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 June 30, 2021

OR

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

For the transition period from _____ to _____

Commission File Number: 001-38891

TransMedics Group, Inc.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

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

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

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

As of July 31, 2021, the registrant had 27,677,048 shares of common stock, no par value per share, outstanding.

FORWARD-LOOKING STATEMENTS

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

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

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

- that we continue to incur losses;
- our need to raise additional funding;
- our existing and any future indebtedness, including our ability to comply with affirmative and negative covenants under our credit agreement to which we will remain subject to until maturity, and our ability to obtain additional financing on favorable terms or at all;
- the fluctuation of our financial results from quarter to quarter;
- our ability to use net operating losses and research and development credit carryforwards;
- our dependence on the success of the Organ Care System, or OCS;
- the rate and degree of market acceptance of the OCS;
- our ability to educate patients, surgeons, transplant centers and private and public payors of benefits offered by the OCS;
- the impact of the outbreak of the novel strain of coronavirus, or COVID-19, and associated containment, remediation and vaccination efforts;
- our ability to improve the OCS platform;
- our dependence on a limited number of customers for a significant portion of our net revenue;
- the timing of and our ability to obtain and maintain regulatory approvals or clearances for our OCS products;
- our ability to adequately respond to the Food and Drug Administration, or FDA, follow-up inquiries in a timely manner;
- the timing of and our ability to commercialize and market our OCS products;
- the performance of our third-party suppliers and manufacturers;
- the timing or results of clinical trials for the OCS;
- our manufacturing, sales, marketing and clinical support capabilities and strategy;
- attacks against our information technology infrastructure;
- the economic, political and other risks associated with our foreign operations;
- our ability to attract and retain key personnel;

- our ability to protect, defend, maintain and enforce our intellectual property rights relating to the OCS and avoid allegations that our products infringe, misappropriate or otherwise violate the intellectual property rights of third parties;
- the pricing of the OCS, as well as the reimbursement coverage for the OCS in the United States and internationally;
- regulatory developments in the United States, European Union and other jurisdictions;
- the extent and success of competing products that are or may become available;
- the impact of any product recalls or improper use of our products;
- our use of proceeds from our equity offerings; and
- our estimates regarding revenues, expenses and needs for additional financing.

TransMedics Group, Inc.
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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)

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

	June 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 25,314	$ 24,581
Marketable securities	86,935	101,061
Accounts receivable	6,271	6,864
Inventory	13,007	11,934
Prepaid expenses and other current assets	3,525	2,326
Total current assets	135,052	146,766
Property and equipment, net	4,954	4,754
Restricted cash	500	500
Other long-term assets	6	6
Total assets	$ 140,512	$ 152,026
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,389	$ 1,206
Accrued expenses and other current liabilities	12,100	10,317
Deferred revenue	473	263
Current portion of deferred rent	117	93
Total current liabilities	15,079	11,879
Long-term debt, net of discount and current portion	34,921	34,657
Deferred rent, net of current portion	1,529	1,599
Total liabilities	51,529	48,135
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, no par value; 25,000,000 shares authorized; no shares issued or outstanding	—	—
Common stock, no par value; 150,000,000 shares authorized; 27,647,234 shares and 27,175,305 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	505,933	502,217
Accumulated other comprehensive loss	(134)	(95)
Accumulated deficit	(416,816)	(398,231)
Total stockholders' equity	88,983	103,891
Total liabilities and stockholders' equity	$ 140,512	$ 152,026

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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Net revenue	$ 8,171	$ 3,391	$ 15,224	$ 10,921
Cost of revenue	2,582	1,482	4,824	4,152
Gross profit	5,589	1,909	10,400	6,769
Operating expenses:				
Research, development and clinical trials	6,295	3,903	10,827	10,128
Selling, general and administrative	9,162	5,867	15,948	12,519
Total operating expenses	15,457	9,770	26,775	22,647
Loss from operations	(9,868)	(7,861)	(16,375)	(15,878)
Other income (expense):				
Interest expense	(965)	(1,001)	(1,917)	(2,043)
Other income (expense), net	171	371	(283)	588
Total other expense, net	(794)	(630)	(2,200)	(1,455)
Loss before income taxes	(10,662)	(8,491)	(18,575)	(17,333)
Provision for income taxes	(6)	(6)	(10)	(16)
Net loss	$ (10,668)	$ (8,497)	$ (18,585)	$ (17,349)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.39)	$ (0.36)	$ (0.68)	$ (0.78)
Weighted average common shares outstanding, basic and diluted	27,620,764	23,330,918	27,495,125	22,259,047

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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Net loss	$ (10,668)	$ (8,497)	$ (18,585)	$ (17,349)
Other comprehensive income (loss):				
Foreign currency translation adjustment	(27)	(42)	(29)	(26)
Unrealized gains (losses) on marketable securities, net of tax of $0	(18)	(149)	(10)	64
Total other comprehensive income (loss)	(45)	(191)	(39)	38
Comprehensive loss	$ (10,713)	$ (8,688)	$ (18,624)	$ (17,311)

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 Income (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

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 Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balances at December 28, 2019	21,184,524	$ 424,134	$ (2)	$ (369,483)	$ 54,649
Issuance of common stock upon the exercise of common stock options	146,793	75	—	—	75
Issuance of common stock in connection with employee stock purchase plan	12,163	197	—	—	197
Stock-based compensation expense	—	385	—	—	385
Foreign currency translation adjustment	—	—	16	—	16
Unrealized gains on marketable securities	—	—	213	—	213
Net loss	—	—	—	(8,852)	(8,852)
Balances at March 31, 2020	21,343,480	424,791	227	(378,335)	46,683
Issuance of common stock upon the exercise of common stock options	42,882	92	—	—	92
Issuance of common stock in public offering, net of discounts and issuance costs of $628	5,750,000	75,042	—	—	75,042
Stock-based compensation expense	—	631	—	—	631
Foreign currency translation adjustment	—	—	(42)	—	(42)
Unrealized losses on marketable securities	—	—	(149)	—	(149)
Net loss	—	—	—	(8,497)	(8,497)
Balances at June 30, 2020	27,136,362	$ 500,556	$ 36	$ (386,832)	$ 113,760

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

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

	Six Months Ended June 30,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (18,585)	$ (17,349)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	896	745
Stock-based compensation expense	2,920	1,016
Non-cash interest expense and end of term accretion expense	264	249
Net amortization of premiums on marketable securities	767	49
Unrealized foreign currency transaction (gains) losses	314	(131)
Changes in operating assets and liabilities:		
Accounts receivable	560	2,135
Inventory	(1,894)	(1,409)
Prepaid expenses and other current assets	(1,209)	(324)
Accounts payable	938	(3,827)
Accrued expenses and other current liabilities	1,990	660
Deferred revenue	219	848
Deferred rent	(46)	623
Net cash used in operating activities	(12,866)	(16,715)
Cash flows from investing activities:		
Purchases of property and equipment	(273)	(397)
Purchases of marketable securities	(45,461)	(63,637)
Proceeds from sales and maturities of marketable securities	58,810	36,025
Net cash provided by (used in) investing activities	13,076	(28,009)
Cash flows from financing activities:		
Payments of public offering costs and other financing costs	—	(339)
Proceeds from issuance of common stock in public offering, net of underwriting discounts and commissions	—	75,670
Proceeds from issuance of common stock upon exercise of stock options	585	167
Proceeds from issuance of common stock in connection with employee stock purchase plan	211	197
Proceeds from Paycheck Protection Program loan	—	2,249
Repayment of Paycheck Protection Program loan	—	(2,249)
Net cash provided by financing activities	796	75,695
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(273)	89
Net increase in cash, cash equivalents and restricted cash	733	31,060
Cash, cash equivalents and restricted cash, beginning of period	25,081	20,592
Cash, cash equivalents and restricted cash, end of period	$ 25,814	$ 51,652
Supplemental disclosure of non-cash investing and financing activities:		
Transfers of inventory to property and equipment	$ 765	$ 78
Purchases of property and equipment included in accounts payable and accrued expenses	$ 70	$ 47
Offering costs included in accounts payable and accrued expenses	$ —	$ 409
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$ 25,314	$ 51,152
Restricted cash	500	500
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	$ 25,814	$ 51,652

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 attributable to the Company of $18.6 million for the six months ended June 30, 2021 and $28.7 million for the year ended December 31, 2020. As of June 30, 2021, the Company had an accumulated deficit of $416.8 million. The Company expects to continue to generate operating losses in the foreseeable future.

The Company believes that its existing cash, cash equivalents, and marketable securities of $112.2 million as of June 30, 2021 will be sufficient to fund its operations, capital expenditures, and debt service payments for at least the next 12 months following the filing of this Quarterly Report on Form 10-Q. The Company may need to seek additional funding through equity financings, debt financings or strategic alliances. The Company may not be able to obtain financing on acceptable terms, or at all, and the terms of any financing may adversely affect the holdings or the rights of the Company's shareholders. If the Company is unable to obtain funding, the Company will be required to delay, reduce or eliminate some or all of its research and development programs, product expansion or commercialization efforts, or the Company may be unable to continue operations.

