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, 2023
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 28, 2023, the registrant had 32,553,650 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, including our acquisitions, joint ventures or strategic investments, are forward-looking statements. The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect," "should," "could," "target," "predict," "seek" and similar expressions are intended to identify forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy, short- and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those 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 ability to attract and retain key personnel;
- 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;
- the fluctuation of our financial results from quarter to quarter;
- our need to raise additional funding and our ability to obtain it on favorable terms, or at all;
- 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;
- our ability to scale our manufacturing and sterilization capabilities to meet increasing demand for our products;
- 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 and develop the next generation of the OCS products;
- our dependence on a limited number of customers for a significant portion of our revenue;
- our ability to maintain regulatory approvals or clearances for our OCS products in the United States and European Union;
- our ability to adequately respond to the Food and Drug Administration, or FDA, follow-up inquiries in a timely manner;
- the performance of our third-party suppliers and manufacturers;

- our dependence on third parties to transport donor organs and medical personnel for our National OCS Program and our ability to establish or acquire an aviation business or strategic relationship to reduce such dependence;
- 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;
- 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 or procedures 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, 2023	December 31, 2022
Assets		
Current assets:		
Cash	$ 195,375	$ 201,182
Accounts receivable	38,620	27,611
Inventory	23,961	20,605
Prepaid expenses and other current assets	3,774	2,896
Total current assets	261,730	252,294
Property and equipment, net	19,161	19,223
Restricted cash	750	500
Operating lease right-of-use assets	4,939	5,130
Other non-current assets	508	—
Total assets	$ 287,088	$ 277,147
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,329	$ 3,341
Accrued expenses and other current liabilities	22,581	18,635
Deferred revenue	244	241
Operating lease liabilities	1,481	1,444
Total current liabilities	28,635	23,661
Long-term debt, net of discount and current portion	58,802	58,696
Operating lease liabilities, net of current portion	7,026	7,415
Total liabilities	94,463	89,772
Commitments and contingencies (Note 8)		
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; 32,534,003 shares and 32,141,368 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	674,156	666,277
Accumulated other comprehensive loss	(218)	(225)
Accumulated deficit	(481,313)	(478,677)
Total stockholders' equity	192,625	187,375
Total liabilities and stockholders' equity	$ 287,088	$ 277,147

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

TRANSMEDICS GROUP, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended March 31,	
	2023	**2022**
Revenue:		
Net product revenue	$ 33,993	$ 14,939
Service revenue	7,561	941
Total revenue	41,554	15,880
Cost of revenue:		
Cost of net product revenue	7,306	3,378
Cost of service revenue	5,482	398
Total cost of revenue	12,788	3,776
Gross profit	28,766	12,104
Operating expenses:		
Research, development and clinical trials	5,871	7,534
Selling, general and administrative	24,984	13,939
Total operating expenses	30,855	21,473
Loss from operations	(2,089)	(9,369)
Other income (expense):		
Interest expense	(1,091)	(960)
Other income (expense), net	555	(227)
Total other expense, net	(536)	(1,187)
Loss before income taxes	(2,625)	(10,556)
Provision for income taxes	(11)	(6)
Net loss	$ (2,636)	$ (10,562)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.08)	$ (0.38)
Weighted average common shares outstanding, basic and diluted	32,260,267	27,950,330

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

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

	Three Months Ended March 31,	
	2023	2022
Net loss	$ (2,636)	$ (10,562)
Other comprehensive income (loss):		
Foreign currency translation adjustment	7	(24)
Unrealized losses on marketable securities, net of tax of $0	—	(73)
Total other comprehensive income (loss)	7	(97)
Comprehensive loss	$ (2,629)	$ (10,659)

The accompanying notes are an integral part of these unaudited 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, 2022	32,141,368	$ 666,277	$ (225)	$ (478,677)	$ 187,375
Issuance of common stock upon the exercise of common stock options	378,500	3,574	—	—	3,574
Issuance of common stock in connection with employee stock purchase plan	14,135	384	—	—	384
Stock-based compensation expense	—	3,921	—	—	3,921
Foreign currency translation adjustment	—	—	7	—	7
Net loss	—	—	—	(2,636)	(2,636)
Balances at March 31, 2023	32,534,003	$ 674,156	$ (218)	$ (481,313)	$ 192,625

