UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2022

OR

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

For the transition period from ________ to ________

Commission File Number: 001-38891

TransMedics Group, Inc.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

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

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

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

As of October 31, 2022, the registrant had 31,924,220 shares of common stock, no par value per share, outstanding.

FORWARD-LOOKING STATEMENTS

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

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

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

- that we continue to incur losses;
- our 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 favourable 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;
- the rate and degree of market acceptance of the OCS;
- our ability to educate patients, surgeons, transplant centers and private and public payors on the benefits offered by the OCS;
- our ability to improve the OCS platform;
- our dependence on a limited number of customers for a significant portion of our net revenue;
- our ability to maintain regulatory approvals or clearances for our OCS products 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 timing and our ability to commercialize and market our OCS products;
- our ability to scale our manufacturing capabilities to meet increasing demand for our products;
- the performance of our third-party suppliers and manufacturers;
- price increases of the components of our products;

- the timing or results of post-approval studies and any clinical trials for the OCS;
- our manufacturing, sales, marketing and clinical support capabilities and strategy;
- attacks against our information technology infrastructure;
- the economic, political and other risks associated with our foreign operations;
- the impact of the outbreak of the novel strain of coronavirus, or COVID-19, including variants of the virus and associated containment, remediation and vaccination efforts;
- our ability to protect, defend, maintain and enforce our intellectual property rights relating to the OCS and avoid allegations that our products infringe, misappropriate or otherwise violate the intellectual property rights of third parties;
- the pricing of the OCS, as well as the reimbursement coverage for the OCS in the United States and internationally;
- regulatory developments in the United States, European Union and other jurisdictions;
- the extent and success of competing products 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.
Table of Contents

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)

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

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 204,462	$ 25,580
Marketable securities	—	66,872
Accounts receivable	22,035	5,934
Inventory	18,575	14,859
Prepaid expenses and other current assets	5,514	5,460
Total current assets	250,586	118,705
Property and equipment, net	18,472	9,841
Restricted cash	500	500
Operating lease right-of-use assets	5,315	5,847
Total assets	$ 274,873	$ 134,893
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,080	$ 6,651
Accrued expenses and other current liabilities	15,976	16,337
Deferred revenue	226	250
Operating lease liabilities	1,407	—
Total current liabilities	20,689	23,238
Long-term debt, net of discount and current portion	58,540	35,197
Operating lease liabilities, net of current portion	7,787	8,604
Total liabilities	87,016	67,039
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, no par value; 25,000,000 shares authorized; no shares issued or outstanding	—	—
Common stock, no par value; 150,000,000 shares authorized; 31,933,984 shares and 27,791,615 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	660,061	510,488
Accumulated other comprehensive loss	(247)	(188)
Accumulated deficit	(471,957)	(442,446)
Total stockholders' equity	187,857	67,854
Total liabilities and stockholders' equity	$ 274,873	$ 134,893

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

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

	Three Months Ended September 30, 2022	Three Months Ended September 30, 2021	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021
Net revenue	$ 25,683	$ 5,370	$ 62,084	$ 20,594
Cost of revenue	7,568	1,597	17,515	6,421
Gross profit	18,115	3,773	44,569	14,173
Operating expenses:				
Research, development and clinical trials	6,808	5,163	21,056	15,990
Selling, general and administrative	16,851	10,335	48,171	26,283
Total operating expenses	23,659	15,498	69,227	42,273
Loss from operations	(5,544)	(11,725)	(24,658)	(28,100)
Other income (expense):				
Interest expense	(787)	(979)	(2,719)	(2,896)
Other expense, net	(1,076)	(249)	(2,087)	(532)
Total other expense, net	(1,863)	(1,228)	(4,806)	(3,428)
Loss before income taxes	(7,407)	(12,953)	(29,464)	(31,528)
Provision for income taxes	(19)	(9)	(47)	(19)
Net loss	$ (7,426)	$ (12,962)	$ (29,511)	$ (31,547)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.25)	$ (0.47)	$ (1.03)	$ (1.14)
Weighted average common shares outstanding, basic and diluted	30,229,936	27,701,252	28,729,649	27,564,589

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Net loss	$ (7,426)	$ (12,962)	$ (29,511)	$ (31,547)
Other comprehensive income (loss):				
Foreign currency translation adjustment	(41)	3	(95)	(26)
Unrealized gains (losses) on marketable securities, net of tax of $0	100	—	36	(10)
Total other comprehensive income (loss)	59	3	(59)	(36)
Comprehensive loss	$ (7,367)	$ (12,959)	$ (29,570)	$ (31,583)

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

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

	Common Stock		Accumulated Other Comprehen-sive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balances at December 31, 2021	27,791,615	$ 510,488	$ (188)	$ (442,446)	$ 67,854
Issuance of common stock upon the exercise of common stock options	164,503	202	—	—	202
Issuance of common stock in connection with employee stock purchase plan	12,465	203	—	—	203
Stock-based compensation expense	—	2,310	—	—	2,310
Foreign currency translation adjustment	—	—	(24)	—	(24)
Unrealized losses on marketable securities	—	—	(73)	—	(73)
Net loss	—	—	—	(10,562)	(10,562)
Balances at March 31, 2022	27,968,583	513,203	(285)	(453,008)	59,910
Issuance of common stock upon the exercise of common stock options	31,592	237	—	—	237
Stock-based compensation expense	—	2,316	—	—	2,316
Issuance of restricted common stock	23,120	—	—	—	—
Foreign currency translation adjustment	—	—	(30)	—	(30)
Unrealized gains on marketable securities	—	—	9	—	9
Net loss	—	—	—	(11,523)	(11,523)
Balances at June 30, 2022	28,023,295	515,756	(306)	(464,531)	50,919
Issuance of common stock in public offering, net of discounts and issuance costs of $676	3,737,500	139,854	—	—	139,854
Issuance of common stock upon the exercise of common stock options	154,316	1,441	—	—	1,441
Issuance of common stock in connection with employee stock purchase plan	17,678	306	—	—	306
Issuance of restricted common stock	2,973	—	—	—	—
Restricted common stock forfeitures	(1,778)	—	—	—	—
Stock-based compensation expense	—	2,704	—	—	2,704
Foreign currency translation adjustment	—	—	(41)	—	(41)
Unrealized gains on marketable securities	—	—	100	—	100
Net loss	—	—	—	(7,426)	(7,426)
Balances at September 30, 2022	31,933,984	$ 660,061	$ (247)	$ (471,957)	$ 187,857