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

The impact of the COVID-19 pandemic has been and will likely continue to be extensive in many aspects of society, which has resulted in and will likely continue to result in significant disruptions to the global economy, as well as businesses and capital markets around the world. Impacts to the Company's business as a result of COVID-19 include: the temporary disruption of transplant procedures at many of the organ transplant centers that purchase OCS products; customer delays or reductions in customer capital expenditures and operating budgets and the related impact on our product sales; disruptions to the Company's manufacturing operations and supply chain caused by facility closures, reductions in operating hours, staggered shifts and other social distancing efforts; labor shortages; decreased productivity and unavailability of materials or components; restrictions on or delays of the Company's clinical trials and studies; delays of reviews and approvals by the Food and Drug Administration ("FDA") and other health authorities, including with respect to the Company's OCS Heart Pre-Market Approval ("PMA") application; limitations on its employees' and customers' ability to travel, and delays in product installations, trainings or shipments to and from affected countries and within the United States. In addition, the Company's sales and clinical adoption team was restricted in visiting many transplant centers in person between April 2020 and September 2020. In response to the pandemic, healthcare providers have, and may need to further, reallocate resources, such as physicians, staff, hospital beds and intensive care unit facilities, and these actions significantly delay the provision of other medical care such as organ transplantation and reduce the number of transplant procedures that are performed, which negatively impacts the Company's revenue and clinical trial activities.

Starting in May 2020, the Company resumed manufacturing and distribution operations to pre-COVID levels. OCS product sales were negatively impacted by the COVID-19 pandemic from the second quarter of 2020 through the second quarter of 2021 and the Company anticipates a negative impact to OCS product sales to continue through 2021. The extent of the future impact on the Company's operations and financial condition will depend on the length and severity of the pandemic, its consequences, the effects of any variants as new strains evolve and containment and vaccination efforts. While the FDA approved emergency use authorization of vaccines starting in December 2020 and vaccination efforts have been ongoing in the United States, it is not yet fully known how vaccination efforts will impact the COVID-19 pandemic, including with respect to the duration of the efficacy of the vaccines, their effectiveness against the Delta variant or any other variants as new strains of the virus evolve.

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, 2020 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 June 30, 2021 and results of operations for the three and six months ended June 30, 2021 and 2020 and cash flows for the six months ended June 30, 2021 and 2020 have been made. The Company's results of operations for the three and six months ended June 30, 2021 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2021.

Use of Estimates

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

Risk of Concentrations of Credit, Significant Customers and Significant Suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash, cash equivalents, marketable securities, and accounts receivable. The Company has not experienced any other-than-temporary losses with respect to its cash, cash equivalents, and marketable securities and does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

Significant customers are those that accounted for 10% or more of the Company's net revenue or accounts receivable. For the three months ended June 30, 2021, no customer accounted for 10% or more of net revenue. For the six months ended June 30, 2021, one customer accounted for 10% of net revenue. For the three and six months ended June 30, 2020, one customer accounted for 17% and 11% of net revenue, respectively. As of June 30, 2021, no customer accounted for 10% or more of accounts receivable. As of December 31, 2020, one customer accounted for 30% of accounts receivable.

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

Fair Value Measurements

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

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

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

Marketable Securities

The Company's marketable securities (non-equity instruments) are classified as available-for-sale and are carried at fair value, with the unrealized gains and losses reported as a component of accumulated other comprehensive income (loss) in stockholders' equity (deficit). Realized gains and losses and declines in value determined to be other than temporary are based on the specific identification method and are included as a component of other income (expense), net in the consolidated statements of operations.

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

Segment Information

The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. The Company is developing and commercializing a proprietary system to preserve human organs for transplant in a near-physiologic condition to address the limitations of cold storage organ preservation. Operating segments are defined as components of an enterprise for which separate financial information is regularly evaluated by the Company's chief operating decision maker, or decision-making group, in deciding how to allocate resources and assess performance. The Company has determined that its chief operating decision maker is its Chief Executive Officer. The Company's chief operating decision maker reviews the Company's financial information on a consolidated basis for purposes of allocating resources and assessing financial performance.

Revenue Recognition

The Company generates revenue primarily from sales of its single-use, organ-specific disposable sets (i.e., its organ-specific OCS Perfusion Sets sold together with its organ-specific OCS Solutions) used on its organ-specific OCS Consoles, each being a component of the Company's OCS products. To a lesser extent, the Company also generates revenue from the sale of OCS Consoles to customers and from the implied rental of OCS Consoles loaned to customers at no charge. For each new transplant procedure, customers purchase an additional OCS disposable set for use on the customer's existing organ-specific OCS Console.

The Company recognizes revenue from sales to customers applying the following five steps: (1) identification of the contract, or contracts, with a customer, (2) identification of the performance obligations in the contract, (3) determination of the transaction price, (4) allocation of the transaction price to the performance obligations in the contract, and (5) recognition of revenue when, or as, performance obligations are satisfied. Because all performance obligations of a customer order are delivered and recognized as revenue at the same time and because revenue allocated to performance obligations other than OCS disposable sets, such as implied rental income and service revenue, is insignificant, all components of revenue from customer arrangements are classified as a single category of revenue in the Company's consolidated statements of operations.

Substantially all of the Company's customer contracts have multiple-performance obligations that contain deliverables consisting of OCS Perfusion Sets and OCS Solutions. In some of those customer contracts, the deliverables also include an OCS Console, whether sold or loaned to the customer. The Company evaluates each promise within a multiple-performance obligation arrangement to determine whether it represents a distinct performance obligation. A performance obligation is distinct if (1) the product or service is separately identifiable from other promises in the contract and (2) the customer can benefit from the product or service on its own or with other resources that are readily available to the customer.

When a customer order includes an OCS Console, whether sold or loaned, the Company has determined that customer training and the equipment set-up of the OCS Console, each performed by the Company, are not distinct because they are not sold on a standalone basis and can only be performed by the Company in conjunction with a sale or loan of its OCS Console. In addition, the Company has determined that the OCS Console itself is not distinct because the customer cannot benefit from the OCS Console without the training and equipment set-up having been completed. As a result, when the order includes an OCS Console, the Company has concluded that training, OCS Console equipment set-up, and the OCS Console itself are highly interdependent and represent a single, combined performance obligation. Consequently, the Company does not recognize any revenue from any component of a customer order that includes an OCS Console, whether sold or loaned, until the OCS Console has arrived at the customer site and the training and equipment set-up have been completed by the Company. The Company has concluded that "transfer of control" of an OCS Console occurs only after the console has arrived at the customer site and the training and equipment set-up have been completed by the Company.

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

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

Revenue is recognized when control of the OCS product or products is transferred to the customer in an amount that reflects the consideration the Company expects to be entitled to in exchange for the product or products.

Performance Obligations

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

- *OCS Console* — The OCS Console is a medical device that houses and controls the function of the OCS. The performance obligation of the OCS Console includes customer training and equipment set-up. Revenue for each OCS Console is recognized at the point in time at which control is transferred to the customer, which is typically only after the console has arrived at the customer site and the training and equipment set-up have been completed by the Company because the customer cannot benefit from the OCS Console without the training and equipment set-up having been completed. At that time, the Company believes that the customer has the significant risks and rewards of ownership.

- *OCS Perfusion Set* — The OCS Perfusion Set is a single-use disposable set that stores the organ and circulates blood. Revenue for each OCS Perfusion Set is recognized at the point in time at which control is transferred to the customer, which is when title transfers to the customer in connection with delivery. In most of the Company's customer arrangements, title to the OCS Perfusion Set transfers when the OCS Perfusion Set arrives at the customer site. In limited instances, title transfers upon shipment to the customer by the Company.
- *OCS Solutions* — The OCS Solutions are a set of nutrient-enriched solutions to optimize the organ's condition outside the human body. Revenue for each OCS Solution is recognized at the point in time at which control is transferred to the customer, which is when title transfers to the customer in connection with delivery. In most of the Company's customer arrangements, title to the OCS Solutions transfers when the OCS Solutions arrive at the customer site. In limited instances, title transfers upon shipment to the customer by the Company.

Payments Made to Customers

Under the Company's customer arrangements that include a customer clinical trial agreement, the Company receives payments from sales to the customer of its OCS products and also makes payments to that customer for reimbursements of clinical trial costs, materials, and for specified clinical documentation related to the customer's use of its OCS products. The Company also makes payments to customers involved in post-approval studies for information related to the transplant procedures performed. The Company determines the appropriate accounting treatments for these payments depending on the nature of the payment and whether they are for distinct goods or services.