	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

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

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

	Three Months Ended March 31,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (2,636)	$ (10,562)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	1,287	507
Stock-based compensation expense	3,921	2,310
Non-cash interest expense and end of term accretion expense	106	137
Non-cash lease expense	191	178
Net amortization of premiums on marketable securities	—	228
Unrealized foreign currency transaction (gains) losses	(137)	214
Changes in operating assets and liabilities:		
Accounts receivable	(10,962)	(5,804)
Inventory	(3,623)	(2,926)
Prepaid expenses and other current assets	(884)	88
Other non-current assets	(54)	—
Accounts payable	1,028	(4,013)
Accrued expenses and other current liabilities	3,454	(4)
Operating lease liabilities	(352)	1,241
Net cash used in operating activities	(8,661)	(18,406)
Cash flows from investing activities:		
Purchases of property and equipment	(927)	(1,953)
Purchases of marketable securities	—	(2,033)
Proceeds from sales and maturities of marketable securities	—	14,500
Net cash provided by (used in) investing activities	(927)	10,514
Cash flows from financing activities:		
Proceeds from issuance of common stock upon exercise of stock options	3,574	202
Proceeds from issuance of common stock in connection with employee stock purchase plan	384	203
Net cash provided by financing activities	3,958	405
Effect of exchange rate changes on cash, cash equivalents and restricted cash	73	(196)
Net decrease in cash, cash equivalents and restricted cash	(5,557)	(7,683)
Cash, cash equivalents and restricted cash, beginning of period	201,682	26,080
Cash, cash equivalents and restricted cash, end of period	$ 196,125	$ 18,397
Supplemental disclosure of non-cash investing and financing activities:		
Transfers of inventory to property and equipment	$ 317	$ 1,030
Purchases of property and equipment included in accounts payable and accrued expenses	$ 30	$ 939
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$ 195,375	$ 17,897
Restricted cash	750	500
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	$ 196,125	$ 18,397

The accompanying notes are an integral part of these unaudited 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 Company also developed its National OCS Program ("NOP"), an innovative turnkey solution to provide outsourced organ retrieval and OCS organ management, to provide transplant programs in the United States with a more efficient process to procure donor organs with the OCS.

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 $2.6 million for the three months ended March 31, 2023 and $36.2 million for the year ended December 31, 2022. As of March 31, 2023, the Company had an accumulated deficit of $481.3 million. The Company expects to continue to generate operating losses in the foreseeable future.

The Company believes that its existing cash of $195.4 million as of March 31, 2023 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. 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. Continued impacts to the Company's business as a result of COVID-19 may include decreased overall frequency of transplant procedures; disruptions to the Company's manufacturing operations and supply chain; labor shortages; decreased productivity and unavailability of materials or components; 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. While the Company maintains an inventory of finished products and raw materials used in its OCS products, a further prolonged pandemic could lead to shortages in the raw materials necessary to manufacture its products.

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, 2022 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, 2023 and results of operations for the three months ended March 31, 2023 and 2022 and cash flows for the three months ended March 31, 2023 and 2022 have been made. The Company's results of operations for the three months ended March 31, 2023 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2023.

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 unaudited 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. 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 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, 2023 and December 31, 2022, the Company had no allowance for credit losses.

Significant customers are those that accounted for 10% or more of the Company's revenue or accounts receivable. For the three months ended March 31, 2023, no customer accounted for more than 10% of revenue. For the three months ended March 31, 2022, three customers accounted for 16%, 15% and 12% of revenue, respectively. As of March 31, 2023 and December 31, 2022, no customer accounted for more than 10% of accounts receivable.

Certain of the components and subassemblies included in the Company's products are obtained from a sole source, a single source or a limited group of suppliers, as are sterilization services. Although the Company seeks to reduce dependence on those limited sources of suppliers, manufacturers and service providers, 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 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 has developed and is 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, 2023 and 2022.

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,	
	2023	2022
Warrants to purchase common stock	14,440	64,440
Options to purchase common stock	3,167,730	3,484,914
Employee stock purchase plan	6,511	5,794
Restricted stock units	182,911	—
Restricted stock awards	24,315	—
	3,395,907	3,555,148

3. Marketable Securities and Fair Value Measurements

The Company did not have marketable securities as of March 31, 2023 or December 31, 2022. The Company also did not have assets or liabilities measured at fair value on a recurring basis as of March 31, 2023 or December 31, 2022.

4. Inventory

Inventory consisted of the following (in thousands):

	March 31, 2023	December 31, 2022
Raw materials	$ 12,265	$ 10,939
Work-in-process	2,264	1,876
Finished goods	9,432	7,790
	$ 23,961	$ 20,605

5. Accrued Expenses and Other Current Liabilities

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

	March 31, 2023	December 31, 2022
Accrued payroll and related expenses	$ 10,991	$ 9,812
Accrued logistics costs	5,415	2,581
Accrued research, development and clinical trials expenses	1,918	1,876
Accrued professional fees	1,600	965
Accrued other	2,657	3,401
	$ 22,581	$ 18,635

6. Long-Term Debt

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

	March 31, 2023	December 31, 2022
Principal amount of long-term debt	$ 60,000	$ 60,000
Less: Current portion of long-term debt	—	—
Long-term debt, net of current portion	60,000	60,000
Debt discount, net of accretion	(1,198)	(1,304)
Long-term debt, net of discount and current portion	$ 58,802	$ 58,696