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

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

	Common Stock		Accumulated Other Comprehen-sive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balances at December 31, 2020	27,175,305	$ 502,217	$ (95)	$ (398,231)	$ 103,891
Issuance of common stock upon the exercise of common stock options	287,705	372	—	—	372
Issuance of common stock in connection with employee stock purchase plan	14,951	211	—	—	211
Stock-based compensation expense	—	1,112	—	—	1,112
Foreign currency translation adjustment	—	—	(2)	—	(2)
Unrealized gains on marketable securities	—	—	8	—	8
Net loss	—	—	—	(7,917)	(7,917)
Balances at March 31, 2021	27,477,961	503,912	(89)	(406,148)	97,675
Issuance of common stock upon the exercise of common stock options	169,273	213	—	—	213
Stock-based compensation expense	—	1,808	—	—	1,808
Foreign currency translation adjustment	—	—	(27)	—	(27)
Unrealized losses on marketable securities	—	—	(18)	—	(18)
Net loss	—	—	—	(10,668)	(10,668)
Balances at June 30, 2021	27,647,234	505,933	(134)	(416,816)	88,983
Issuance of common stock upon the exercise of common stock options	104,753	344	—	—	344
Issuance of common stock in connection with employee stock purchase plan	12,898	208	—	—	208
Stock-based compensation expense	—	1,973	—	—	1,973
Foreign currency translation adjustment	—	—	3	—	3
Net loss	—	—	—	(12,962)	(12,962)
Balances at September 30, 2021	27,764,885	$ 508,458	$ (131)	$ (429,778)	$ 78,549

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

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

	Nine Months Ended September 30,	
	2022	2021
Cash flows from operating activities:		
Net loss	$ (29,511)	$ (31,547)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	2,193	1,351
Stock-based compensation expense	7,330	4,893
Loss on extinguishment of debt	575	—
Loss on sale of marketable securities	107	—
Non-cash interest expense and end of term accretion expense	309	401
Non-cash lease expense	532	—
Net amortization of premiums on marketable securities	381	1,075
Unrealized foreign currency transaction losses	1,733	587
Changes in operating assets and liabilities:		
Accounts receivable	(16,287)	2,650
Inventory	(6,094)	(3,964)
Prepaid expenses and other current assets	(98)	(1,392)
Accounts payable	(3,534)	1,226
Accrued expenses and other current liabilities	(8)	2,356
Deferred revenue	—	72
Operating lease liabilities	590	—
Deferred rent	—	76
Net cash used in operating activities	(41,782)	(22,216)
Cash flows from investing activities:		
Purchases of property and equipment	(9,143)	(341)
Purchases of marketable securities	(10,496)	(66,694)
Proceeds from sales and maturities of marketable securities	76,916	86,310
Net cash provided by investing activities	57,277	19,275
Cash flows from financing activities:		
Proceeds from issuance of long-term debt, net of issuance costs	58,509	—
Repayments of long-term debt	(36,050)	—
Proceeds from issuance of common stock in public offering, net of underwriting discounts and commissions and issuance costs paid	140,014	—
Proceeds from issuance of common stock upon exercise of stock options	1,880	929
Proceeds from issuance of common stock in connection with employee stock purchase plan	509	419
Net cash provided by financing activities	164,862	1,348
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(1,475)	(493)
Net increase (decrease) in cash, cash equivalents and restricted cash	178,882	(2,086)
Cash, cash equivalents and restricted cash, beginning of period	26,080	25,081
Cash, cash equivalents and restricted cash, end of period	$ 204,962	$ 22,995
Supplemental disclosure of non-cash investing activities:		
Transfers of inventory to property and equipment	$ 2,055	$ 935
Purchases of property and equipment included in accounts payable and accrued expenses	$ 926	$ 342
Offering costs included in accounts payable and accrued expenses	$ 160	$ —
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$ 204,462	$ 22,495
Restricted cash	500	500
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	$ 204,962	$ 22,995

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

1. Nature of the Business and Basis of Presentation

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

The accompanying consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the ordinary course of business. The Company has incurred recurring losses since inception, including net losses of $29.5 million for the nine months ended September 30, 2022 and $44.2 million for the year ended December 31, 2021. As of September 30, 2022, the Company had an accumulated deficit of $472.0 million. The Company expects to continue to generate operating losses in the foreseeable future.

The Company believes that its existing cash and cash equivalents of $204.5 million as of September 30, 2022 will be sufficient to fund its operations, capital expenditures, and debt service payments for at least the next 12 months following the filing of this Quarterly Report on Form 10-Q. The Company may need to seek additional funding through equity financings, debt financings or strategic alliances. The Company may not be able to obtain financing on acceptable terms, or at all, and the terms of any financing may adversely affect the holdings or the rights of the Company’s shareholders. If the Company is unable to obtain funding, the Company will be required to delay, reduce or eliminate some or all of its research and development programs, product expansion or commercialization efforts, or the Company may be unable to continue operations.

The Company is subject to risks and uncertainties common to companies in the medical device industry and of similar size, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, uncertainty of market acceptance of products, and the need to obtain additional financing to fund operations. 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 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, prolonged pandemic-related disruptions 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, 2021 included in the Company’s Annual Report on Form 10-K filed with the SEC. In the opinion of management, all adjustments, consisting only of normal recurring adjustments necessary for a fair statement of the Company’s financial position as of September 30, 2022 and results of operations for the three and nine months ended September 30, 2022 and 2021 and cash flows for the nine months ended September 30, 2022 and 2021 have been made. The Company’s results of operations for the three and nine months ended September 30, 2022 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2022.

Use of Estimates

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

Risk of Concentrations of Credit, Significant Customers and Significant Suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash, cash equivalents, marketable securities, and accounts receivable. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships. As of September 30, 2022 and December 31, 2021, the Company had no allowance for credit losses.

Significant customers are those that accounted for 10% or more of the Company’s net revenue or accounts receivable. For the three months ended September 30, 2022, one customer accounted for 13% of net revenue. For the nine months ended September 30, 2022, one customer accounted for 15% of net revenue. For the three months ended September 30, 2021, two customers accounted for 16% and 12% of net revenue, respectively. For the nine months ended September 30, 2021, one customer accounted for 10% of net revenue. As of September 30, 2022, there were no customers that accounted for more than 10% of accounts receivable. As of December 31, 2021, two customers accounted for 21% and 15% of accounts receivable, respectively.

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

Fair Value Measurements

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

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

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

Segment Information

The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. The Company 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 and nine months ended September 30, 2022 and 2021.