The Company has determined that the payments made to the customer for reimbursement of clinical trial materials and customer's costs incurred to execute specific clinical trial protocols related to the Company's OCS products do not provide the Company with a distinct good or service transferred by the customer, and therefore such payments are recorded as a reduction of revenue from the customer in the Company's consolidated statements of operations. Reductions of revenue related to such payments made to customers for reimbursements are recognized when the Company recognizes the revenue for the sale of its OCS disposable sets. The Company recorded reimbursable clinical costs as a reduction of revenue of $0.5 million and $1.1 million for the three and six months ended June 30, 2021, respectively, and $0.5 million and $1.2 million for the three and six months ended June 30, 2020, respectively, as presented below in disaggregated revenue.

The Company has also determined that payments made to customers to obtain information related to post-approval studies or existing standard-of-care protocols (i.e., unrelated to the Company's OCS products) do meet the criteria to be classified as a cost because the Company receives a distinct good or service transferred by the customer separate from the customer's purchase of the Company's OCS products and the consideration paid represents the fair value of the distinct good or service received by the Company. As a result, these payments made to the customers for information related to post-approval studies or standard-of-care protocols are recorded as 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 $0.7 million and $1.2 million for the three and six months ended June 30, 2021, respectively, and $0.4 million and $0.8 million for the three and six months ended June 30, 2020, respectively, as operating expenses.

Variable Consideration

Revenue is reported net of any taxes assessed by a governmental authority that are directly imposed on a revenue-producing transaction (e.g., sales, use, and value added taxes). The Company only includes estimated variable amounts in the transaction price to the extent it is probable that a significant reversal of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is resolved.

Revenue from reimbursements of out-of-pocket expenses, including travel, lodging, and meals, is accounted for as variable consideration and was insignificant during each of the three and six months ended June 30, 2021 and 2020.

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

Contract Assets and Liabilities

The Company recognizes a receivable at the point in time at which it has an unconditional right to payment. Such receivables are not contract assets. Payment terms for customer orders, including for each of the Company's primary performance obligations, are typically 30 days for customers in the United States and 30 to 90 days for customers in non-U.S. markets, and such payments do not include payments that are variable, dependent on specified factors or events.

Contract assets arise from unbilled amounts in customer arrangements when revenue recognized exceeds the amount billed to the customer and the Company's right to payment is not just subject to the passage of time. The Company had no contract assets as of June 30, 2021 and December 31, 2020.

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 June 30, 2021, the Company's wholly- or partially-unsatisfied performance obligations totaled $1.3 million and are expected to be completed within the next year.

Disaggregated Revenue

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Gross revenue from sales to customers	$ 8,667	$ 3,923	$ 16,304	$ 12,166
Less: clinical trial payments reducing revenue	496	532	1,080	1,245
Total net revenue	$ 8,171	$ 3,391	$ 15,224	$ 10,921

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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Net revenue by OCS product:				
OCS Lung net revenue	$ 3,572	$ 435	$ 6,002	$ 2,443
OCS Heart net revenue	4,599	2,220	8,780	6,351
OCS Liver net revenue	—	736	442	2,127
Total net revenue	$ 8,171	$ 3,391	$ 15,224	$ 10,921

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Net revenue by country(1):				
United States	$ 5,758	$ 2,440	$ 11,515	$ 7,648
United Kingdom	1,099	355	1,571	1,467
All other countries	1,314	596	2,138	1,806
Total net revenue	$ 8,171	$ 3,391	$ 15,224	$ 10,921

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

Other Revenue Considerations

The Company does not assess whether promised goods or services are performance obligations if they are deemed immaterial in the context of the contract with the customer. Additionally, the Company does not assess whether a contract has a significant financing component if the expectation at contract inception is that the period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less.

Distributors

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

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

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

Stock-Based Compensation

The Company measures stock-based option awards granted to employees, non-employees and directors based on their fair value on the date of grant using the Black-Scholes option-pricing model. Generally, the Company issues awards with only service-based vesting conditions. Compensation expense for those awards is recognized over the vesting period of the respective award using the straight-line method. The Company accounts for forfeitures as they occur and records compensation cost assuming all option holders will complete the requisite service period. When the unvested portion of an award is forfeited, the Company reverses compensation expense previously recognized in the period of the forfeiture.

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

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 six months ended June 30, 2021 and 2020.

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 June 30,	
	2021	2020
Warrants to purchase common stock	64,440	64,440
Options to purchase common stock	2,708,303	2,253,691
Employee stock purchase plan	12,898	10,534
	2,785,641	2,328,665

Recently Issued Accounting Pronouncements

The Company qualifies as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 and elected not to "opt out" of the extended transition related to complying with new or revised accounting standards, which means that when a standard is issued or revised and it has different application dates for public and nonpublic companies, the Company will adopt the new or revised standard at the time nonpublic companies adopt the new or revised standard and will do so until such time that the Company either (i) irrevocably elects to "opt out" of such extended transition period or (ii) no longer qualifies as an emerging growth company. Since the Company's common stock held by non-affiliates exceeded $700.0 million as of June 30, 2021, the Company will cease to qualify as an emerging growth company as of December 31, 2021 and will instead be a "large accelerated filer". As a result, the Company will be subject to certain requirements that apply to other public companies but did not previously apply to the Company due to its status as an emerging growth company, including the provisions of Section 404 of the Sarbanes-Oxley Act, which requires that the Company's independent registered public accounting firm provide an attestation report on the effectiveness of the Company's internal control over financial reporting in the Company's Annual Report on Form 10-K for the year ending December 31, 2021.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* ("ASU 2016-02"), which sets out the principles for the recognition, measurement, presentation, and disclosure of leases for both parties to a contract (i.e., lessees and lessors). The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or less may be accounted for similar to existing guidance for operating leases today. For public entities, the guidance has been effective for annual reporting periods beginning after December 15, 2018 and for interim periods within those years. ASU 2016-02 initially required adoption using a modified retrospective approach, under which all years presented in the financial statements would be prepared under the revised guidance. In July 2018, the FASB issued ASU No. 2018-11, *Leases (Topic 842)*, which added an optional transition method under which financial statements may be prepared under the revised guidance for the year of adoption, but not for prior years. Under the latter method, entities will recognize a cumulative catch-up adjustment to the opening balance of retained earnings in the period of adoption. In November 2019, the FASB issued ASU No. 2019-10, which deferred the effective date for nonpublic entities to annual reporting periods beginning after December 15, 2020, and interim periods within years beginning after December 15, 2021. In June 2020, the FASB issued ASU No. 2020-05, which grants a one-year effective-date delay for nonpublic entities to annual reporting periods beginning after December 15, 2021 and to interim periods within years beginning after December 15, 2022. Since the Company will cease to be an emerging growth company as of December 31, 2021, the Company is required to adopt the standard during the fourth quarter of 2021. The Company plans to adopt ASU 2016-02 using the modified retrospective approach transition method as of the date of adoption such that prior periods will not be restated. The Company is currently assessing the impact of adoption of this guidance on its consolidated financial statements.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments – Credit Losses (Topic 326)*. The new standard adjusts the accounting for assets held at amortized costs basis, including marketable securities accounted for as available for sale, and trade receivables. The standard eliminates the probable initial recognition threshold and requires an entity to reflect its current estimate of all expected credit losses. The allowance for credit losses is a valuation account that is deducted from the amortized cost basis of the financial assets to present the net amount expected to be collected. For public entities except smaller reporting companies, the guidance is effective for annual reporting periods beginning after December 15, 2019 and for interim periods within those years. For nonpublic entities and smaller reporting companies, the guidance was effective for annual reporting periods beginning after December 15, 2021. Early adoption is permitted for all entities. In November 2019, the FASB issued ASU No. 2019-10, which deferred the effective date for nonpublic entities to annual reporting periods beginning after December 15, 2022, including interim periods within those years. Early application continues to be allowed. Since the Company will cease to be an emerging growth company as of December 31, 2021, the Company is required to adopt the standard during the fourth quarter of 2021. The Company is currently assessing the impact of the adoption of this guidance on its consolidated financial statements.

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes – Simplifying the Accounting for Income Taxes (Topic 740)*. The amendments in this update simplify the accounting for income taxes by removing certain exceptions to the general principles as well as clarifying and amending existing guidance to improve consistent application. For public entities, the guidance is effective for annual reporting periods beginning after December 15, 2020 and for interim periods within those fiscal years. For nonpublic entities, the guidance is effective for annual reporting periods beginning after December 15, 2021 and to interim periods within fiscal years beginning after December 15, 2022. Early adoption is permitted for all entities. Depending on the amendment, adoption may be applied on the retrospective, modified retrospective or prospective basis. Since the Company will cease to be an emerging growth company as of December 31, 2021, the Company is required to adopt the standard during the fourth quarter of 2021. The Company is currently assessing the impact of the adoption of this guidance on its consolidated financial statements.