In July 2022, the Company entered into a credit agreement with Canadian Imperial Bank of Commerce (“CIBC”), pursuant to which the Company borrowed $60.0 million (the “CIBC Credit Agreement”). In connection with the CIBC Credit Agreement, the Company repaid all amounts due under its previously outstanding credit agreement with OrbiMed Royalty Opportunities II, LP, including $35.0 million of principal repayments and a $1.1 million end of term payment, as well as accrued interest and the OrbiMed Credit Agreement was terminated. Upon repayment of the outstanding amounts, the Company recorded a loss on extinguishment of debt of $0.6 million, which was classified as other expense in the consolidated statements of operations.

Borrowings under the CIBC Credit Agreement bear interest at an annual rate equal to either, at the Company’s option, (i) the secured overnight financing rate for an interest period selected by the Company, subject to a minimum of 1.5%, plus 2.0% or (ii) 1.0% plus the higher of a) the prime rate subject to a minimum of 4.0% or b) the Federal Funds Effective Rate, plus 0.5%. Borrowings under the CIBC Credit Agreement are payable in monthly interest-only payments for the first 24 months, and then payable in equal monthly principal payments plus accrued interest until the maturity date of the CIBC Credit Agreement in July 2027. As certain revenue milestones were met in the three months ended March 31, 2023, the Company will be able to extend the interest-only repayment period by one additional year. At the Company’s option, the Company may prepay borrowings outstanding under the CIBC Credit Agreement, subject to a prepayment fee of 2.0% of outstanding borrowings if paid prior to 12 months after the closing date, and 1.0% if paid on or after 12 months after the closing date but prior to 24 months after the closing date.

In connection with entering into the CIBC Credit Agreement, the Company paid upfront fees and other costs of $1.5 million, which were recorded by the Company as a debt discount. The debt discount is reflected as a reduction of the carrying value of long-term debt on the Company's consolidated balance sheet and is being accreted to interest expense over the term of the CIBC Credit Agreement using the effective interest method.

All obligations under the CIBC 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. Under the CIBC Credit Agreement, the Company has agreed to customary representations and warranties, events of default and certain affirmative and negative covenants to which it will remain subject until maturity. The financial covenants include, among other covenants, (x) a requirement to maintain a minimum liquidity amount of the greater of either (i) the consolidated adjusted EBITDA loss (or gain) for the trailing four month period (only if EBITDA is negative) and (ii) $10.0 million, and (y) a requirement to maintain total net revenue of at least 75% of the level set forth in the total revenue plan presented to CIBC. The obligations under the CIBC 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 and a material adverse change in the Company's business, operations or financial condition. As of March 31, 2023, the Company was in compliance with all financial covenants of the CIBC Credit Agreement.

During the continuance of an event of default, the interest rate per annum will be equal to the rate that would have otherwise been applicable at the time of the event of default plus 2.0%. If an event of default (other than certain events of bankruptcy or insolvency) occurs and is continuing, CIBC 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.

The Company assessed all terms and features of the CIBC Credit Agreement in order to identify any potential embedded features that would require bifurcation. As part of this analysis, the Company assessed the economic characteristics and risks of the debt. The Company determined that all features of the CIBC Credit Agreement are either clearly and closely associated with a debt host or have a *de minimis* fair value and, as such, do not require separate accounting as a derivative liability.

As of March 31, 2023, the interest rate applicable to borrowings under the CIBC Credit Agreement was 6.6%. During the three months ended March 31, 2023, the weighted average effective interest rate on outstanding borrowings under the CIBC Credit Agreement was approximately 7.3%.

7. 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 canceled 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 awards have been or 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, 2023, 400,541 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 were initially reserved for issuance under the 2019 ESPP. During the three months ended March 31, 2023, 14,135 shares of common stock were issued under the 2019 ESPP and as of March 31, 2023, 276,318 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 nonqualified 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, 2023, 458,384 shares of common stock remained available for issuance under the Inducement Plan.

Stock Option Activity

During the three months ended March 31, 2023, the Company granted options under the 2019 Plan and the Inducement Plan with service-based vesting for the purchase of an aggregate of 326,751 shares of common stock with a weighted average grant-date fair value of $43.26 per share.

Restricted Stock Unit Activity

During the three months ended March 31, 2023, the Company granted 182,911 restricted stock units under the 2019 Plan and the Inducement Plan with service-based vesting conditions and a weighted-average grant-date fair value of $66.10 per share.

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,	
	2023	2022
Cost of revenue	$ 49	$ 25
Research, development and clinical trials expenses	518	321
Selling, general and administrative expenses	3,354	1,964
	$ 3,921	$ 2,310

As of March 31, 2023, total unrecognized compensation cost related to unvested share-based awards was $44.3 million, which is expected to be recognized over a weighted average period of 2.6 years.