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

	As of September 30,	
	2022	**2021**
Warrants to purchase common stock	64,440	64,440
Options to purchase common stock	3,309,558	2,757,648
Employee stock purchase plan	8,886	3,956
Restricted stock awards	24,315	—
	3,407,199	2,826,044

3. Marketable Securities

The Company did not have marketable securities as of September 30, 2022. Marketable securities by security type as of December 31, 2021 consisted of the following (in thousands):

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

4. Fair Value of Financial Assets and Liabilities

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

	Fair Value Measurements at September 30, 2022 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 182,091	$ —	$ —	$ 182,091
	$ 182,091	$ —	$ —	$ 182,091

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

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

5. Inventory

Inventory consisted of the following (in thousands):

	September 30, 2022	December 31, 2021
Raw materials	$ 9,439	$ 7,274
Work-in-process	1,721	1,932
Finished goods	7,415	5,653
	$ 18,575	$ 14,859

During the nine months ended September 30, 2022 and 2021, the Company made non-cash transfers of OCS Consoles from inventory to property and equipment (OCS Consoles loaned to customers) of $2.1 million and $0.9 million, respectively.

6. Accrued Expenses and Other Current Liabilities

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

	September 30, 2022	December 31, 2021
Accrued research, development and clinical trials expenses	$ 2,735	$ 4,567
Accrued payroll and related expenses	6,064	5,173
Accrued professional fees	1,424	1,973
Accrued other	5,753	4,624
	$ 15,976	$ 16,337

7. Long-Term Debt

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

	September 30, 2022	December 31, 2021
Principal amount of long-term debt	$ 60,000	$ 35,000
Less: Current portion of long-term debt	—	—
Long-term debt, net of current portion	60,000	35,000
Debt discount, net of accretion	(1,460)	(511)
Accrued end-of-term payment	—	708
Long-term debt, net of discount and current portion	$ 58,540	$ 35,197

OrbiMed Credit Agreement

The Company entered into a credit agreement with OrbiMed Royalty Opportunities II, LP (the “OrbiMed Credit Agreement”) in June 2018, pursuant to which TransMedics borrowed $35.0 million. Borrowings under the OrbiMed Credit Agreement bore interest at an annual rate equal to the London Interbank Offered Rate (“LIBOR”), subject to a minimum of 1.0% and a maximum of 4.0%, plus 8.5% (the “Applicable Margin”), subject in the aggregate to a maximum interest rate of 11.5%. In addition, borrowings under the OrbiMed Credit Agreement bore paid-in-kind (“PIK”) interest at an annual rate equal to the amount by which LIBOR plus the Applicable Margin exceeded 11.5%, but not to exceed 12.5%. The PIK interest was added to the principal amount of the borrowings outstanding at the end of each quarter until the repayment of the borrowings in July 2022. Borrowings under the OrbiMed Credit Agreement were repayable in quarterly interest-only payments until the maturity date, at which time all principal and accrued interest was due and payable. At its option, the company could prepay outstanding borrowings under the OrbiMed Credit Agreement. The Company was required to make a final payment in an amount equal to 3.0% of the principal amount of any prepayment or repayment. The final payment and debt discount amounts were being accreted to interest expense over the term of the OrbiMed Credit Agreement using the effective interest method.

In July 2022, the Company repaid amounts due under the OrbiMed Credit Agreement, 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.

Canadian Imperial Bank of Commerce Credit Agreement

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").

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. If certain revenue milestones are met after the first 24 months, the Company may 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 September 30, 2022, 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 September 30, 2022, the interest rate applicable to borrowings under the CIBC Credit Agreement was 4.5%. During the three months ended September 30, 2022, the weighted average effective interest rate on outstanding borrowings under the CIBC Credit Agreement was approximately 5.2%.

8. Stock-Based Compensation

2019 Stock Incentive Plan

The Company's 2019 Stock Incentive Plan (the "2019 Plan") provides for the grant of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock, restricted stock units, unrestricted stock, unrestricted stock units, and other stock-based awards to employees, directors, and consultants of the Company and its subsidiaries. The number of shares of common stock of TransMedics Group initially available for issuance under the 2019 Plan was 3,428,571 shares, plus the number of shares underlying awards under the previously outstanding 2014 Stock Incentive Plan (the "2014 Plan"), not to exceed 1,595,189 shares, that expire or are terminated, surrendered, or 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 future awards will be made under the 2014 Plan.

Shares withheld in payment of the exercise or purchase price of an award or in satisfaction of tax withholding requirements, and the shares covered by a stock appreciation right for which any portion is settled in stock, will reduce the number of shares available for issuance under the 2019 Plan. In addition, the number of shares available for issuance under the 2019 Plan (i) will not be increased by any shares delivered under the 2019 Plan that are subsequently repurchased using proceeds directly attributable to stock option exercises and (ii) will not be reduced by any awards that are settled in cash or that expire, become unexercisable, terminate or are forfeited to or repurchased by TransMedics Group without the issuance of stock under the 2019 Plan. As of September 30, 2022, 819,791 shares of common stock were available for issuance under the 2019 Plan.

2019 Employee Stock Purchase Plan

Pursuant to the Company's 2019 Employee Stock Purchase Plan (the "2019 ESPP"), certain employees of the Company are eligible to purchase common stock of the Company at a reduced price during offering periods. The 2019 ESPP permits participants to purchase common stock using funds contributed through payroll deductions, subject to the limitations set forth in the Internal Revenue Code, at a purchase price of 85% of the lower of the closing price of the Company's common stock on the first trading day of the offering period or the closing price on the applicable purchase date, which is the final trading day of the applicable offering period. A total of 371,142 shares of the Company's common stock are reserved for issuance under the 2019 ESPP. During the nine months ended September 30, 2022, 30,143 shares of common stock were issued under the 2019 ESPP and as of September 30, 2022, 290,453 shares of common stock remained available for issuance.

2021 Inducement Plan

In August 2021, the Company's board of directors approved the TransMedics Group, Inc. Inducement Plan (the "Inducement Plan"). Pursuant to the terms of the Inducement Plan, the Company may grant nonstatutory stock options, stock appreciation rights, restricted stock, unrestricted stock, restricted stock unit awards and performance awards to individuals who were not previously employees or directors of the Company or individuals returning to employment after a bona fide period of non-employment with the Company. A total of 1,000,000 shares of the Company's common stock were initially available for issuance under the Inducement Plan. As of September 30, 2022, 616,100 shares of common stock remained available for issuance under the Inducement Plan.

Stock Option Activity

During the nine months ended September 30, 2022, the Company granted options under the 2019 Plan and the Inducement Plan to its employees and directors with service-based vesting for the purchase of an aggregate of 1,057,510 shares of common stock with a weighted average grant-date fair value of $8.91 per share.

Restricted Common Stock Activity

During the nine months ended September 30, 2022, the Company granted shares of restricted common stock. Shares of unvested restricted common stock may not be sold or transferred by the holder. If the holder's service to the Company and its affiliates ceases for any reason, unvested shares of restricted common stock held by these individuals will immediately be forfeited for no consideration, as defined in the restricted stock agreement.