3. Marketable Securities

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

	June 30, 2021			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury securities (due within one year)	$ 76,931	$ 6	$ (6)	$ 76,931
U.S. government agency bonds (due within one year)	10,003	1	—	10,004
	$ 86,934	$ 7	$ (6)	$ 86,935

	December 31, 2020			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury securities (due within one year)	$ 74,066	$ 10	$ (3)	$ 74,073
U.S. government agency bonds (due within one year)	26,984	4	—	26,988
	$ 101,050	$ 14	$ (3)	$ 101,061

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 June 30, 2021 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 15,498	$ —	$ —	$ 15,498
Marketable securities:				
U.S. Treasury securities	—	76,931	—	76,931
U.S. government agency bonds	—	10,004	—	10,004
	$ 15,498	$ 86,935	$ —	$ 102,433

	Fair Value Measurements at December 31, 2020 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 13,829	$ —	$ —	$ 13,829
Marketable securities:				
U.S. Treasury securities	—	74,073	—	74,073
U.S. government agency bonds	—	26,988	—	26,988
	$ 13,829	$ 101,061	$ —	$ 114,890

Money market funds were valued by the Company based on quoted market prices, which represent a Level 1 measurement within the fair value hierarchy. U.S. Treasury securities and U.S. government agency bonds were valued by the Company using quoted prices in active markets for similar securities, which represent a Level 2 measurement within the fair value hierarchy. During the three and six months ended June 30, 2021 and 2020, there were no transfers between Level 1, Level 2, and Level 3.

5. Inventory

Inventory consisted of the following (in thousands):

	June 30, 2021	December 31, 2020
Raw materials	$ 6,577	$ 6,770
Work-in-process	1,322	1,102
Finished goods	5,108	4,062
	$ 13,007	$ 11,934

During the six months ended June 30, 2021 and 2020, the Company made non-cash transfers of OCS Consoles from inventory to property and equipment (OCS Consoles loaned to customers) of $0.8 million and $0.1 million, respectively.

6. Accrued Expenses and Other Current Liabilities

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

	June 30, 2021	December 31, 2020
Accrued research, development and clinical trials expenses	$ 5,676	$ 4,426
Accrued payroll and related expenses	3,692	4,030
Accrued professional fees	1,184	344
Accrued other	1,548	1,517
	$ 12,100	$ 10,317

7. Long-Term Debt

TransMedics has a credit agreement (the "Credit Agreement") with OrbiMed Royalty Opportunities II, LP ("OrbiMed"), entered into in June 2018, pursuant to which TransMedics borrowed $35.0 million. Long-term debt consisted of the following (in thousands):

	June 30, 2021	December 31, 2020
Principal amount of long-term debt	$ 35,000	$ 35,000
Less: Current portion of long-term debt	—	—
Long-term debt, net of current portion	35,000	35,000
Debt discount, net of accretion	(675)	(834)
Accrued end-of-term payment	596	491
Long-term debt, net of discount and current portion	$ 34,921	$ 34,657

Borrowings under the Credit Agreement bear interest at an annual rate equal to the London Interbank Offered Rate ("LIBOR"), subject to a minimum of 1.0% and a maximum of 4.0%, plus 8.5% (the "Applicable Margin"), subject in the aggregate to a maximum interest rate of 11.5%. In addition, borrowings under the Credit Agreement bear paid-in-kind ("PIK") interest at an annual rate equal to the amount by which LIBOR plus the Applicable Margin exceeds 11.5%, but not to exceed 12.5%. The PIK interest is added to the principal amount of the borrowings outstanding at the end of each quarter until the maturity date of the Credit Agreement in June 2023. Borrowings under the Credit Agreement are repayable in quarterly interest-only payments until the maturity date, at which time all principal and accrued interest is due and payable. At its option, the Company may prepay outstanding borrowings under the Credit Agreement, subject to a prepayment premium that decreased to zero in June 2021. The Company is also required to make a final payment in an amount equal to 3.0% of the principal amount of any prepayment or repayment. The final payment and debt discount amounts are being accreted to interest expense over the term of the Credit Agreement using the effective interest method.

All obligations under the Credit Agreement are guaranteed by the Company and each of its material subsidiaries. All obligations of the Company and each guarantor are secured by substantially all of the Company's and each guarantor's assets, including their intellectual property, subject to certain exceptions, including a perfected security interest in substantially all tangible and intangible assets of the Company and each guarantor. Under the Credit Agreement, the Company has agreed to certain affirmative and negative covenants to which it will remain subject until maturity. The financial covenants include maintaining a minimum liquidity amount of $3.0 million; the requirement, on an annual basis, to deliver to OrbiMed annual audited financial statements with an unqualified audit opinion from the Company's independent registered public accounting firm; and restrictions on the Company's activities, including limitations on dispositions, mergers or acquisitions; encumbering its intellectual property; incurring indebtedness or liens; paying dividends; making certain investments; and engaging in certain other business transactions. As of June 30, 2021, the Company was in compliance with the financial covenants under the Credit Agreement.

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

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

As of June 30, 2021, the interest rate applicable to borrowings under the Credit Agreement was 9.5%. During the six months ended June 30, 2021, the weighted average effective interest rate on outstanding borrowings under the Credit Agreement was approximately 11.22%.

8. Equity

Preferred Stock

As of June 30, 2021, the Company's articles of organization authorized the Company to issue up to 25,000,000 shares of preferred stock, no par value per share, all of which is undesignated.

Common Stock

As of June 30, 2021, the Company's articles of organization authorized the Company to issue up to 150,000,000 shares of common stock, no par value per share. Each share of common stock is entitled to one vote on all matters submitted to a vote of the Company's shareholders. The holders of common stock are entitled to receive dividends, if any, as may be declared by the board of directors. Through June 30, 2021, no dividends had been declared or paid.

Warrants

As of June 30, 2021, the Company has outstanding warrants to purchase 50,000 shares of common stock at an exercise price of $8.75 per share with an expiration date of November 7, 2022 and warrants to purchase 14,440 shares of common stock at an exercise price of $17.47 per share with an expiration date of May 6, 2024.

9. Stock-Based Compensation

2019 Stock Incentive Plan and Option Grants

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

Shares withheld in payment of the exercise or purchase price of an award or in satisfaction of tax withholding requirements, and the shares covered by a stock appreciation right for which any portion is settled in stock, will reduce the number of shares available for issuance under the 2019 Plan. In addition, the number of shares available for issuance under the 2019 Plan (i) will not be increased by any shares delivered under the 2019 Plan that are subsequently repurchased using proceeds directly attributable to stock option exercises and (ii) will not be reduced by any awards that are settled in cash or that expire, become unexercisable, terminate or are forfeited to or repurchased by TransMedics Group without the issuance of stock under the 2019 Plan. As of June 30, 2021, 1,543,355 shares of common stock were available for issuance under the 2019 Plan.

During the six months ended June 30, 2021, the Company granted options to its employees and directors with service-based vesting for the purchase of an aggregate of 910,675 shares of common stock with a weighted average grant-date fair value of $19.65 per share.

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 six months ended June 30, 2021, 14,951 shares of common stock were issued under the 2019 ESPP and as of June 30, 2021, 333,494 shares of common stock remained available for issuance.

Stock-Based Compensation

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Cost of revenue	$ 19	$ 8	$ 32	$ 12
Research, development and clinical trials expenses	320	129	517	183
Selling, general and administrative expenses	1,469	494	2,371	821
	$ 1,808	$ 631	$ 2,920	$ 1,016

As of June 30, 2021, total unrecognized compensation cost related to unvested share-based awards was $20.9 million, which is expected to be recognized over a weighted average period of 3.0 years.

10. Commitments and Contingencies

Operating Leases

The Company leases its office, laboratory and manufacturing space under two noncancelable operating leases, as amended, that expire in December 2027. Annual base rent for the premises is approximately $1.9 million for the period commencing on December 23, 2020 and ending December 22, 2021 and will increase at an average of 2.5% each year until the end of the term. The Company is also obligated to pay the landlord certain costs, taxes, and operating expenses, subject to certain exclusions.

The Company's lease agreements, as amended, include payment escalations, rent holidays, and other lease incentives, which are accrued or deferred as appropriate such that rent expense for each lease is recognized on a straight-line basis over the respective lease terms, recording deferred rent for rent expense incurred but not yet paid. The Company recorded rent expense of $0.4 million and $0.5 million in the three months ended June 30, 2021 and 2020, respectively. The Company recorded rent expense of $0.9 million and $1.0 million in the six months ended June 30, 2021 and 2020, respectively. Under the amended operating leases, the landlord will contribute up to $3.4 million towards the Company's leasehold improvements. Costs incurred by the Company for tenant improvements but not yet reimbursed by the landlord are presented on the accompanying consolidated balance sheets as a tenant receivable within prepaid expenses and other current assets. As of June 30, 2021, the Company did not have a tenant receivable.

