UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended September 30, 2023
OR
☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to
Commission File Number: 001-38891

TransMedics Group, Inc.
(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

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

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

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

As of October 31, 2023, the registrant had 32,647,698 shares of common stock, no par value per share, outstanding.

FORWARD-LOOKING STATEMENTS

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

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

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

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

- our use of third parties to transport donor organs and medical personnel for our National OCS Program and our ability to maintain and grow our aviation capabilities to support our National OCS Program to reduce dependence on third party transportation, including by means of the acquisition of fixed-wing aircraft or other acquisitions, joint ventures or strategic investments;
- our ability to maintain Federal Aviation Administration, or FAA, or other regulatory licenses or approvals for our aircraft services;
- price increases of the components of our products and maintenance, parts and fuel for our aircraft;
- the timing or results of post-approval studies and any clinical trials for the OCS;
- our manufacturing, sales, marketing and clinical support capabilities and strategy;
- attacks against our information technology infrastructure;
- the economic, political and other risks associated with our foreign operations;
- our ability to protect, defend, maintain and enforce our intellectual property rights relating to the OCS and avoid allegations that our products infringe, misappropriate or otherwise violate the intellectual property rights of third parties;
- the pricing of the OCS, as well as the reimbursement coverage for the OCS in the United States and internationally;
- regulatory developments in the United States, European Union and other jurisdictions;
- the extent and success of competing products or procedures that are or may become available;
- our ability to service our 1.50% convertible senior notes, due 2028;
- the impact of any product recalls or improper use of our products; and
- our estimates regarding revenue, expenses and needs for additional financing.

TransMedics Group, Inc.
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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)

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

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash	$ 427,110	$ 201,182
Accounts receivable	60,654	27,611
Inventory	39,365	20,605
Prepaid expenses and other current assets	9,595	2,896
Total current assets	536,724	252,294
Property, plant and equipment, net	131,004	19,223
Operating lease right-of-use assets	6,861	5,130
Restricted cash	500	500
Goodwill	11,673	—
Acquired intangible assets, net	2,405	—
Other non-current assets	60	—
Total assets	$ 689,227	$ 277,147
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 12,836	$ 3,341
Accrued expenses and other current liabilities	31,651	18,635
Deferred revenue	2,629	241
Operating lease liabilities	1,985	1,444
Total current liabilities	49,101	23,661
Convertible senior notes, net	446,448	—
Long-term debt, net	58,986	58,696
Operating lease liabilities, net of current portion	8,232	7,415
Total liabilities	562,767	89,772
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, no par value; 25,000,000 shares authorized; no shares issued or outstanding	—	—
Common stock, no par value; 150,000,000 shares authorized; 32,642,130 shares and 32,141,368 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	634,458	666,277
Accumulated other comprehensive loss	(262)	(225)
Accumulated deficit	(507,736)	(478,677)
Total stockholders' equity	126,460	187,375
Total liabilities and stockholders' equity	$ 689,227	$ 277,147

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenue:				
Net product revenue	$ 47,740	$ 21,299	$ 124,195	$ 54,160
Service revenue	18,690	4,384	$ 36,254	7,924
Total revenue	66,430	25,683	160,449	62,084
Cost of revenue:				
Cost of net product revenue	11,086	4,231	26,950	11,689
Cost of service revenue	14,682	3,337	27,330	5,826
Total cost of revenue	25,768	7,568	54,280	17,515
Gross profit	40,662	18,115	106,169	44,569
Operating expenses:				
Research, development and clinical trials	11,132	6,808	25,294	21,056
Acquired in-process research and development expenses	27,212	—	27,212	—
Selling, general and administrative	30,653	16,851	84,993	48,171
Total operating expenses	68,997	23,659	137,499	69,227
Loss from operations	(28,335)	(5,544)	(31,330)	(24,658)
Other income (expense):				
Interest expense	(3,590)	(787)	(7,186)	(2,719)
Other income (expense), net	4,996	(1,076)	7,982	(2,087)
Total other income (expense), net	1,406	(1,863)	796	(4,806)
Loss before income taxes	(26,929)	(7,407)	(30,534)	(29,464)
(Provision) benefit for income taxes	1,507	(19)	1,475	(47)
Net loss	$ (25,422)	$ (7,426)	$ (29,059)	$ (29,511)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.78)	$ (0.25)	$ (0.89)	$ (1.03)
Weighted average common shares outstanding, basic and diluted	32,614,059	30,229,936	32,474,522	28,729,649