During the nine months ended September 30, 2022, the Company granted 26,093 shares of restricted common stock under the 2019 Plan to consultants with service-based vesting conditions and a weighted-average grant-date fair value of $28.74 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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Cost of revenue	$ 33	$ 20	$ 89	$ 52
Research, development and clinical trials expenses	394	312	1,079	829
Selling, general and administrative expenses	2,277	1,641	6,162	4,012
	$ 2,704	$ 1,973	$ 7,330	$ 4,893

As of September 30, 2022, total unrecognized compensation cost related to unvested share-based awards was $21.1 million, which is expected to be recognized over a weighted average period of 2.6 years.

9. Commitments and Contingencies

Operating Leases

The Company leases office, laboratory and manufacturing space under two non-cancelable operating leases. There have been no material changes to the Company's leases during the nine months ended September 30, 2022. For additional information, please read Note 12 *Leases,* to the consolidated financial statements in the Company's Form 10-K for the year ended December 31, 2021.

License Agreement with the Department of Veterans Affairs

In 2002, the Company entered into a license agreement with the Department of Veterans Affairs (the "VA"), under which the Company was granted an exclusive, worldwide license under specified patents to make, use, sell and import certain technology used in the Company's products and a non-exclusive, worldwide license to make, use, sell and import solutions for use in or with those products. The rights under the license agreement continued until the expiration of the last to expire of the licensed patents. The majority of the licensed U.S. patents expired in 2017, and the foreign patents expired in September 2018. However, the Company requested a patent term extension for one U.S. patent covered by the VA license agreement, U.S. Patent No. 6100082 (the "'082 patent"). The Company received a Notice of Final Determination on June 27, 2022 from the United States Patent and Trademark Office ("USPTO") finding the '082 patent's term extension expired on November 6, 2021, and as a result the license has terminated. The termination of the license is not expected to have a material impact on the Company's financial results.

As consideration for the licenses granted by the VA, the Company was obligated to pay tiered royalties ranging from a low single-digit to a mid single-digit percentage on net sales of each product covered by a licensed patent (subject to a minimum aggregate royalty payment of less than $0.1 million per year during each of the first five years after the first commercial sale, after which no minimum is required). Royalties were paid by the Company on a licensed product-by-licensed product and country-by-country basis, beginning on the first commercial sale of such licensed product in such country until expiration of the last valid patent claim covering such licensed product in such country. The Company was also responsible for all costs related to the amendment, prosecution and maintenance of the licensed patent rights. As all of the licensed patents expired as of November 6, 2021, the Company no longer has an obligation to pay royalties.

401(k) Savings Plan

The Company has a defined-contribution savings plan under Section 401(k) of the Internal Revenue Code. This plan covers substantially all employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. Company contributions to the plan may be made at the discretion of the board of directors. As of September 30, 2022 and December 31, 2021, the Company had not made any contributions to the plan.

Indemnification Agreements

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

The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not currently aware of any indemnification claims and had not accrued any liabilities related to such obligations in its consolidated financial statements as of September 30, 2022 and December 31, 2021.

Unconditional Purchase Commitment

In January 2021, the Company entered into an unconditional $9.5 million purchase commitment, in the ordinary course of business, for goods with specified annual minimum quantities to be purchased through December 2029. The contract is not cancellable without penalty. The remaining purchase commitment as of September 30, 2022 was $8.0 million.

Legal Proceedings

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

10. Segment Reporting and Geographic Data

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

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

	September 30, 2022	December 31, 2021
Long-lived assets by country(1):		
United States	$ 17,886	$ 9,085
All other countries	586	756
Total long-lived assets	$ 18,472	$ 9,841

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

11. Revenue

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Gross revenue from sales to customers	$ 24,303	$ 5,413	$ 60,704	$ 21,717
Less: clinical trial payments	(1,380)	43	(1,380)	1,123
Total net revenue	$ 25,683	$ 5,370	$ 62,084	$ 20,594

Clinical trial payments for the three and nine months ended September 30, 2022 include adjustments for certain clinical trial accrual estimates. 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 $0.5 million and $1.0 million for the three and nine months ended September 30, 2022, respectively, 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 $0.4 million and $1.6 million for the three and nine months ended September 30, 2021, respectively, as operating expenses.

Disaggregated Revenue

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Net revenue by OCS product:				
OCS Lung net revenue	$ 1,599	$ 2,522	$ 6,736	$ 8,524
OCS Heart net revenue	11,541	2,848	25,318	11,628
OCS Liver net revenue	12,543	—	30,030	442
Total net revenue	$ 25,683	$ 5,370	$ 62,084	$ 20,594

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Net revenue by country(1):				
United States	$ 23,285	$ 3,112	$ 54,984	$ 14,627
All other countries	2,398	2,258	7,100	5,967
Total net revenue	$ 25,683	$ 5,370	$ 62,084	$ 20,594

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

When a customer order includes disposable sets and organ retrieval or OCS organ management services, the Company has determined that the disposable sets and services constitute separate performance obligations and recognizes revenue as the disposable sets and services are delivered to the customer. Net revenue during the three and nine months ended September 30, 2022 included service revenue comprising approximately 17% and 13%, respectively, of net revenue relating to organ retrieval and OCS organ management services sold under the National OCS Program, the Company's turnkey solution to provide outsourced organ retrieval and OCS organ management.

Contract Assets and Liabilities

The Company recognizes a receivable at the point in time at which it has an unconditional right to payment. Such receivables are not contract assets. Contract assets arise from unbilled amounts in customer arrangements when revenue recognized exceeds the amount billed to the customer and the Company's right to payment is not just subject to the passage of time. The Company had no contract assets as of September 30, 2022 and December 31, 2021.

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

The Company generally satisfies performance obligations within one year of the contract inception date. As of September 30, 2022, the Company's wholly or partially unsatisfied performance obligations totaled $1.6 million and are expected to be completed within the next year.