Future minimum lease payments under operating leases as of June 30, 2021 are as follows (in thousands):

Year Ending:	
December 31, 2021 (remaining 6 months)	$ 951
December 31, 2022	1,948
December 31, 2023	1,997
December 31, 2024	2,047
December 31, 2025	2,098
Thereafter	4,353
	$ 13,394

License Agreement with the Department of Veterans Affairs

In 2002, the Company entered into a license agreement with the Department of Veterans Affairs (the "VA"), under which the Company was granted an exclusive, worldwide license under specified patents to make, use, sell and import certain technology used in the Company's products and a non-exclusive, worldwide license to make, use, sell and import solutions for use in or with those products. The rights under the license agreement continue until the expiration of the last to expire of the licensed patents. The majority of the licensed U.S. patents expired in 2017, and the foreign patents expired in September 2018. However, the Company has requested a patent term extension for one U.S. patent covered by the VA license agreement, U.S. Patent No. 6100082. The Company has been granted an interim patent term extension for this patent until September 23, 2021. The Company has not received final approval of the patent extension beyond the interim patent term extension already granted. The maximum extension requested would be through May 2022; however, the length of the patent term extension will be determined by the United States Patent and Trademark Office ("USPTO") based on input from the FDA. On February 8, 2021, the FDA provided to the USPTO a determined regulatory review period for the OCS Lung. Under the FDA's analysis, the patent term extension of the '082 patent would be until November 6, 2021. The license includes the right to grant sublicenses, subject to approval by the VA and other restrictions, and is subject to the U.S. government's right to practice the licensed patents on its own behalf without payment of a royalty and obligation to grant certain sublicenses as necessary to fulfill public health, welfare and safety needs. The license agreement also requires the Company to make its products covered by the licensed patents available to the public on reasonable terms and to provide the U.S. government such products at the lowest price.

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

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

401(k) Savings Plan

The Company has a defined-contribution savings plan under Section 401(k) of the Internal Revenue Code. This plan covers substantially all employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. Company contributions to the plan may be made at the discretion of the board of directors. As of June 30, 2021 and December 31, 2020, 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 June 30, 2021 and December 31, 2020.

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.

Legal Proceedings

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

11. Segment Reporting and Geographic Data

The Company has determined that it operates in one segment (see Note 2 for disaggregated net revenue by geographical area). Long-lived assets by geographical area are summarized as follows (in thousands):

	June 30, 2021	December 31, 2020
Long-lived assets by country(2):		
United States	$ 4,238	$ 4,114
All other countries	716	640
Total long-lived assets	$ 4,954	$ 4,754

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

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 $0.1 million and $0.2 million in total compensation for the three and six months ended June 30, 2021, respectively, and $0.1 million and $0.2 million in total compensation for the three and six months ended June 30, 2020, 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, 2020, as filed with the SEC on March 11, 2021 ("2020 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 2020 Form 10-K, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

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

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

We designed the OCS to be a platform that allows us to leverage core technologies across products for multiple organs. To date, we have developed three OCS products, one for each of lung, heart and liver transplantations, making the OCS the only multi-organ technology platform. We have commercialized the OCS Lung and OCS Heart outside of the United States and received our first Pre-Market Approval ("PMA") from the Food and Drug Administration (the "FDA") in March 2018 for the use in the United States of the OCS Lung for donor lungs currently utilized for transplantation and a PMA from the FDA in May 2019 for the use in the United States of the OCS Lung for donor lungs currently unutilized for transplantation.

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

Since our inception, we have incurred significant operating losses. Our ability to generate net revenue sufficient to achieve profitability will depend on the successful further development and commercialization of our products. We generated net revenue of $15.2 million and incurred a net loss of $18.6 million for the six months ended June 30, 2021. We generated net revenue of $25.6 million and incurred a net loss of $28.7 million for the year ended December 31, 2020. As of June 30, 2021, we had an accumulated deficit of $416.8 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 sales and clinical adoption team, which will pursue increasing commercial sales and clinical adoption of our OCS products; scaling our manufacturing operations; continuing research, development and clinical trial efforts; 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.

We believe that our cash and cash equivalents and marketable securities will be sufficient for us to fund our operating expenses, capital expenditure requirements and debt service payments for at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See "—Liquidity and Capital Resources".

COVID-19

The impact of the COVID-19 pandemic has been and will likely continue to be extensive in many aspects of society, which has resulted in and will likely continue to result in significant disruptions to the global economy, as well as businesses and capital markets around the world. Impacts to our business as a result of COVID-19 include: the temporary disruption of transplant procedures at many of the organ transplant centers who purchase OCS products; customer delays or reductions in customer capital expenditures and operating budgets and the related impact on our product sales; disruptions to our manufacturing operations and supply chain caused by facility closures, reductions in operating hours, staggered shifts and other social distancing efforts; labor shortages; decreased productivity and unavailability of materials or components; restrictions on or delays of our clinical trials and studies; delays of reviews and approvals by the FDA and other health authorities, including with respect to the Company's OCS Heart PMA application; limitations on our employees' and customers' ability to travel; and delays in product installations, trainings or shipments to and from affected countries and within the United States. In addition, our sales and clinical adoption team was restricted in visiting many transplant centers in person between April 2020 and September 2020. In response to the pandemic, healthcare providers have, and may need to further, reallocate resources, such as physicians, staff, hospital beds and intensive care unit facilities, and these actions significantly delay the provision of other medical care such as organ transplantation and reduce the number of transplant procedures that are performed, which has a negative impact on our revenue and clinical trial activities.

In April 2020, we announced several steps to respond to the COVID-19 pandemic intended to protect the health and safety of our employees, to establish a process to support the continuous supply of our OCS products at transplant centers globally and to maintain financial flexibility. These actions included transitioning most employees to a remote work environment, except for those who are deemed essential to product supply, and reducing near-term expenses, such as reducing non-essential discretionary expenses and deferring a portion of executive and employee compensation from April 2020 through August 31, 2020.

OCS product sales were negatively impacted by the COVID-19 pandemic from the second quarter of 2020 through the second quarter of 2021 and we anticipate a negative impact to OCS product sales to continue through 2021. We have observed recovery in the overall frequency of transplant procedures to pre-pandemic levels in most countries during the most recent quarter. In addition, while the number of transplant procedures performed declined during the COVID-19 pandemic, organ transplantations are non-elective, life-saving procedures and we believe that the need for these procedures has persisted and will continue to persist as demonstrated by procedure recovery.

We continue to monitor developments regarding the COVID-19 pandemic and its impact on our business, financial condition, results of operations and prospects. The extent of the future impact on our operations and financial condition is difficult to predict and will depend on the length and severity of the pandemic, its consequences, and containment and vaccination efforts. In particular, the speed of the continued spread of COVID-19 globally, and the magnitude, duration and frequency of interventions to contain the spread of the virus, such as government-imposed quarantines, including shelter-in-place mandates, sweeping restrictions on travel, mandatory shutdowns for non-essential businesses, requirements regarding social distancing, and other public health safety measures, will determine the impact of the pandemic on our business. While the FDA approved emergency use authorization of vaccines starting in December 2020 and vaccination efforts have been ongoing in the United States, it is not yet fully known how vaccination efforts will impact the COVID-19 pandemic, including with respect to the duration of the efficacy of the vaccines, their effectiveness against the Delta variant or any other variants as new strains of the virus evolve.

Recent Developments

On July 14, 2021, the FDA's Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee convened for an advisory committee meeting to review our clinical evidence from the OCS Liver PROTECT Trial and to provide the FDA with non-binding recommendations with respect to our OCS Liver PMA application. At the advisory committee meeting, the panel voted: 14 to zero that the OCS Liver is safe for patients; 14 to zero that the OCS Liver is effective for use in patients; and 12 to one (with one panel member abstaining) that the benefits of the OCS Liver outweigh its risks. We anticipate the FDA will issue a decision regarding whether to approve or deny approval of our OCS Liver PMA application within three to four months following the advisory committee meeting, which decision may or may not follow the advisory committee's recommendation.

On July 30, 2021, the FDA provided a 510(k) clearance for use of the OCS Lung Solution in lung transplantations using cold storage.

Components of Our Results of Operations

Net Revenue

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

All of our revenue has been generated by sales to transplant centers in the United States, Europe and Asia-Pacific, or, in some cases, to distributors selling to transplant centers in select countries. Substantially all of our customer 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.

