0 million, partially offset by an increase in operating lease liabilities of $1.2 million related to the reimbursement of tenant improvement costs.

During the three months ended March 31, 2021, operating activities used $7.3 million of cash, primarily resulting from our net loss of $7.9 million and net cash used by changes in our operating assets and liabilities of $2.0 million, partially offset by net non-cash charges of $2.6 million. Net cash used by changes in our operating assets and liabilities for the three months ended March 31, 2021 consisted primarily of a $0.9 million increase in prepaid expenses and other current assets, a $0.6 million increase in accounts receivable, a $0.4 million increase in inventory and a $0.3 million decrease in accounts payable and accrued expenses and other current liabilities, partially offset by a $0.2 million increase in deferred revenue.

Changes in accounts receivable, inventory, accounts payable, and accrued expenses and other current liabilities in each reporting period are generally due to growth in our business and timing of invoices and payments.

Investing Activities

During the three months ended March 31, 2022, net cash provided by investing activities of $10.5 million consisted of proceeds from sales and maturities of marketable securities of $14.5 million, partially offset by purchases of marketable securities of $2.0 million and purchases of property and equipment of $2.0 million.

During the three months ended March 31, 2021, net cash provided by investing activities of $9.3 million consisted of proceeds from sales and maturities of marketable securities of $21.0 million, partially offset by $11.7 million in purchases of marketable securities.

Financing Activities

During the three months ended March 31, 2022, net cash provided by financing activities of $0.4 million consisted of proceeds from the issuance of common stock upon exercise of stock options of $0.2 million and proceeds from the issuance of common stock in connection with the 2019 Employee Stock Purchase Plan of $0.2 million.

During the three months ended March 31, 2021, net cash provided by financing activities of $0.6 million consisted of proceeds from the issuance of common stock in connection with the 2019 Employee Stock Purchase Plan of $0.2 million and proceeds from the issuance of common stock upon exercise of stock options of $0.4 million.

Long-Term Debt

We have a Credit Agreement with OrbiMed, pursuant to which we borrowed $35.0 million.

Borrowings under the Credit Agreement bear interest at an annual rate equal to the LIBOR subject to a minimum of 1.0% and a maximum of 4.0%, plus 8.5%, or the Applicable Margin, subject in the aggregate to a maximum interest rate of 11.5%. In addition, borrowings under the Credit Agreement bear paid-in-kind, or PIK interest, at an annual rate equal to the amount by which LIBOR plus the Applicable Margin exceeds 11.5%, but not to exceed 12.5%. The PIK interest is added to the principal amount of the borrowings outstanding at the end of each quarter until the maturity date of the Credit Agreement in June 2023. Borrowings under the Credit Agreement are repayable in quarterly interest-only payments until the maturity date, at which time all principal and accrued interest is due and payable. At our option, we may prepay outstanding borrowings under the Credit Agreement. We are required to make a final payment in an amount equal to 3.0% of the principal amount of any prepayment or repayment, which we are accreting to interest expense over the term of the Credit Agreement using the effective interest method.

All obligations under the Credit Agreement are guaranteed by us and each of our material subsidiaries. All obligations of us and each guarantor are secured by substantially all of our and each guarantor’s assets, including their intellectual property, subject to certain exceptions, including a perfected security interest in substantially all tangible and intangible assets of us and each guarantor. Under the Credit Agreement, we have agreed to certain affirmative and negative covenants to which we will remain subject until maturity. The financial covenants include maintaining a minimum liquidity amount of $3.0 million; the requirement, on an annual basis, to deliver to OrbiMed annual audited financial statements with an unqualified audit opinion from our independent registered public accounting firm; and restrictions on our activities, including limitations on dispositions, mergers or acquisitions; encumbering our intellectual property; incurring indebtedness or liens; paying dividends; making certain investments; and engaging in certain other business transactions. The obligations under the Credit Agreement are subject to acceleration upon the occurrence of specified events of default, including payment default, change in control, bankruptcy, insolvency, certain defaults under other material debt, certain events with respect to governmental approvals (if such events could cause a material adverse change in our business), failure to comply with certain covenants, including the minimum liquidity and unqualified audit opinion covenants, and a material adverse change in our business, operations or other financial condition. As of March 31, 2022, we were in compliance with all of the covenants under the Credit Agreement.