12. Related Party Transactions

Employment of Dr. Amira Hassanein

Dr. Amira Hassanein, who serves as Product Director for the Company's OCS Lung program, is the sister of Dr. Waleed Hassanein, the Company's President and Chief Executive Officer and a member of the Company's board of directors. The Company paid Dr. Amira Hassanein approximately $0.1 million and $0.3 million in total compensation for the three and nine months ended September 30, 2022, respectively, and $0.1 million and $0.3 million in total compensation for the three and nine months ended September 30, 2021, respectively, for her services as an employee.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the year ended December 31, 2021, as filed with the SEC on March 1, 2022 ("2021 Form 10-K"). Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Item 1A. Risk Factors" section of this Quarterly Report on Form 10-Q and the "Item 1A. Risk Factors" section of our 2021 Form 10-K, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a commercial-stage medical technology company transforming organ transplant therapy for end-stage organ failure patients across multiple disease states. We developed the OCS to replace a decades-old standard of care that we believe is significantly limiting access to life-saving transplant therapy for hundreds of thousands of patients worldwide. Our innovative OCS technology replicates many aspects of the organ's natural living and functioning environment outside of the human body. As such, the OCS represents a paradigm shift that transforms organ preservation for transplantation from a static state to a dynamic environment that enables new capabilities, including organ optimization and assessment. We have developed our National OCS Program, a turnkey solution to provide outsourced organ retrieval and OCS organ management, to provide transplant programs with a more efficient process to procure donor organs with the OCS. We believe the use of the OCS 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 lung, heart and liver transplantations, making the OCS the only multi-organ technology platform. We have commercialized the OCS Lung and OCS Heart outside of the United States. All three of our products, OCS Lung, OCS Heart, and OCS Liver have received Pre-Market Approval, or PMA, from the Food and Drug Administration, or FDA, as follows:

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

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

Since our inception, we have incurred significant operating losses. Our ability to generate net revenue sufficient to achieve profitability will depend on the successful further development and commercialization of our products. We generated net revenue of $62.1 million and incurred a net loss of $29.5 million for the nine months ended September 30, 2022. We generated net revenue of $30.3 million and incurred a net loss of $44.2 million for the year ended December 31, 2021. As of September 30, 2022, we had an accumulated deficit of $472.0 million. We expect to continue to incur net losses for the foreseeable future as we focus on growing commercial sales of our products in both the United States and select non-U.S. markets, including growing our commercial team, which will pursue increasing commercial sales of our OCS products; growing our National OCS Program; scaling our manufacturing operations; building our commercial operations; developing the next generation OCS; continuing research, development and clinical trial efforts; seeking regulatory clearance for new products and product enhancements, including new indications, in both the United States and select non-U.S. markets; and operating as a public company. As a result, we will need substantial additional funding for expenses related to our operating activities, including selling, general and administrative expenses and research, development and clinical trials expenses.

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

As of September 30, 2022, we had cash and cash equivalents of $204.5 million. We believe that our cash and cash equivalents 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 and market prices, 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 difficulty in forecasting our financial results. A weak or declining economy also could strain our suppliers, possibly resulting in supply chain disruptions.

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. Continued impacts to our business as a result of COVID-19 may include 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

Net Revenue

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

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

Solutions. In some of those contracts, the promises also include an OCS Console, whether sold or loaned to the customer, as well as organ retrieval and OCS organ management services under our National OCS Program.

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.

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 delivered to the customer. Net revenue relating to organ retrieval and OCS organ management services sold under our National OCS Program represented approximately 17% of net revenue for the three months ended September 30, 2022 and 13% of net revenue for the nine months ended September 30, 2022.

Under some of our customer clinical trial agreements, we made payments to our customers for reimbursements of clinical trial materials and for specified clinical documentation related to their use of our OCS products. Because some of these payments did not provide us with a separately identifiable benefit, we recorded such payments as a reduction of revenue from the customer, resulting in our net revenue presentation.

Through September 30, 2022, 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 12 months.

We expect that our net revenue will increase over the long term as a result of receiving PMAs for the OCS Lung, OCS Heart and OCS Liver in the United States. We also expect that our net revenue will increase over the long term as a result of anticipated growth in non-U.S. sales if national healthcare systems begin to reimburse transplant centers for the use of the OCS, if transplant centers utilize the OCS in more transplant cases, and if more transplant centers adopt the OCS in their programs.

Cost of Revenue, Gross Profit and Gross Margin

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

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

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

Operating Expenses

Research, Development and Clinical Trials Expenses

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

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

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

Selling, General and Administrative Expenses

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

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

Other Income (Expense)

Interest Expense

Interest expense consists of interest expense associated with outstanding borrowings under our loan 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 September 30, 2022 and 2021

The following table summarizes our results of operations for the three months ended September 30, 2022 and 2021:

	Three Months Ended September 30,		
	2022	2021	Change
		(in thousands)	
Net revenue	$ 25,683	$ 5,370	$ 20,313
Cost of revenue	7,568	1,597	5,971
Gross profit	18,115	3,773	14,342
Operating expenses:			
Research, development and clinical trials	6,808	5,163	1,645
Selling, general and administrative	16,851	10,335	6,516
Total operating expenses	23,659	15,498	8,161
Loss from operations	(5,544)	(11,725)	6,181
Other income (expense):			
Interest expense	(787)	(979)	192
Other expense, net	(1,076)	(249)	(827)
Total other expense, net	(1,863)	(1,228)	(635)
Loss before income taxes	(7,407)	(12,953)	5,546
Provision for income taxes	(19)	(9)	(10)
Net loss	$ (7,426)	$ (12,962)	$ 5,536

Net Revenue

	Three Months Ended September 30,		
	2022	2021	Change
		(in thousands)	
Net revenue by geography:			
United States	$ 23,285	$ 3,112	$ 20,173
Outside the U.S.	2,398	2,258	140
Total net revenue	$ 25,683	$ 5,370	$ 20,313
Net revenue by OCS product:			
OCS Lung net revenue	$ 1,599	$ 2,522	$ (923)
OCS Heart net revenue	11,541	2,848	8,693
OCS Liver net revenue	12,543	—	12,543
Total net revenue	$ 25,683	$ 5,370	$ 20,313

Net revenue from customers in the United States was $23.3 million in the three months ended September 30, 2022 and increased by $20.2 million compared to the three months ended September 30, 2021, primarily due to higher sales volumes of our OCS Liver and OCS Heart disposable sets as a result of the FDA approval for these two products in the third quarter of 2021 along with the expansion of our National OCS Program to provide a streamlined solution for transplant centers to use the OCS for all FDA-approved indications for lung, heart and liver. The increase in OCS Liver and OCS Heart net revenue was partially offset by lower sales volumes of our OCS Lung disposable sets. Net revenue from customers who participated in our National OCS Program accounted for approximately 90% of total net revenue from customers in the United States for the three months ended September 30, 2022. Net revenue for each of our disposable products in the table above includes net revenue from sales of disposable sets as well as service revenue for organ retrieval and OCS organ management services under the National OCS Program. Net revenue relating to organ retrieval and OCS organ management services sold under our National OCS Program represented approximately 17% of net revenue for the three months ended September 30, 2022. Net revenue from sales of OCS Liver disposable sets in the United States increased by $12.5 million due primarily to higher sales volumes of OCS Liver disposable sets resulting from the recent FDA approval of the OCS Liver product. Net revenue from sales of OCS Heart disposable sets in the United States increased by $8.5 million also primarily as a result of the FDA approval of the OCS Heart in the third quarter of 2021 and the additional DCD Heart PMA supplement indication approved by the FDA in April 2022. Net revenue from sales of OCS Lung disposable sets in the United States decreased by $0.9 million due to a decrease in sales volumes of OCS Lung disposable sets.