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

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

Under some of our customer clinical trial agreements, we make payments to our customers for reimbursements of clinical trial materials and for specified clinical documentation related to their use of our OCS products. Because some of these payments do not provide us with a separately identifiable benefit, we record such payments as a reduction of revenue from the customer, resulting in our net revenue presentation. We recorded reimbursable clinical trial costs as a reduction of revenue of $0.5 million and $1.1 million for the three and six months ended June 30, 2021, respectively, and $0.5 million and $1.2 million for the three and six months ended June 30, 2020.

In March 2018, we received our first FDA PMA for the OCS Lung, and we began commercial sales of this product in the United States during the fourth quarter of 2018. In May 2019, we received an FDA PMA for the OCS Lung for additional clinical indications. Therefore, our net revenue in the United States for the OCS Lung is now derived from commercial sales and consists of sales of OCS disposable sets and, to a much lesser extent, sales of OCS Consoles.

In the United States, we expect to continue to only have clinical trial sales for our OCS Heart and OCS Liver products until we receive similar FDA PMAs for those products. Our net revenue in the United States for OCS Heart and OCS Liver products fluctuates from period to period as a result of the timing of patient enrollment in our clinical trials. Historically, our net revenue during periods of patient enrollment has been higher due to the sale of OCS disposable sets for use during these clinical trials, as compared to periods during which our clinical trials were not actively enrolling. Our OCS Heart EXPAND CAP trial began patient enrollment in May 2019 and is currently enrolling patients. Our OCS Liver PROTECT CAP trial began patient enrollment in February 2020 and completed initial enrollment in the first quarter of 2021. Our net revenue may continue to fluctuate from period to period as a result of the timing of ongoing clinical trials in which our OCS products are used.

Through June 30, 2021, all of our sales outside of the United States have been commercial sales (unrelated to any clinical trials) and our net revenue has been generated primarily from sales of OCS disposable sets and, to a much lesser extent, sales of OCS Consoles. Commercial sales of OCS disposable sets generally have a higher average selling price than clinical trial sales of OCS disposable sets.

We expect that our net revenue will increase over the long term as a result of receiving our first two FDA PMAs for the OCS Lung in the United States in March 2018 and May 2019 and any potential future FDA approvals in the United States for OCS Heart and OCS Liver. We expect to receive decisions from the FDA regarding whether to approve the PMA for the use of the OCS Heart and OCS Liver in the United States in 2021 following the advisory committee meetings held on April 6, 2021 and July 14, 2021, respectively. 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, in all served geographies, if transplant centers utilize the OCS in more transplant cases, and if more transplant centers adopt the OCS in their programs. We expect that net revenue will continue to be negatively impacted in 2021 a result of the COVID-19 pandemic.

Cost of Revenue, Gross Profit and Gross Margin

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

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

We expect that cost of revenue as a percentage of net revenue will decrease and gross margin and gross profit will increase over the long term as our sales and production volumes increase and our cost per unit of our OCS disposable sets decreases due to economies of scale. We intend to use our design, engineering and manufacturing capabilities to further advance and improve the efficiency of our manufacturing processes, which we believe will reduce costs and increase our gross margin. As utilization by customers of our OCS products increases, we expect that a greater number of OCS disposable sets will be used per year on the same OCS Console, thereby driving overall gross margin improvement. Because we expect that the number of OCS disposable sets sold over time will be significantly greater than the number of OCS Consoles sold or loaned to customers over that same period, we expect that our gross margin improvement will not be significantly affected by the number of OCS Consoles that we sell or loan to customers. While we expect gross margin to increase over the long term, it will likely fluctuate from quarter to quarter.

Operating Expenses

Research, Development and Clinical Trials Expenses

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

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

We expense research, development and clinical trials costs as incurred. In the future, we expect that research, development and clinical trials expenses will increase 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 sales and clinical adoption team and personnel in executive, marketing, finance and administrative functions. Selling, general and administrative expenses also include direct and allocated facility-related costs, promotional activities, marketing, conferences and trade shows as well as professional fees for legal, patent, consulting, investor and public relations, accounting and audit services. We expect to continue to increase headcount in our sales and clinical adoption team and increase marketing efforts as we continue to grow commercial sales of our OCS products in both U.S. and select non-U.S. markets.

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

Other Income (Expense)

Interest Expense

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

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.

Provision for Income Taxes

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

As of December 31, 2020, we had U.S. federal and state net operating loss carryforwards of $322.0 million and $252.7 million, respectively, which may be available to offset future taxable income and begin to expire in 2021 and 2030, respectively. Our federal net operating losses include $108.0 million, which can be carried forward indefinitely. As of December 31, 2020, we also had U.S. federal and state research and development tax credit carryforwards of $7.6 million and $5.0 million, respectively, which may be available to offset future tax liabilities and begin to expire in 2021 and 2024, respectively. As of December 31, 2020, we had no foreign net operating loss carryforwards. We have recorded a full valuation allowance against our net deferred tax assets at each balance sheet date.

Results of Operations

Comparison of the Three Months Ended June 30, 2021 and 2020

The following table summarizes our results of operations for the three months ended June 30, 2021 and 2020:

	Three Months Ended June 30,		
	2021	2020	Change
	(in thousands)		
Net revenue	$ 8,171	$ 3,391	$ 4,780
Cost of revenue	2,582	1,482	1,100
Gross profit	5,589	1,909	3,680
Operating expenses:			
Research, development and clinical trials	6,295	3,903	2,392
Selling, general and administrative	9,162	5,867	3,295
Total operating expenses	15,457	9,770	5,687
Loss from operations	(9,868)	(7,861)	(2,007)
Other income (expense):			
Interest expense	(965)	(1,001)	36
Other income (expense), net	171	371	(200)
Total other expense, net	(794)	(630)	(164)
Loss before income taxes	(10,662)	(8,491)	(2,171)
Provision for income taxes	(6)	(6)	—
Net loss	$ (10,668)	$ (8,497)	$ (2,171)

Net Revenue

	Three Months Ended June 30,		
	2021	2020	Change
	(in thousands)		
Net revenue by geography:			
United States	$ 5,758	$ 2,440	$ 3,318
Outside the U.S.	2,413	951	1,462
Total net revenue	$ 8,171	$ 3,391	$ 4,780
Net revenue by OCS product:			
OCS Lung net revenue	$ 3,572	$ 435	$ 3,137
OCS Heart net revenue	4,599	2,220	2,379
OCS Liver net revenue	—	736	(736)
Total net revenue	$ 8,171	$ 3,391	$ 4,780

Net revenue from customers in the United States was $5.8 million in the three months ended June 30, 2021 and increased by $3.3 million compared to the three months ended June 30, 2020, primarily due to higher sales volumes of our OCS Lung and OCS Heart disposable sets. Net revenue from sales of OCS Lung disposable sets in the United States increased from $0.4 million in the three months ended June 30, 2020 to $3.5 million in the three months ended June 30, 2021. The increase was due primarily to higher sales volume of OCS Lung disposable sets as the adverse impact of COVID-19 had less of an impact in the 2021 period. Net revenue from OCS Heart disposable sets in the United States increased by $1.0 million. The increase in net revenue from OCS Heart disposable sets is attributed to a higher volume of OCS Heart disposable sets sold to customers for use in the OCS Heart DCD CAP Trial in the United States. We did not have revenue from OCS Liver disposable sets during the three months ended June 30, 2021 as we had completed enrollment in our OCS Liver Protect CAP Trial in the first quarter of 2021.

Net revenue from customers outside the United States was $2.4 million in the three months ended June 30, 2021 compared to $1.0 million in the three months ended June 30, 2020. The increase in net revenue from customers outside the United States was primarily due to higher sales volumes of OCS Heart and OCS Lung disposable sets. Net revenue from sales of OCS Lung disposable sets outside the United States increased by $0.1 million from the three months ended June 30, 2020 to the three months ended June 30, 2021. Net revenue from sales of OCS Heart disposable sets outside of the United States increased by $1.4 million from the three months ended June 30, 2020 to the three months ended June 30, 2021.

Cost of Revenue, Gross Profit and Gross Margin

Cost of revenue increased by $1.1 million in the three months ended June 30, 2021 compared to the three months ended June 30, 2020. Gross profit increased by $3.7 million in the three months ended June 30, 2021 compared to the three months ended June 30, 2020. Gross margin was 68% and 56% for the three months ended June 30, 2021 and 2020, respectively. Gross margin increased primarily as a result of higher margin OCS disposable sets sold and improvements in the efficiency of the production process.