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Net loss	$ (25,422)	$ (7,426)	$ (29,059)	$ (29,511)
Other comprehensive income (loss):				
Foreign currency translation adjustment	(42)	(41)	(37)	(95)
Unrealized gains on marketable securities, net of tax of $0	—	100	—	36
Total other comprehensive income (loss)	(42)	59	(37)	(59)
Comprehensive loss	$ (25,464)	$ (7,367)	$ (29,096)	$ (29,570)

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

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

	Common Stock		Accumulated Other Comprehen-sive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balances at December 31, 2022	32,141,368	$ 666,277	$ (225)	$ (478,677)	$ 187,375
Issuance of common stock upon the exercise of common stock options	378,500	3,574	—	—	3,574
Issuance of common stock in connection with employee stock purchase plan	14,135	384	—	—	384
Stock-based compensation expense	—	3,921	—	—	3,921
Foreign currency translation adjustment	—	—	7	—	7
Net loss	—	—	—	(2,636)	(2,636)
Balances at March 31, 2023	32,534,003	674,156	(218)	(481,313)	192,625
Issuance of common stock upon the exercise of common stock options	39,158	705	—	—	705
Stock-based compensation expense	—	4,958	—	—	4,958
Purchases of capped calls related to convertible senior notes	—	(52,072)	—	—	(52,072)
Issuance of restricted common stock	9,772	—	—	—	—
Foreign currency translation adjustment	—	—	(2)	—	(2)
Net loss	—	—	—	(1,001)	(1,001)
Balances at June 30, 2023	32,582,933	627,747	(220)	(482,314)	145,213
Issuance of common stock upon the exercise of common stock options	47,438	952	—	—	952
Issuance of common stock in connection with employee stock purchase plan	11,759	571	—	—	571
Stock-based compensation expense	—	5,188	—	—	5,188
Foreign currency translation adjustment	—	—	(42)	—	(42)
Net loss	—	—	—	(25,422)	(25,422)
Balances at September 30, 2023	32,642,130	$ 634,458	$ (262)	$ (507,736)	$ 126,460

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

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

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

	Nine Months Ended September 30,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (29,059)	$ (29,511)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	4,572	2,193
Stock-based compensation expense	14,067	7,330
Acquired in-process research and development expenses	27,212	—
Deferred taxes	(1,540)	—
Loss on extinguishment of debt	—	575
Loss on sale of marketable securities	—	107
Non-cash interest expense and end of term accretion expense	1,358	309
Non-cash lease expense	728	532
Net amortization of premiums on marketable securities	—	381
Unrealized foreign currency transaction losses	118	1,733
Changes in operating assets and liabilities, net of acquired assets and liabilities:		
Accounts receivable	(30,997)	(16,287)
Inventory	(21,029)	(6,094)
Prepaid expenses and other current assets	(2,170)	(98)
Other non-current assets	(54)	—
Accounts payable	6,541	(3,534)
Accrued expenses and other current liabilities	9,257	(8)
Deferred revenue	765	—
Operating lease liabilities	(1,101)	590
Net cash used in operating activities	(21,332)	(41,782)
Cash flows from investing activities:		
Purchases of property, plant and equipment	(110,029)	(9,143)
Purchase of business, net of cash acquired	(14,894)	—
Purchase of in-process research and development assets	(27,212)	—
Purchases of marketable securities	—	(10,496)
Proceeds from sales and maturities of marketable securities	—	76,916
Net cash provided by (used in) investing activities	(152,135)	57,277
Cash flows from financing activities:		
Proceeds from issuance of convertible senior notes, net of issuance costs paid of $14,620	445,380	—
Purchases of capped calls related to convertible senior notes	(52,072)	—
Proceeds from issuance of long-term debt, net of issuance costs and issuance costs paid	—	58,509
Repayments of long-term debt	—	(36,050)
Proceeds from issuance of common stock in public offering, net of underwriting discounts and commissions	—	140,014
Proceeds from issuance of common stock upon exercise of stock options	5,231	1,880
Proceeds from issuance of common stock in connection with employee stock purchase plan	955	509
Net cash provided by financing activities	399,494	164,862
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(99)	(1,475)
Net increase in cash, cash equivalents and restricted cash	225,928	178,882
Cash, cash equivalents and restricted cash, beginning of period	201,682	26,080
Cash, cash equivalents and restricted cash, end of period	$ 427,610	$ 204,962
Supplemental disclosure of non-cash activities:		
Transfers of inventory to property, plant and equipment	$ 2,224	$ 2,055
Purchases of property, plant and equipment included in accounts payable and accrued expenses	$ 1,724	$ 926
Operating lease liabilities arising from obtaining right-of-use assets	$ 2,171	$ —
Offering costs included in accounts payable and accrued expenses	$ —	$ 160
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$ 427,110	$ 204,462
Restricted cash	500	500
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	$ 427,610	$ 204,962