Net revenue from customers outside the United States was $2.4 million in the three months ended September 30, 2022 and increased by $0.1 million compared to the three months ended September 30, 2021. Net revenue outside of the United States increased for the three months ended September 30, 2022 compared to the three months ended September 30, 2021 due to increased pricing. This increase was partially offset by an unfavorable impact of foreign exchange rates of $0.3 million.

Cost of Revenue, Gross Profit and Gross Margin

Cost of revenue increased by $6.0 million in the three months ended September 30, 2022 compared to the three months ended September 30, 2021. Gross profit increased by $14.3 million in the three months ended September 30, 2022 compared to the three months ended September 30, 2021. Gross profit in the three months ended September 30, 2022 included a favorable impact of $1.4 million as a result of changes in estimates of certain clinical trial accruals. Gross margin was 71% and 70% for the three months ended September 30, 2022 and 2021, respectively.

Operating Expenses

Research, Development and Clinical Trials Expenses

	Three Months Ended September 30,		
	2022	**2021**	**Change**
		(in thousands)	
Personnel related (including stock-based compensation expense)	$ 2,351	$ 2,141	$ 210
Clinical trials costs	630	738	(108)
Consulting and third-party testing	815	720	95
Laboratory supplies and research materials	1,581	593	988
Other	1,431	971	460
Total research, development and clinical trials expenses	$ 6,808	$ 5,163	$ 1,645

Total research, development and clinical trials expenses increased by $1.6 million from $5.2 million in the three months ended September 30, 2021 to $6.8 million in the three months ended September 30, 2022. Laboratory supplies and research materials and other costs increased by $1.0 million and $0.5 million, respectively, due to increased activity in our next generation program and ongoing existing research activities.

Selling, General and Administrative Expenses

	Three Months Ended September 30,		
	2022	2021	Change
	(in thousands)		
Personnel related (including stock-based compensation expense)	$ 9,961	$ 5,607	$ 4,354
Professional and consultant fees	1,789	1,638	151
Tradeshows and conferences	838	246	592
Other	4,263	2,844	1,419
Total selling, general and administrative expenses	$ 16,851	$ 10,335	$ 6,516

Total selling, general and administrative expenses increased by $6.5 million from $10.3 million in the three months ended September 30, 2021 to $16.9 million in the three months ended September 30, 2022 due to increases in personnel related costs, professional and consultant fees, tradeshows and conferences and other costs. Personnel related costs increased by $4.4 million primarily due to the continued expansion of our team to support the National OCS Program and commercial growth of our OCS Lung, OCS Heart and OCS Liver products in the United States, as well as an increase in stock-based compensation expense of $0.6 million due primarily to additional grants to new and existing employees. Tradeshows and conferences costs increased by $0.6 million as a result of an increase in in-person activities as restrictions implemented in response to the COVID-19 pandemic were eased. Other costs increased by $1.4 million due to increased start-up and logistics costs related to the expansion of our National OCS Program.

Other Income (Expense)

Interest Expense

Interest expense was $0.8 million and $1.0 million for the three months ended September 30, 2022 and 2021, respectively. The increase in principal under our new debt agreement was more than offset by a lower interest rate on our new debt.

Other Expense, Net

Other expense, net for the three months ended September 30, 2022 and 2021 included interest income of $0.4 million and less than $0.1 million, respectively, from interest earned on invested cash balances, and $0.9 million and $0.3 million of realized and unrealized foreign currency transactions losses, respectively. Other expense, net for the three months ending September 30, 2022 also includes a loss on extinguishment of debt of $0.6 million.

Comparison of the Nine Months Ended September 30, 2022 and 2021

The following table summarizes our results of operations for the nine months ended September 30, 2022:

	Nine Months Ended September 30,		
	2022	2021	Change
	(in thousands)		
Net revenue	$ 62,084	$ 20,594	$ 41,490
Cost of revenue	17,515	6,421	11,094
Gross profit	44,569	14,173	30,396
Operating expenses:			
Research, development and clinical trials	21,056	15,990	5,066
Selling, general and administrative	48,171	26,283	21,888
Total operating expenses	69,227	42,273	26,954
Loss from operations	(24,658)	(28,100)	3,442
Other income (expense):			
Interest expense	(2,719)	(2,896)	177
Other expense, net	(2,087)	(532)	(1,555)
Total other expense, net	(4,806)	(3,428)	(1,378)
Loss before income taxes	(29,464)	(31,528)	2,064
Provision for income taxes	(47)	(19)	(28)
Net loss	$ (29,511)	$ (31,547)	$ 2,036

Net Revenue

	Nine Months Ended September 30,		
	2022	2021	Change
	(in thousands)		
Net revenue by geography:			
United States	$ 54,984	$ 14,627	$ 40,357
Outside the U.S.	7,100	5,967	1,133
Total net revenue	$ 62,084	$ 20,594	$ 41,490
Net revenue by OCS product:			
OCS Lung net revenue	$ 6,736	$ 8,524	$ (1,788)
OCS Heart net revenue	25,318	11,628	13,690
OCS Liver net revenue	30,030	442	29,588
Total net revenue	$ 62,084	$ 20,594	$ 41,490

Net revenue from customers in the United States was $55.0 million in the nine months ended September 30, 2022 and increased by $40.4 million compared to the nine months ended September 30, 2021, primarily due to higher sales volumes of our OCS Liver and OCS Heart disposable sets as a result of the FDA approval for these two products in the third quarter of 2021 along with the expansion of our National OCS Program to provide a streamlined solution for transplant centers to use the OCS for all FDA-approved indications for lung, heart and liver. The increase in OCS Liver and OCS Heart net revenue was partially offset by lower sales volumes of our OCS Lung disposable sets. Net revenue from customers who participated in our National OCS Program accounted for approximately 85% of total net revenue from customers in the United States for the nine months ended September 30, 2022. Net revenue for each of our disposable products in the table above includes net revenue from sales of disposable sets as well as service revenue for organ retrieval and OCS organ management services under the National OCS Program. Net revenue relating to organ retrieval and OCS organ management services sold under our National OCS Program represented 13% of net revenue for the nine months ended September 30, 2022. Net revenue from sales of OCS Liver disposable sets in the United States increased by $29.6 million due primarily to higher sales volumes of OCS Liver disposable sets resulting from the recent FDA approval of the OCS Liver product. Net revenue from sales of OCS Heart disposable sets in the United States increased by $12.8 million also primarily as a result of the FDA approval of the OCS Heart in the third quarter of 2021 and the additional DCD Heart PMA supplement indication approved by the FDA in April 2022. Net revenue from sales of OCS Lung disposable sets in the United States decreased by $2.0 million due to a decrease in sales volumes of OCS Lung disposable sets.