8. 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, 2023. 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, 2022.

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, 2023 and December 31, 2022, 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, 2023 and December 31, 2022.

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, 2023 was $7.0 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.

9. Segment Reporting and Geographic Data

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

See Note 10 for revenue by country. Long-lived assets by geography are summarized as follows (in thousands):

	March 31, 2023	December 31, 2022
Long-lived assets by country(1):		
United States	$ 18,479	$ 18,568
All other countries	682	655
Total long-lived assets	$ 19,161	$ 19,223

(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.

10. Revenue

Payments to Customers

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. There were no such adjustments to revenue for either of the three months ended March 31, 2023 or 2022. As clinical trials reach the end of their follow up period, the Company updates its accrual estimates. The Company will continue to update its clinical trial accrual estimates as all information related to clinical trial payments is received.

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 $0.1 million and $0.5 million for the three months ended March 31, 2023 and 2022, respectively, as operating expenses.

Disaggregated Revenue

The Company disaggregates revenue from contracts with customers by organ 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,	
	2023	2022
Revenue by country by organ(1):		
United States		
Lung total revenue	$ 1,431	$ 1,951
Heart total revenue	12,956	3,741
Liver total revenue	23,114	7,869
Total United States revenue	37,501	13,561
All other countries		
Lung revenue	251	348
Heart revenue	3,802	1,971
Total all other countries revenue	4,053	2,319
Total revenue	$ 41,554	$ 15,880

(1) Revenue by country is categorized based on the location of the end customer. Total revenue includes product and service revenue.

11. 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, 2023 and 2022, 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, 2022, as filed with the SEC on February 27, 2023 ("2022 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 2022 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 have also developed our National OCS Program, or NOP, an innovative turnkey solution to provide outsourced organ retrieval and OCS organ management, to provide transplant programs in the United States with a more efficient process to procure donor organs with the OCS. We believe the use of the OCS combined with the NOP has the potential to significantly increase the number of organ transplants and improve post-transplant outcomes.

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 heart, lung and liver transplantations, making the OCS the only FDA approved, portable, multi-organ, warm perfusion technology platform. All three of our products, OCS Heart, OCS Lung and OCS Liver, have received Pre-Market Approval, or PMA, from the Food and Drug Administration, or FDA for both organs donated after brain death, or DBD organs, and organs donated after circulatory death, or DCD organs.

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 and expanding our NOP; developing and expanding 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 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 and NOP services.

Since our inception, we have incurred significant operating losses. Our ability to generate revenue sufficient to achieve profitability will depend on the successful further development and commercialization of our products. We generated total revenue of $41.6 million and incurred a net loss of $2.6 million for the three months ended March 31, 2023. We generated total revenue of $93.5 million and incurred a net loss of $36.2 million for the year ended December 31, 2022. As of March 31, 2023, we had an accumulated deficit of $481.3 million. We expect to continue to incur net losses for the foreseeable future as we focus on growing commercial sales of our products in both the United States and select non-U.S. markets, including growing our commercial team, which will pursue increasing commercial sales of our OCS products; expanding our NOP; scaling our manufacturing and sterilization operations; developing the next generation OCS; continuing research, development and clinical trial efforts; seeking regulatory clearance for new products and product enhancements, including additional indications or other organs, 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, commercialization and regulations of our industry, 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 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. Additionally, in March 2023, the U.S. Department of Health and Human Services' Health Resources and Services Administration, or HRSA, announced initiatives designed to improve the Organ Procurement and Transplantation network, or OPTN, including its intent to solicit contract proposals to manage the OPTN, which is currently operated by the United Network for Organ Sharing, or UNOS, under a contract that expires in September 2023. The potential impact of these initiatives on our business, including on our NOP, is uncertain at this time.

As of March 31, 2023, we had cash of $195.4 million. We believe that our cash 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".

Economic Impacts and COVID-19

Inflation, changes in trade policies, and the imposition of duties and tariffs have and could continue to adversely impact the price or availability of raw materials, the components of our products as well as shipping and transportation costs. For example, the global economy has experienced extreme volatility and disruptions, including significant volatility in commodity, other material and labor costs, declines in consumer confidence, declines in economic growth, supply chain interruptions, uncertainty about economic stability and record inflation globally. Unfavorable economic conditions have and could continue to result in a variety of risks to our business, including impacts on demand and pricing for our products and pricing and availability of raw materials and components for our products, which could make it difficult to forecast our inventory needs and financial results.

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 or spikes in infection rates. Continued impacts to our business as a result of COVID-19 may include decreased overall frequency of transplant procedures; disruptions to our manufacturing operations and supply chain; labor shortages; decreased productivity and unavailability of materials or components; 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.