Operating Expenses

Research, Development and Clinical Trials Expenses

	Three Months Ended June 30,		
	2021	2020	Change
	(in thousands)		
Personnel related (including stock-based compensation expense)	$ 2,086	$ 2,036	$ 50
Clinical trials costs	1,071	728	343
Consulting and third-party testing	1,059	259	800
Laboratory supplies and research materials	1,088	221	867
Other	991	659	332
Total research, development and clinical trials expenses	$ 6,295	$ 3,903	$ 2,392

Total research, development and clinical trials expenses increased by $2.4 million from $3.9 million in the three months ended June 30, 2020 to $6.3 million in the three months ended June 30, 2021. Clinical trial costs increased by $0.3 million due to an increase in ongoing trial enrollment activity primarily related to the OCS Heart DCD CAP Trial. Consulting and third-party testing increased by $0.8 million due to increased regulatory activity, including costs related to preparation for both the OCS Heart FDA advisory committee panel in April and the OCS Liver FDA advisory committee panel in July. The increase in laboratory supplies and research materials costs of $0.9 million and other costs of $0.3 million is due primarily to increased research activities, product development and other activities as restrictions implemented in response to the COVID-19 pandemic were eased.

Selling, General and Administrative Expenses

	Three Months Ended June 30,		
	2021	2020	Change
	(in thousands)		
Personnel related (including stock-based compensation expense)	$ 4,934	$ 3,057	$ 1,877
Professional and consultant fees	1,868	1,586	282
Tradeshows and conferences	617	—	617
Other	1,743	1,224	519
Total selling, general and administrative expenses	$ 9,162	$ 5,867	$ 3,295

Total selling, general and administrative expenses increased by $3.3 million from $5.9 million in the three months ended June 30, 2020 to $9.2 million in the three months ended June 30, 2021 due to an increase in personnel related costs, professional and consultant fees, tradeshows and conferences and other costs. Personnel related costs increased primarily due to the continued expansion of our commercial team to support commercial sales of our OCS Lung product in the United States. Stock-based compensation expense also increased by $1.0 million due primarily to additional grants to new and existing employees and an increase in the respective grant date fair values due to the increased market price of our stock. The increase in professional and consultant fees, trade shows and conferences and other costs is a result of an increase in activities as restrictions implemented in response to the COVID-19 pandemic were eased.

Other Income (Expense)

Interest Expense

Interest expense was $1.0 million for each of the three months ended June 30, 2021 and 2020.

Other Income (Expense), Net

Other income (expense), net for the three months ended June 30, 2021 and 2020 included interest income of less than $0.1 million and $0.2 million, respectively, resulting from interest earned on invested cash balances, and $0.1 million and $0.2 million of realized and unrealized foreign currency transaction gains, respectively.

Comparison of the Six Months Ended June 30, 2021 and 2020

The following table summarizes our results of operations for the six months ended June 30, 2021 and 2020:

	Six Months Ended June 30,		
	2021	2020	Change
	(in thousands)		
Net revenue	$ 15,224	$ 10,921	$ 4,303
Cost of revenue	4,824	4,152	672
Gross profit	10,400	6,769	3,631
Operating expenses:			
Research, development and clinical trials	10,827	10,128	699
Selling, general and administrative	15,948	12,519	3,429
Total operating expenses	26,775	22,647	4,128
Loss from operations	(16,375)	(15,878)	(497)
Other income (expense):			
Interest expense	(1,917)	(2,043)	126
Other income (expense), net	(283)	588	(871)
Total other expense, net	(2,200)	(1,455)	(745)
Loss before income taxes	(18,575)	(17,333)	(1,242)
Provision for income taxes	(10)	(16)	6
Net loss	$ (18,585)	$ (17,349)	$ (1,236)

Net Revenue

	Six Months Ended June 30,		
	2021	2020	Change
	(in thousands)		
Net revenue by geography:			
United States	$ 11,515	$ 7,648	$ 3,867
Outside the U.S.	3,709	3,273	436
Total net revenue	$ 15,224	$ 10,921	$ 4,303
Net revenue by OCS product:			
OCS Lung net revenue	$ 6,002	$ 2,443	$ 3,559
OCS Heart net revenue	8,780	6,351	2,429
OCS Liver net revenue	442	2,127	(1,685)
Total net revenue	$ 15,224	$ 10,921	$ 4,303

Net revenue from customers in the United States was $11.5 million in the six months ended June 30, 2021 and increased by $3.9 million compared to the six months ended June 30, 2020, primarily due to higher sales volumes of our OCS Lung and OCS Heart disposable sets. Net revenue from sales of OCS Lung disposable sets in the United States increased from $2.3 million in the six months ended June 30, 2020 to $5.8 million in the six months ended June 30, 2021. The increase was due primarily to higher sales volume of OCS Lung disposable sets. Net revenue from OCS Heart disposable sets sold to customers for use in our ongoing clinical trials in the United States increased by $2.1 million, while net revenue from OCS Liver disposable sets sold in the United States decreased by $1.7 million. The increase in net revenue from OCS Heart disposable sets is attributed to higher volume of OCS Heart disposable sets sold in the OCS Heart DCD CAP Trial. The lower sales volume of OCS Liver disposable sets was primarily a result of the completion of enrollment of approved patients in our OCS Liver Protect CAP Trial early in the first quarter of 2021.

Net revenue from customers outside the United States was $3.7 million in the six months ended June 30, 2021 compared to $3.3 million in the six months ended June 30, 2020. The increase in net revenue from customers outside the United States was primarily due to higher sales volumes of OCS Lung and OCS Heart disposable sets. Net revenue from sales of OCS Lung disposable sets outside the United States increased by $0.1 million and net revenue from OCS Heart disposable sets increased by $0.3 million from the six months ended June 30, 2020 to the six months ended June 30, 2021.

Cost of Revenue, Gross Profit and Gross Margin

Cost of revenue increased by $0.7 million in the six months ended June 30, 2021 compared to the six months ended June 30, 2020. Gross profit increased by $3.6 million in the six months ended June 30, 2021 compared to the six months ended June 30, 2020. Gross margin was 68% and 62% for the six months ended June 30, 2021 and 2020, respectively. Gross margin increased primarily as a result of increased activity, higher margin OCS disposable sets sold and improvements in the efficiency of the production process.

Operating Expenses

Research, Development and Clinical Trials Expenses

	Six Months Ended June 30,		
	2021	2020	Change
	(in thousands)		
Personnel related (including stock-based compensation expense)	$ 4,216	$ 4,184	$ 32
Clinical trials costs	2,048	2,714	(666)
Consulting and third-party testing	1,371	938	433
Laboratory supplies and research materials	1,498	845	653
Other	1,694	1,447	247
Total research, development and clinical trials expenses	$ 10,827	$ 10,128	$ 699

Total research, development and clinical trials expenses increased by $0.7 million from $10.1 million in the six months ended June 30, 2020 to $10.8 million in the six months ended June 30, 2021. Clinical trial costs decreased by $0.7 million due to a reduction in ongoing trial enrollment activity primarily related to the OCS Heart DCD CAP Trial and completion of our OCS Liver Protect Trial. Consulting and third-party testing costs increased by $0.4 million due primarily to increased regulatory activity, including costs related to preparation for both the OCS Heart FDA advisory committee panel in April and the OCS Liver FDA advisory committee panel in July. The increase in laboratory supplies and research materials costs of $0.7 million is due primarily to increased research activities, product development and other activities as restrictions implemented in response to the COVID-19 pandemic were eased.

Selling, General and Administrative Expenses

	Six Months Ended June 30,		
	2021	2020	Change
	(in thousands)		
Personnel related (including stock-based compensation expense)	$ 8,772	$ 6,129	$ 2,643
Professional and consultant fees	3,270	3,198	72
Tradeshows and conferences	805	487	318
Other	3,101	2,705	396
Total selling, general and administrative expenses	$ 15,948	$ 12,519	$ 3,429

Total selling, general and administrative expenses increased by $3.4 million from $12.5 million in the six months ended June 30, 2020 to $15.9 million in the six months ended June 30, 2021 due to increases in personnel related costs, tradeshows and conferences and other expenses. Personnel related costs increased from the continued expansion of our commercial team to support commercial sales of our OCS Lung product in the United States. Stock-based compensation expense also increased by $1.6 million due primarily to additional grants to new and existing employees and an increase in the respective grant date fair values from the increased price of our stock. The increase in tradeshows and conferences and other expenses was due to a gradual return to normal activity as restrictions implemented in response to the COVID-19 pandemic were eased, which resulted in higher activity levels for the six months ended June 30, 2021 as compared to the six months ended June 30, 2020 and a resulting increase in related expenses.

Other Income (Expense)

Interest Expense

Interest expense was $1.9 million and $2.0 million for the six months ended June 30, 2021 and 2020, respectively.

Other Income (Expense), Net

Other income (expense), net for the six months ended June 30, 2021 and 2020 included interest income of $0.1 million and $0.5 million, respectively, resulting from interest earned on invested cash balances, and $0.4 million of realized and unrealized foreign currency transaction losses and $0.1 million of realized and unrealized foreign currency transaction gains, respectively.

Liquidity and Capital Resources

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

Since May 2019, we have funded our operations with the proceeds from our 2019 initial public offering of our common stock and our 2020 follow-on public offering. The follow-on public offering was completed on May 26, 2020 and resulted in net proceeds of $75.1 million.