Net revenue from customers outside the United States was $7.1 million in the nine months ended September 30, 2022 compared to $6.0 million in the nine months ended September 30, 2021. The increase in net revenue from customers outside the United States was primarily due to a progressive return to pre-COVID-19 volumes of transplant procedures in the European market. Net revenue from sales of OCS Heart disposable sets and OCS Lung disposable sets outside the United States increased due to higher sales volumes and to a lesser extent price increases. The increase in net revenue outside of the United States was partially offset by an unfavorable impact of foreign exchange rates of $2.4 million.

Cost of Revenue, Gross Profit and Gross Margin

Cost of revenue increased by $11.1 million in the nine months ended September 30, 2022 compared to the nine months ended September 30, 2021. Gross profit increased by $30.4 million in the nine months ended September 30, 2022 compared to the nine months ended September 30, 2021. Gross profit in the nine months ended September 30, 2022 included a favorable impact of $1.4 million as a result of changes in estimates of certain clinical trial accruals. Gross margin was 72% and 69% for the nine months ended September 30, 2022 and 2021, respectively. Gross margin increased primarily as a result of economies of scale from higher sales volumes, partially offset by the unfavorable impact of foreign exchange rates.

Operating Expenses

Research, Development and Clinical Trials Expenses

	Nine Months Ended September 30,		
	2022	2021	Change
	(in thousands)		
Personnel related (including stock-based compensation expense)	$ 6,851	$ 6,357	$ 494
Clinical trials costs	1,738	2,786	(1,048)
Consulting and third-party testing	4,448	2,091	2,357
Laboratory supplies and research materials	4,209	2,091	2,118
Other	3,810	2,665	1,145
Total research, development and clinical trials expenses	$ 21,056	$ 15,990	$ 5,066

Total research, development and clinical trials expenses increased by $5.1 million from $16.0 million in the nine months ended September 30, 2021 to $21.1 million in the nine months ended September 30, 2022. Personnel related costs increased by $0.5 million primarily due to an increase in stock-based compensation expense of $0.3 million related to additional grants to new and existing employees. Consulting and third-party testing, laboratory supplies and research materials and other costs increased by $2.4 million, $2.1 million and $1.1 million, respectively, due to increased activity in our next generation program and ongoing existing research activities. Clinical trial costs decreased by $1.0 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

	Nine Months Ended September 30, 2022	2021	Change
	(in thousands)		
Personnel related (including stock-based compensation expense)	$ 27,557	$ 14,379	$ 13,178
Professional and consultant fees	6,018	4,908	1,110
Tradeshows and conferences	2,478	1,051	1,427
Other	12,118	5,945	6,173
Total selling, general and administrative expenses	$ 48,171	$ 26,283	$ 21,888

Total selling, general and administrative expenses increased by $21.9 million from $26.3 million in the nine months ended September 30, 2021 to $48.2 million in the nine months ended September 30, 2022 due to increases in personnel related costs, professional and consultant fees, tradeshows and conferences and other costs. Personnel related costs increased by $13.2 million primarily due to the continued expansion of our team to support the National OCS Program and commercial growth of our OCS Heart and OCS Liver products in the United States, as well as an increase in stock-based compensation expense of $2.2 million due primarily to additional grants to new and existing employees. Professional and consultant fees increased by $1.1 million due to additional sales and administration costs related to the expansion of our National OCS Program. Tradeshows and conferences costs increased by $1.4 million as a result of an increase in in-person activities as restrictions implemented in response to the COVID-19 pandemic were eased. Other costs increased by $6.2 million due to increased start-up and logistics costs related to the expansion of our National OCS Program.

Other Income (Expense)

Interest Expense

Interest expense was $2.7 million and $2.9 million for the nine months ended September 30, 2022 and 2021, respectively. The increase in principal under our new debt agreement was more than offset by a lower interest rate on our new debt.

Other Expense, Net

Other expense, net for the nine months ended September 30, 2022 and 2021 included interest income of $0.4 million and $0.1 million, respectively, resulting from interest earned on invested cash balances, and $1.9 million and $0.6 million of realized and unrealized foreign currency transactions losses, respectively. Other expense, net for the nine months ending September 30, 2022 also includes a loss on extinguishment of debt of $0.6 million.

Liquidity and Capital Resources

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.

On August 9, 2022 we completed an underwritten public offering of our common stock, which resulted in the sale of 3,737,500 shares of common stock, inclusive of 487,500 shares we sold pursuant to the full exercise of the underwriters' option to purchase additional shares. The aggregate net proceeds received by us from the offering were approximately $139.9 million, after deducting underwriting discounts and commissions as well as other offering costs of $0.7 million.

As of September 30, 2022, we had cash and cash equivalents of $204.5 million.

Cash Flows

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

	Nine Months Ended September 30, 2022	Nine Months Ended September 30, 2021
	(in thousands)	
Net cash used in operating activities	$ (41,782)	$ (22,216)
Net cash provided by investing activities	57,277	19,275
Net cash provided by financing activities	164,862	1,348
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(1,475)	(493)
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 178,882	$ (2,086)

Operating Activities

During the nine months ended September 30, 2022, operating activities used $41.8 million of cash, primarily resulting from our net loss of $29.5 million and net cash used by changes in our operating assets and liabilities of $25.4 million, partially offset by net non-cash charges of $13.2 million. Net cash used by changes in our operating assets and liabilities for the nine months ended September 30, 2022 consisted primarily of an increase in accounts receivable of $16.3 million, an increase in inventory of $6.1 million, and a decrease in accounts payable and accrued expenses and other current liabilities of $3.5 million, partially offset by an increase in operating lease liabilities of $0.6 million.

During the nine months ended September 30, 2021, operating activities used $22.2 million of cash, primarily resulting from our net loss of $31.5 million, partially offset by net cash provided by changes in our operating assets and liabilities of $1.0 million and net non-cash charges of $8.3 million. Net cash provided by changes in our operating assets and liabilities for the nine months ended September 30, 2021 consisted primarily of a decrease in accounts receivable of $2.7 million and an increase in accounts payable and accrued expenses and other current liabilities of $3.6 million, partially offset by an increase in inventory of $4.0 million and an increase in prepaid expenses and other current assets of $1.4 million.

Investing Activities

During the nine months ended September 30, 2022, net cash provided by investing activities of $57.3 million consisted of proceeds from sales and maturities of marketable securities of $76.9 million, partially offset by purchases of marketable securities of $10.5 million and purchases of property and equipment of $9.1 million.