While we maintain an inventory of finished products and raw materials used in our OCS products, further prolonged pandemic-related disruptions could lead to shortages in the raw materials necessary to manufacture our products. The extent to which COVID-19 impacts operations of our third-party partners will depend on future developments, which are highly uncertain and cannot be predicted with confidence. If we experience a prolonged disruption in our manufacturing, supply chains, or commercial operations, we would expect to experience a material adverse impact on our business, financial condition, results of operations and prospects.

Components of Our Results of Operations

Revenue

We generate net product 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 product revenue from the sale of OCS Consoles to customers and the implied rental of OCS Consoles loaned to customers at no charge. For each new transplant procedure, customers purchase an additional OCS disposable set for use on the customer's existing organ-specific OCS Console. We also generate service revenue by providing outsourced organ retrieval and OCS organ management services under our NOP in the United States.

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, and may also contain promises for organ retrieval and OCS organ management services under our NOP, and an OCS Console, whether sold or loaned to the customer.

When a customer order includes disposable sets and organ retrieval or OCS organ management services, we have determined that the disposable sets and services constitute separate performance obligations and we recognize revenue as the disposable sets and services are each delivered 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.

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 product revenue presentation. There were no such adjustments to revenue for either of the three months ended March 31, 2023 or 2022.

Through March 31, 2023, all of our sales outside of the United States have been commercial sales (unrelated to any clinical trials). Our sales in the EU are dependent on obtaining and maintaining the CE Mark certifications for each of our OCS products. As required by the EU Medical Devices Regulation (Regulation 2017/745), or the MDR, we received recertification of the CE Mark in September 2022 for each of the OCS Heart and OCS Lung systems, which includes the OCS Console, the OCS disposables, and the OCS solution additives. We also received the recertification of the CE Mark in September 2022 for the OCS Liver Console and disposables. We have applied for and expect to receive the CE Mark for the OCS Liver combined with our solution additives under the MDR within the next nine months.

We expect that our 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, and as a result of the continued expansion of the NOP in the United States. We also expect that our 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 net product revenue consists 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 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 it over its five-year estimated useful life. Included in the cost of OCS disposable sets are the costs of our OCS Lung, OCS Heart and OCS Liver Solutions. Cost of service revenue primarily consists of labor and overhead and transportation costs that directly support organ retrieval and OCS organ management services. We expect that cost of revenue will increase or decrease in absolute dollars primarily as, and to the extent that, our revenue increases or decreases.

Gross profit is the amount by which our revenue exceeds our cost of revenue in each reporting period. We calculate gross margin as gross profit divided by 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 cost of services provided under the NOP and the selling price of our OCS products and NOP services.

We expect that the cost of net product revenue as a percentage of net product 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, our product enhancements and improved manufacturing efficiency. 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. We also expect to see modest improvements in the future in our gross margin on services as we provide more services and

the efficiency in provisioning of these services improves due to scale and experience. While we expect our gross margins to increase over the long term, they 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, logistics 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 and our NOP.

Other Income (Expense)

Interest Expense

Interest expense consists of interest expense associated with outstanding borrowings under our loan agreements as well as the amortization of debt discount associated with such agreements. In July 2022, we entered into a credit agreement with Canadian Imperial Bank of Commerce, or CIBC, under which we borrowed $60.0 million. At that time, we repaid the remaining $35.0 million of principal that had been outstanding under our prior credit agreement with OrbiMed Royalty Opportunities II, LP, or OrbiMed.

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, 2023 and 2022

The following table summarizes our results of operations for the three months ended March 31, 2023 and 2022:

	Three Months Ended March 31,		
	2023	2022	Change
		(in thousands)	
Revenue:			
Net product revenue	$ 33,993	$ 14,939	$ 19,054
Service revenue	7,561	941	6,620
Total revenue	41,554	15,880	25,674
Cost of revenue:			
Cost of net product revenue	7,306	3,378	3,928
Cost of service revenue	5,482	398	5,084
Total cost of revenue	12,788	3,776	9,012
Gross profit	28,766	12,104	16,662
Operating expenses:			
Research, development and clinical trials	5,871	7,534	(1,663)
Selling, general and administrative	24,984	13,939	11,045
Total operating expenses	30,855	21,473	9,382
Loss from operations	(2,089)	(9,369)	7,280
Other income (expense):			
Interest expense	(1,091)	(960)	(131)
Other income (expense), net	555	(227)	782
Total other expense, net	(536)	(1,187)	651
Loss before income taxes	(2,625)	(10,556)	7,931
Provision for income taxes	(11)	(6)	(5)
Net loss	$ (2,636)	$ (10,562)	$ 7,926