Upon the occurrence of an event of default and until such event of default is no longer continuing, the Applicable Margin will increase by 4.0% per annum. If an event of default (other than certain events of bankruptcy or insolvency) occurs and is continuing, OrbiMed may declare all or any portion of the outstanding principal amount of the borrowings plus accrued and unpaid interest to be due and payable. Upon the occurrence of certain events of bankruptcy or insolvency, all of the outstanding principal amount of the borrowings plus accrued and unpaid interest will automatically become due and payable. In addition, we may be required to prepay outstanding borrowings, subject to certain exceptions, with portions of net cash proceeds of certain asset sales and certain casualty and condemnation events. While we do not expect that the transition from LIBOR, including any legal or regulatory changes made in response to its future phase out, or the risks related to its discontinuance will have a material effect on our financing costs, the impact is uncertain at this time.

Funding Requirements

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

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

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

We may need to raise additional funding, which might not be available on favorable terms or at all. See “Item 1A. Risk Factors—Risks Related to Our Financial Position and Need for Additional Capital” in our 2021 Form 10-K.

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States. The preparation of our consolidated financial statements and related disclosures requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenue, costs and expenses, and related disclosures. We evaluate our estimates on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

There have been no material changes to our critical accounting policies and estimates from those disclosed in our consolidated financial statements and the related notes and other financial information included in our 2021 Form 10-K.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position, results of operations or cash flows is disclosed in Note 2 to our consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

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

operating and financing activities. There has been no material change in the foreign currency exchange risk or interest rate risk discussed in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in our 2021 Form 10-K.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our President and Chief Executive Officer and our Chief Financial Officer (our principal executive officer and principal financial and accounting officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2022. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of March 31, 2022, 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 three months ended March 31, 2022 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We are not currently subject to any material legal proceedings.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. For a detailed discussion of the risks that affect our business, please refer to the section titled “Item 1A. Risk Factors” in our 2021 Form 10-K.

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

Use of Proceeds

We completed our IPO pursuant to a registration statement on Form S-1 (File No. 333-230736), which was declared effective by the SEC on May 1, 2019 and a registration statement on Form S-1MEF (File No. 333-231166), which was automatically effective upon filing with the SEC on May 1, 2019. The net offering proceeds to us, after deducting underwriting discounts and commissions and other offering expenses, were $91.4 million. None of the net proceeds were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning 10.0% or more of any class of our equity securities or to any other affiliates, other than payments in the ordinary course of business to officers for salaries and to non-employee directors as compensation for board or board committee service. As of March 31, 2022, we estimate that we used all of the net proceeds from our IPO for commercialization of our OCS products, research and development, and general corporate purposes. There has been no material change in our planned use of the net proceeds from the IPO as described in the final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act, with the SEC, on May 2, 2019.

Item 6. Exhibits.

Exhibit Number	Description
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 - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Presentation Linkbase Document.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith

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

SIGNATURES

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

Date: May 5, 2022

TRANSMEDICS GROUP, INC.

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

Date: May 5, 2022

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 5, 2022

/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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 5, 2022

/s/ Stephen Gordon

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

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of TransMedics Group, Inc. (the "Company") for the period ended March 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Waleed Hassanein, M.D., President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

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

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

Date: May 5, 2022

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

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

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of TransMedics Group, Inc. (the "Company") for the period ended March 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Stephen Gordon, Chief Financial Officer, Treasurer and Secretary of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

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

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

Date: May 5, 2022

By:/s/ Stephen Gordon

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