As of June 30, 2021, we had cash, cash equivalents, and marketable securities of $112.2 million.

Cash Flows

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

	Six Months Ended June 30,	
	2021	2020
	(in thousands)	
Cash used in operating activities	$ (12,866)	$ (16,715)
Cash provided by (used in) investing activities	13,076	(28,009)
Cash provided by financing activities	796	75,695
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(273)	89
Net increase in cash, cash equivalents and restricted cash	$ 733	$ 31,060

Operating Activities

During the six months ended June 30, 2021, operating activities used $12.9 million of cash, primarily resulting from our net loss of $18.6 million, partially offset by net cash provided by changes in our operating assets and liabilities of $0.6 million and net non-cash charges of $5.2 million. Net cash provided by changes in our operating assets and liabilities for the six months ended June 30, 2021 consisted primarily of a decrease in accounts receivable of $0.6 million and an increase in accounts payable and accrued expenses and other current liabilities of $2.9 million, partially offset by a $1.9 million increase in inventory and a $1.2 million increase in prepaid expenses and other current assets.

During the six months ended June 30, 2020, operating activities used $16.7 million of cash, primarily resulting from our net loss of $17.3 million and net cash used by changes in our operating assets and liabilities of $1.3 million, partially offset by net non-cash charges of $1.9 million. Net cash used by changes in our operating assets and liabilities for the six months ended June 30, 2020 consisted primarily of a $3.2 million decrease in accounts payable and accrued expenses and other current liabilities, a $1.4 million increase in inventory and a $0.3 million increase in prepaid expenses and other current assets, partially offset by a $2.1 million decrease in accounts receivable, a $0.8 million increase in deferred revenue and a $0.6 million increase in deferred rent.

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

Investing Activities

During the six months ended June 30, 2021, net cash provided by investing activities of $13.1 million consisted of proceeds from sales and maturities of marketable securities of $58.8 million, partially offset by purchases of marketable securities of $45.5 million and purchases of property and equipment of $0.3 million.

During the six months ended June 30, 2020, net cash used in investing activities of $28.0 million consisted of $63.6 million in purchases of marketable securities and $0.4 million in purchases of property and equipment, partially offset by proceeds from sales and maturities of marketable securities of $36.0 million.

Financing Activities

During the six months ended June 30, 2021, net cash provided by financing activities of $0.8 million consisted of proceeds from the issuance of common stock in connection with the employee stock purchase plan of $0.2 million and proceeds from the issuance of common stock upon exercise of stock options of $0.6 million.

During the six months ended June 30, 2020, net cash provided by financing activities of $75.7 million consisted primarily of proceeds from the issuance of common stock in our public offering and employee share ownership plans of $76.0 million, partially offset by payments of offering costs of $0.3 million. We also received proceeds from the Paycheck Protection Loan of $2.2 million, which we then fully repaid in the same period.

Long-Term Debt

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

Borrowings under the Credit Agreement bear interest at an annual rate equal to the LIBOR subject to a minimum of 1.0% and a maximum of 4.0%, plus 8.5%, or the Applicable Margin, subject in the aggregate to a maximum interest rate of 11.5%. In addition, borrowings under the Credit Agreement bear paid-in-kind, or PIK interest, at an annual rate equal to the amount by which LIBOR plus the Applicable Margin exceeds 11.5%, but not to exceed 12.5%. The PIK interest is added to the principal amount of the borrowings outstanding at the end of each quarter until the maturity date of the Credit Agreement in June 2023. Borrowings under the Credit Agreement are repayable in quarterly interest-only payments until the maturity date, at which time all principal and accrued interest is due and payable. At our option, we may prepay outstanding borrowings under the Credit Agreement, subject to a prepayment premium that decreased to zero in June 2021. Our current prepayment premium is zero. We are also required to make a final payment in an amount equal to 3.0% of the principal amount of any prepayment or repayment, which we are accreting to interest expense over the term of the Credit Agreement using the effective interest method.

All obligations under the Credit Agreement are guaranteed by us and each of our material subsidiaries. All obligations of us and each guarantor are secured by substantially all of our and each guarantor's assets, including their intellectual property, subject to certain exceptions, including a perfected security interest in substantially all tangible and intangible assets of us and each guarantor. Under the Credit Agreement, we have agreed to certain affirmative and negative covenants to which we will remain subject until maturity. The financial covenants include maintaining a minimum liquidity amount of $3.0 million; the requirement, on an annual basis, to deliver to OrbiMed annual audited financial statements with an unqualified audit opinion from our independent registered public accounting firm; and restrictions on our activities, including limitations on dispositions, mergers or acquisitions; encumbering our intellectual property; incurring indebtedness or liens; paying dividends; making certain investments; and engaging in certain other business transactions. The obligations under the Credit Agreement are subject to acceleration upon the occurrence of specified events of default, including payment default, change in control, bankruptcy, insolvency, certain defaults under other material debt, certain events with respect to governmental approvals (if such events could cause a material adverse change in our business), failure to comply with certain covenants, including the minimum liquidity and unqualified audit opinion covenants, and a material adverse change in our business, operations or other financial condition. As of June 30, 2021, we were in compliance with all of the covenants under the Credit Agreement.

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

Funding Requirements

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

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

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

We may need to raise additional funding, which might not be available on favorable terms or at all. See “Item 1A. Risk Factors—Risks Related to Our Financial Position and Need for Additional Capital” in our 2020 Form 10-K.

Contractual Obligations and Commitments

There have been no material changes to our contractual obligations and commitments from those disclosed in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in our 2020 Form 10-K.

Inflation Risk

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

Critical Accounting Policies and Significant Judgments and Estimates

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

There have been no material changes to our critical accounting policies and estimates from those disclosed in our consolidated financial statements and the related notes and other financial information included in our 2020 Form 10-K.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Recently Issued Accounting Pronouncements

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

Emerging Growth Company Status

The Jumpstart Our Business Startups Act of 2012 permits an "emerging growth company" such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected not to "opt out" of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that we either (i) irrevocably elect to "opt out" of such extended transition period or (ii) no longer qualify as an emerging growth company. As of June 30, 2021, the market value of our common stock held by non-affiliates exceeded $700 million. As a result, we will no longer be an emerging growth company as of December 31, 2021 and will be a large accelerated filer beginning January 1, 2022.

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 2020 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 June 30, 2021. 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 June 30, 2021, 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 June 30, 2021 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 2020 Form 10-K and the additional risk below.

We will no longer qualify as an "emerging growth company" after December 31, 2021, and, as a result, we will have to comply with increased disclosure and compliance requirements.

We are currently an "emerging growth company" as defined in the JOBS Act. However, because the market value of our common stock held by non-affiliates exceeded $700 million as of June 30, 2021, we will no longer qualify as an "emerging growth company" as of December 31, 2021 and will be a large accelerated filer beginning January 1, 2022.

As a large accelerated filer, we will be subject to certain disclosure and compliance requirements that apply to other public companies but that did not previously apply to us due to our status as an emerging growth company. These requirements include, but are not limited to:

- the requirement that our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act of 2002;
- compliance with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- the requirement that we provide full and more detailed disclosures regarding executive compensation; and
- the requirement that we hold a non-binding advisory vote on executive compensation and obtain stockholder approval of any golden parachute payments not previously approved.

We expect that the loss of emerging growth company status and compliance with the additional requirements of being a large accelerated filer will increase our legal, accounting and financial compliance costs and costs associated with investor relations activities, and cause management and other personnel to divert attention from operational and other business matters to devote substantial time to public company reporting requirements. In addition, if we are not able to comply with changing requirements in a timely manner, the market price of our stock could decline and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC or other regulatory authorities, which would require additional financial and management resources.

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

Use of Proceeds

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

The offer and sale of all of the shares of our common stock in our IPO were registered under the Securities Act pursuant to a registration statement on Form S-1, as amended (File No. 333-230736), which was declared effective by the SEC on May 1, 2019 and a registration statement on Form S-1MEF (File No. 333-231166), which was automatically effective upon filing with the SEC on May 1, 2019.

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

As of June 30, 2021, we have used approximately $60.8 million of net offering proceeds primarily for commercialization of OCS Lung, research and development, and general corporate purposes. We are holding a significant portion of the remaining net proceeds in money market funds, U.S. Treasury securities and U.S. government agency bonds. There has been no material change in our planned use of the net proceeds from the IPO as described in the final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act, with the SEC, on May 2, 2019.

Item 6. Exhibits.

Exhibit Number	Description
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: August 6, 2021

TRANSMEDICS GROUP, INC.

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

Date: August 6, 2021

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: August 6, 2021

/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: August 6, 2021

/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 June 30, 2021, 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: August 6, 2021

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 June 30, 2021 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: August 6, 2021

By:/s/ Stephen Gordon

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