Revenue

	Three Months Ended March 31,		
	2023	2022	Change
		(in thousands)	
Revenue by country by organ:			
United States			
Lung total revenue	$ 1,431	$ 1,951	(520)
Heart total revenue	12,956	3,741	9,215
Liver total revenue	23,114	7,869	15,245
Total United States revenue	37,501	13,561	23,940
All other countries			
Lung total revenue	251	348	(97)
Heart total revenue	3,802	1,971	1,831
Total all other countries revenue	4,053	2,319	1,734
Total revenue	$ 41,554	$ 15,880	$ 25,674

Revenue from customers in the United States was $37.5 million in the three months ended March 31, 2023 and increased by $23.9 million compared to the three months ended March 31, 2022, primarily due to higher sales volumes of our OCS Liver and OCS Heart disposable sets, partially offset by lower sales volumes of our OCS Lung disposable sets. Revenue for each organ in the table above includes net product revenue from sales of disposable sets as well as service revenue for organ retrieval and OCS organ management services under the NOP in the United States. Revenue from customers who participated in our NOP accounted for approximately 94% and 78% of total revenue from customers in the United States for the three months ended March 31, 2023 and 2022, respectively. Revenue from sales of OCS Liver disposable sets and organ retrieval and OCS organ management services in the United States increased by $15.2 million due primarily to higher sales volumes of OCS Liver disposable sets resulting from the commercialization of the OCS Liver product and the expansion of our NOP. Revenue from sales of OCS Heart disposable sets and organ retrieval and OCS organ management services in the United States increased by $9.2 million also primarily as a result of the commercialization of the OCS Heart product as well as the expansion of the NOP. Revenue from sales of OCS Lung disposable sets and organ retrieval and OCS organ management services in the United States decreased by $0.5 million due to a decrease in sales volumes of OCS Lung disposable sets.

Revenue from customers outside the United States was $4.1 million in the three months ended March 31, 2023 and increased by $1.7 million compared to the three months ended March 31, 2022. Revenue outside of the United States increased for the three months ended March 31, 2023 compared to the three months ended March 31, 2022 due primarily to increased sales volume of OCS Heart disposable sets.

Cost of Revenue, Gross Profit and Gross Margin

Cost of net product revenue increased by $3.9 million in the three months ended March 31, 2023 compared to the three months ended March 31, 2022. Cost of service revenue increased by $5.1 million from $0.4 million in the three months ended March 31, 2022 to $5.5 million in the three months ended March 31, 2023 as we expanded the NOP, which launched in late 2021. Gross profit increased by $16.7 million in the three months ended March 31, 2023 compared to the three months ended March 31, 2022.

Gross margin from net product revenue was 79% and 77% for the three months ended March 31, 2023 and 2022, respectively. Gross margin from net product revenue increased primarily as a result of economies of scale from higher sales volumes and increased U.S. sales, which are higher margin than non-US sales. Gross margin from service revenue was 27% and 58% for the three months ended March 31, 2023 and 2022, respectively, and consisted primarily of organ retrieval and OCS organ management services under our NOP. Service revenue gross margin during the three months ended March 31, 2022 included our initial launch of the NOP program and did not include a full period of our NOP service offering.

Operating Expenses

Research, Development and Clinical Trials Expenses

	Three Months Ended March 31,		
	2023	2022	Change
		(in thousands)	
Personnel related (including stock-based compensation expense)	$ 2,579	$ 2,252	$ 327
Clinical trials costs	144	563	(419)
Consulting and third-party testing	771	2,479	(1,708)
Laboratory supplies and research materials	1,151	1,137	14
Other	1,226	1,103	123
Total research, development and clinical trials expenses	$ 5,871	$ 7,534	$ (1,663)

Total research, development and clinical trials expenses decreased by $1.7 million from $7.5 million in the three months ended March 31, 2022 to $5.9 million in the three months ended March 31, 2023. Consulting and third-party testing costs decreased by $1.7 million, due to timing of development efforts for our next generation program. 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,		
	2023	2022	Change
		(in thousands)	
Personnel related (including stock-based compensation expense)	$ 13,797	$ 8,387	$ 5,410
Logistics and other	6,654	3,011	3,643
Professional and consultant fees	3,199	2,088	1,111
Tradeshows and conferences	1,334	453	881
Total selling, general and administrative expenses	$ 24,984	$ 13,939	$ 11,045

Total selling, general and administrative expenses increased by $11.0 million from $13.9 million in the three months ended March 31, 2022 to $25.0 million in the three months ended March 31, 2023 due to increases in personnel related costs, logistics and other costs, and professional and consultant fees. Personnel related costs increased by $5.4 million primarily due to the continued expansion of our team to support the NOP and commercial growth of our products in the United States, as well as an increase in stock-based compensation expense of $1.4 million, due primarily to additional grants to new and existing employees. Logistics and other costs increased by $3.6 million due to increased logistics costs related to the expansion of our NOP. Professional and consultant fees increased by $1.1 million due to additional investment in digital tools to support the NOP along with higher legal fees related to the business growth.