During the nine months ended September 30, 2021, net cash provided by investing activities of $19.3 million consisted of proceeds from sales and maturities of marketable securities of $86.3 million, partially offset by purchases of marketable securities of $66.7 million and purchases of property and equipment of $0.3 million.

Financing Activities

During the nine months ended September 30, 2022, net cash provided by financing activities of $164.9 million consisted of net proceeds from our public offering of $140.0 million, proceeds from the issuance of long-term debt, net of issuance costs of $58.5 million, proceeds from the issuance of common stock upon exercise of stock options of $1.9 million and proceeds from the issuance of common stock in connection with the 2019 Employee Stock Purchase Plan of $0.5 million, partially offset by the repayments of long-term debt of $36.1 million.

During the nine months ended September 30, 2021, net cash provided by financing activities of $1.3 million consisted of proceeds from the issuance of common stock upon exercise of stock options of $0.9 million and proceeds from the issuance of common stock in connection with the employee stock purchase plan of $0.4 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, 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. If certain revenue milestones are met after the first 24 months, we may 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 September 30, 2022, 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 National OCS Program, scale our manufacturing and sterilization operations, continue research, development and clinical trial efforts, and seek regulatory approval for new products and product enhancements, including new indications, both in the United States and in select non-U.S. markets. 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 revenue generated by sales of our OCS Consoles, OCS disposable sets and other products that may be approved in the United States and select non-U.S. markets;
- the costs and expenses of expanding our U.S. and non-U.S. sales and marketing infrastructure and our manufacturing operations;
- the extent to which our OCS products are adopted by the transplant community;
- the ability of our customers to obtain adequate reimbursement from third-party payors for procedures performed using the OCS products;
- the degree of success we experience in commercializing our OCS products for additional indications;
- the costs, timing and outcomes of post-approval studies or any future clinical studies and regulatory reviews, including to seek and obtain approvals for new indications for our OCS products;

- the emergence of competing or complementary technologies 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;
- 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 and cash equivalents will enable us to fund our operating expenses, capital expenditure requirements, and debt service payments for at least 12 months following the filing of this Quarterly Report on Form 10-Q.

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

Critical Accounting Policies and Significant Judgments and Estimates

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

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

Recently Issued Accounting Pronouncements

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

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

We are exposed to changes in interest rates and foreign currency exchange rates because we finance certain operations through variable rate debt instruments, hold investments and denominate our transactions in a variety of foreign currencies. Changes in these rates may have an impact on future cash flow and earnings. We manage these risks through normal operating and financing activities. There has been no material change in the foreign currency exchange risk or interest rate risk discussed in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in our 2021 Form 10-K.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our President and Chief Executive Officer and our Chief Financial Officer (our principal executive officer and principal financial and accounting officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2022. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2022, our President and Chief Executive Officer and our Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three months ended September 30, 2022 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We are not currently subject to any material legal proceedings.

Item 1A. Risk Factors

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

Our existing and any future indebtedness could adversely affect our ability to operate our business.

As of September 30, 2022, our outstanding principal balance of long-term debt under our credit agreement with Canadian Imperial Bank of Commerce, or CIBC, was $60.0 million, which we refer to as the CIBC Credit Agreement. We could incur additional indebtedness in the future. Our payment obligations under the CIBC Credit Agreement reduce cash available to fund working capital, capital expenditures, research and development and general corporate needs. In addition, indebtedness under the CIBC Credit Agreement bears interest at a variable rate, making us vulnerable to increases in market interest rates. If market rates increase substantially, we will have to pay additional interest on this indebtedness, which would further reduce cash available for our other business needs. We may not have sufficient funds, and may be unable to arrange for additional financing, to pay the amounts due under or refinance our indebtedness under the CIBC Credit Agreement, which matures in July 2027.

Our obligations under the CIBC Credit Agreement are secured by substantially all of our assets and the assets of our wholly-owned material subsidiaries. The security interest granted over our assets could limit our ability to obtain additional debt financing. In addition, the CIBC Credit Agreement contains covenants requiring certain financial performance metrics and restricting our activities, including (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. Failure to comply with the covenants in the CIBC Credit Agreement, including the financial covenants, could result in the acceleration of our obligations under the CIBC Credit Agreement, which are also subject to acceleration upon the occurrence of specified events of default, including payment default, change in control, bankruptcy, insolvency, certain defaults under other material debt, certain events with respect to regulatory approvals and a material adverse change in our business, operations or other financial condition. If an event of default (other than certain events of bankruptcy or insolvency) occurs and is continuing, 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. If such acceleration were to occur, it would materially and adversely affect our business, financial condition, operating results, cash flows and prospects.

Our outstanding indebtedness and any future indebtedness, combined with our other financial obligations, could increase our vulnerability to adverse changes in general economic, industry and market conditions, limit our flexibility in planning for, or reacting to, changes in our business and the industry and impose a competitive disadvantage compared to our competitors that have less debt or better debt servicing options. See "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—Long-term Debt" in this Quarterly Report on Form 10-Q.

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

None.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Description
10.1	Credit Agreement, dated as of July 25, 2022, by and among TransMedics Group, Inc., the lenders party thereto and Canadian Imperial Bank of Commerce, as administrative agent and collateral agent (incorporated by reference to the Registrant’s Current Report on Form 8-K (File No. 001-38891) filed with the SEC on July 29, 2022).
10.2	Guarantee and Collateral Agreement, dated as of July 25, 2022, by and among TransMedics Group, Inc., TransMedics, Inc., TransMedics B.V. and Canadian Imperial Bank of Commerce (incorporated by reference to the Registrant’s Current Report on Form 8-K (File No. 001-38891) filed with the SEC on July 29, 2022).
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: November 4, 2022	TRANSMEDICS GROUP, INC.
	By: /s/ Waleed H. Hassanein, M.D. Waleed H. Hassanein, M.D. President and Chief Executive Officer (Principal Executive Officer)
Date: November 4, 2022	By: /s/ Stephen Gordon Stephen Gordon Chief Financial Officer, Treasurer and Secretary (Principal Financial and Accounting Officer)

Exhibit 31.1

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

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

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

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

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

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

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

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

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

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

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

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

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

Date: November 4, 2022

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

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

Exhibit 31.2

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

I, Stephen Gordon, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 4, 2022

/s/ Stephen Gordon

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

Exhibit 32.1

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

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of TransMedics Group, Inc. (the “Company”) for the period ended September 30, 2022, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), the undersigned, Waleed Hassanein, M.D., President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

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

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

Date: November 4, 2022

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

Exhibit 32.2

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

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of TransMedics Group, Inc. (the “Company”) for the period ended September 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), the undersigned, Stephen Gordon, Chief Financial Officer, Treasurer and Secretary of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

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

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

Date: November 4, 2022

By:/s/ Stephen Gordon

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