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

1. Nature of the Business and Basis of Presentation

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

On August 16, 2023, the Company acquired Summit Aviation, Inc. and Northside Property Group, LLC (together "Summit"). Summit is a charter flight operator based in Bozeman, Montana. The acquisition enabled TransMedics to add aircraft transportation services to its NOP and become a comprehensive national provider of donor organ retrieval and delivery in the United States.

The accompanying consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the ordinary course of business. The Company has incurred recurring losses since inception, including net losses of $29.1 million for the nine months ended September 30, 2023 and $36.2 million for the year ended December 31, 2022. As of September 30, 2023, the Company had an accumulated deficit of $507.7 million. The Company expects to continue to generate operating losses in the foreseeable future.

The Company believes that its existing cash of $427.1 million as of September 30, 2023 will be sufficient to fund its operations, capital expenditures, and debt service payments for at least the next 12 months following the filing of this Quarterly Report on Form 10-Q. The Company may need to seek additional funding through equity financings, debt financings or strategic alliances. The Company may not be able to obtain financing on acceptable terms, or at all, and the terms of any financing may adversely affect the holdings or the rights of the Company's shareholders. If the Company is unable to obtain funding, the Company will be required to delay, reduce or eliminate some or all of its research and development programs, product expansion or commercialization efforts, or the Company may be unable to continue operations.

The Company is subject to risks and uncertainties common to companies in the medical device industry and of similar size, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, uncertainty of market acceptance of products, and the need to obtain additional financing to fund operations. Products currently under development will require additional research and development efforts, including additional clinical testing and regulatory approval, prior to commercialization. These efforts require additional capital, adequate personnel, infrastructure and extensive compliance-reporting capabilities. The Company's research and development may not be successfully completed, adequate protection for the Company's technology may not be obtained, the Company may not obtain necessary government regulatory approval on its expected timeline or at all, and approved products may not prove commercially viable. The Company operates in an environment of rapid change in technology and competition.

Continued impacts to the Company's business as a result of the COVID-19 pandemic may include decreased overall frequency of transplant procedures; disruptions to the Company's manufacturing operations and supply chain; labor shortages; decreased productivity and unavailability of materials or components; limitations on its employees' and customers' ability to travel, and delays in product installations, trainings or shipments to and from other affected countries and within the United States. While the Company maintains an inventory of finished products and raw materials used in its OCS products, a further prolonged pandemic could lead to shortages in the raw materials necessary to manufacture its products.

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

2. Summary of Significant Accounting Policies

Unaudited Interim Financial Information

The accompanying unaudited interim financial statements and related notes have been prepared by the Company pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC") for interim financial statements. Certain information and footnote disclosures normally included in the financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. These consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and the notes thereto for the year ended December 31, 2022 included in the Company's Annual Report on Form 10-K filed with the SEC. In the opinion of management, all adjustments, consisting only of normal recurring adjustments necessary for a fair statement of the Company's financial position as of September 30, 2023 and results of operations for the three and nine months ended September 30, 2023 and 2022 and cash flows for the nine months ended September 30, 2023 and 2022 have been made. The Company's results of operations for the three and nine months ended September 30, 2023 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2023.