Other Income (Expense)

Interest Expense

Interest expense was $1.1 million and $1.0 million for the three months ended March 31, 2023 and 2022, respectively. The increase was due primarily to an increase in the principal amount of the loan outstanding compared to the principal that had been outstanding under our prior credit agreement with OrbiMed, partially offset by a lower interest rate for our indebtedness under the CIBC Credit Agreement.

Other Income (Expense), Net

Other income (expense), net for the three months ended March 31, 2023 and 2022 included interest income of $0.5 million and less than $0.1 million, respectively, from interest earned on invested cash balances. Other income (expense), net also included $0.1 million of realized and unrealized foreign currency transactions gains during the three months ended March 31, 2023 and $0.2 million of realized and unrealized foreign currency transactions losses during the three months ended March 31, 2022.

Liquidity and Capital Resources

At March 31, 2023, our principal source of liquidity was cash of $195.4 million. Since our inception, we have incurred significant operating losses. To date, we have funded our operations primarily with proceeds from 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 and NOP services.

Cash Flows

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

	Three Months Ended March 31,	
	2023	2022
	(in thousands)	
Net cash used in operating activities	$ (8,661)	$ (18,406)
Net cash provided by (used in) investing activities	(927)	10,514
Net cash provided by financing activities	3,958	405
Effect of exchange rate changes on cash, cash equivalents and restricted cash	73	(196)
Net decrease in cash, cash equivalents and restricted cash	$ (5,557)	$ (7,683)

Operating Activities

During the three months ended March 31, 2023, operating activities used $8.7 million of cash, primarily resulting from our net loss of $2.6 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 $5.4 million. Net cash used by changes in our operating assets and liabilities for the three months ended March 31, 2023 consisted primarily of an increase in accounts receivable of $11.0 million and an increase in inventory of $3.6 million, partially offset by an increase in accounts payable and accrued expenses and other current liabilities of $4.5 million.

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.

Investing Activities

During the three months ended March 31, 2023, net cash used by investing activities of $0.9 million consisted of purchases of property and equipment.

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.

Financing Activities

During the three months ended March 31, 2023, net cash provided by financing activities of $4.0 million consisted of proceeds from the issuance of common stock upon exercise of stock options of $3.6 million and proceeds from the issuance of common stock in connection with the 2019 Employee Stock Purchase Plan of $0.4 million.

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.

Long-Term Debt

In July 2022, we entered into a credit agreement with CIBC pursuant to which we borrowed $60.0 million, referred to herein as the CIBC Credit Agreement. We used proceeds of the CIBC Credit Agreement to repay all amounts due under our credit agreement with OrbiMed, which was entered into in June 2018.

Borrowings under the CIBC Credit Agreement bear interest at an annual rate equal to either, at our option, (i) the secured overnight financing rate for an interest period selected by us, subject to a minimum of 1.5%, plus 2.0% or (ii) 1.0% plus the higher of a) the prime rate, subject to a minimum of 4.0% or b) the Federal Funds Effective Rate, plus 0.5%. Borrowings under the CIBC Credit Agreement are payable in monthly interest-only payments for the first 24 months, and then payable in equal monthly principal payments plus accrued interest until the maturity date of the CIBC Credit Agreement in July 2027. As certain revenue milestones were met in the three months ended March 31, 2023,we will be able to extend the interest-only repayment period by one additional year. At our option, we may prepay borrowings outstanding under the CIBC Credit Agreement, subject to a prepayment fee of 2.0% of outstanding borrowings if paid prior to 12 months after the closing date, and 1.0% if paid after 12 months but prior to 24 months after the closing date.

All obligations under the CIBC 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. Under the CIBC Credit Agreement, we have agreed to customary representations and warranties, events of default and certain affirmative and negative covenants to which we will remain subject until maturity. The financial covenants include, among other covenants, (x) a requirement to maintain a minimum liquidity amount of the greater of either (i) the consolidated adjusted EBITDA loss (or gain) for the trailing four month period (only if EBITDA is negative) and (ii) $10.0 million, and (y) a requirement to maintain total net revenue of at least 75% of the level set forth in the total revenue plan presented to CIBC. The obligations under the CIBC 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 and a material adverse change in our business, operations or financial condition. As of March 31, 2023, we were in compliance with all covenants of the CIBC Credit Agreement.

During the continuance of an event of default, the interest rate per annum will be equal to the rate that would have otherwise been applicable at the time of the event of default plus 2.0%. If an event of default (other than certain events of bankruptcy or insolvency) occurs and is continuing, CIBC may declare all or any portion of the outstanding principal amount of the borrowings plus accrued and unpaid interest to be due and payable. Upon the occurrence of certain events of bankruptcy or insolvency, all of the outstanding principal amount of the borrowings plus accrued and unpaid interest will automatically become due and payable. In addition, we may be required to prepay outstanding borrowings, subject to certain exceptions, with portions of net cash proceeds of certain asset sales and certain casualty and condemnation events.

Funding Requirements

As we continue to pursue and increase commercial sales of our OCS products, we expect our costs and expenses to increase in the future, particularly as we expand our commercial team, grow our NOP, scale our manufacturing and sterilization operations, continue research, development and clinical trial efforts, seek regulatory approval for new products and product enhancements, including new indications, both in the United States and in select non-U.S. markets, and intend to seek greater control of air and ground transport for our NOP. For example, if the demand for our products exceeds our existing manufacturing and sterilization capacity, our ability to fulfill orders would be limited until we have sufficiently expanded such operations. 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 product 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, revenue generated by our services, and expansion of the NOP;
- 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 or procedures;
- the number and types of future products we develop and commercialize;
- the cost of development of the next generation OCS;
- the costs associated with building our commercial operations, including the NOP;
- the costs associated with establishing an aviation and logistics business or strategic relationship, including by means of acquisitions, joint ventures or strategic investments;
- 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 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 2022 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 2022 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 2022 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, 2023. 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, 2023, 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, 2023 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 2022 Form 10-K and additional risks below.

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

The efficient operation of our business depends on our information technology systems. We rely on our information technology systems to effectively manage sales and marketing data, accounting and financial functions, inventory management, product development tasks, clinical data, donor and patient data, customer service and technical support functions. However, our information technology systems are vulnerable to damage or interruption, including from earthquakes, fires, floods and other natural disasters; terrorist attacks; cyber-based attacks; attacks by computer viruses or hackers; power losses, computer system or data network failures; security breaches and data corruption. The failure of either our or our service providers' information technology could disrupt our entire operation or result in decreased sales, increased overhead costs and product shortages, all of which could materially and adversely affect our business, financial condition, operating results, reputation, cash flows and prospects. In addition, our software systems include cloud-based applications that are hosted by third-party service providers with security and information technology systems subject to similar risks, and we may not have accurate or complete information about the risks they face or the security of their systems.

As the cyber-threat landscape evolves, attacks are growing in frequency, sophistication and intensity, are becoming increasingly difficult to detect, and are being perpetrated by a broadening array of threat actors, including criminal hackers, hacktivists, nation-states and state-sponsored actors, perpetrators of industrial espionage and sabotage, and inside threats. New and expanding threats to our information systems, including computer viruses, ransomware and phishing attacks, insider attacks, and more sophisticated and targeted cyber-related attacks, as well as cybersecurity failures resulting from human error and technological errors, pose a risk to the security of our systems and the systems of our customers, business partners and suppliers, as well the confidentiality, availability and integrity of the data we process. For example, during the second quarter of 2023, we became aware of an infiltration of portions of our information technology network. As part of our investigation into this incident, we engaged outside security experts and have identified unauthorized theft of data from our network that included employee and financial data. The Company's investigation is ongoing. We do not store patient related data on our network or anywhere within the company premises. We have implemented additional security safeguards that we believe have secured the system, however, these additional security safeguards may not be successful. While we maintain insurance coverage for these types of incidents, such policies, may not provide coverage for, or offset the costs of responding to and remediating this infiltration or any other such incidents or any other liability that may arise from this infiltration or any other such incident.

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

While we attempt to mitigate these risks by employing a number of measures, including employee training and maintenance of protective systems, such measures did not prevent the infiltration described above and may not prove adequate to prevent cyberattacks, and we remain potentially vulnerable to additional known or unknown threats. The impact from such threats could be material. A significant cybersecurity incident could result in a range of potentially material negative consequences for us, including lost revenue; unauthorized access to, disclosure, modification, misuse, loss or destruction of company systems or data; theft of sensitive, regulated or confidential data, such as personal identifying information or our intellectual property; the loss of functionality of critical systems through ransomware, denial of service or other attacks; business delays, service or system disruptions, damage to equipment and injury to persons or property, and increased insurance premiums. The costs and operational consequences of defending against, preparing for, responding to and remediating an incident may be substantial. Further, we could be exposed to litigation, regulatory enforcement or other

legal action as a result of an incident, carrying the potential for damages, fines, sanctions or other penalties, as well injunctive relief requiring costly compliance measures. Any cybersecurity incident could also impact our brand, harm our reputation and adversely impact our relationship with our customers, employees and stockholders.

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

None.

Item 5. Other Information.

None.

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 4, 2023

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 4, 2023

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 4, 2023

/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 4, 2023

/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, 2023, 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 4, 2023

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, 2023 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 4, 2023

By: /s/ Stephen Gordon

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