Use of Estimates

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

Risk of Concentrations of Credit, Significant Customers and Significant Suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and accounts receivable. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships. As of September 30, 2023 and December 31, 2022, the Company had no allowance for credit losses.

Significant customers are those that accounted for 10% or more of the Company's revenue or accounts receivable. For the three and nine months ended September 30, 2023, no customer accounted for more than 10% of revenue. For the three months ended September 30, 2022, one customer accounted for 13% of revenue. For the nine months ended September 30, 2022, one customer accounted for 15% of revenue. As of September 30, 2023 one customer accounted for 13% of accounts receivable. As of December 31, 2022, no customer accounted for more than 10% of accounts receivable.

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

Business Combinations

In determining whether an acquisition should be accounted for as a business combination or asset acquisition, the Company first determines whether substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or a group of similar identifiable assets. If this is the case, the single identifiable asset or the group of similar assets is not deemed to be a business and the acquisition is accounted for as an asset acquisition. If this is not the case, the Company then further evaluates whether the acquisition includes, at a minimum, an input and a substantive process that together significantly contribute to the ability to create outputs. If so, the Company concludes that the acquisition is a business and accounts for it as a business combination.

The Company accounts for business combinations using the acquisition method of accounting. In accordance with this method, assets acquired and liabilities assumed are recorded at their respective fair values at the acquisition date. The fair value of the consideration paid is assigned to the assets acquired and liabilities assumed based on their respective fair values. Goodwill represents the excess of the purchase price over the estimated fair values of the assets acquired and liabilities assumed.

Determining the fair value of assets acquired and liabilities assumed is judgmental in nature and can involve the use of significant estimates and assumptions. Fair value and useful life determinations are based on, among other things, valuations that use information and assumptions provided by management, which consider management's best estimates of inputs and assumptions that a market participant would use. Actual results may vary from these estimates and may result in adjustments to goodwill and acquisition date fair values of assets and liabilities during a measurement period or upon a final determination of asset and liability fair values, whichever comes first. Adjustments to fair values of assets and liabilities made after the end of the measurement period are recorded within operating results.

Transaction costs related to business combinations are expensed as incurred and are included in general and administrative expense in the consolidated statements of operations.

Asset Acquisitions

The Company measures and recognizes asset acquisitions that are not deemed to be business combinations based on the cost to acquire the asset or group of assets, which includes transaction costs. Goodwill is not recognized in asset acquisitions. In an asset acquisition, the cost allocated to acquire in-process research and development ("IPR&D") with no alternative future use is charged to expense at the acquisition date.

Goodwill and Acquired Intangible Assets

The Company records goodwill when consideration paid in a business combination exceeds the value of the net assets acquired. The Company's estimates of fair value are based upon assumptions believed to be reasonable at that time, but that are inherently uncertain and unpredictable. Goodwill is not amortized, but rather is tested for impairment annually in the fourth quarter, or more frequently if facts and circumstances warrant a review, such as significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets.

The Company has determined that there is a single reporting unit for the purpose of conducting this goodwill impairment assessment. The Company has the option of performing either a qualitative or quantitative assessment to determine whether further impairment testing is necessary. If it is more-likely-than-not that the fair value of a reporting unit is less than its carrying amount, a quantitative impairment test will be required. The quantitative goodwill impairment test requires management to estimate and compare the fair value of the reporting unit with its carrying value. If the fair value of the reporting unit exceeds the carrying value of the net assets, goodwill is not impaired. If the fair value of the reporting unit is less than the carrying value, the difference is recorded as an impairment loss up to the amount of goodwill.

Intangible assets are recorded at their estimated fair values at the date of acquisition and are reported net of accumulated amortization. The Company amortizes acquired intangible assets with finite lives over their estimated useful lives based on the pattern of consumption of the economic benefits or, if that pattern cannot be readily determined, on a straight-line basis.

Fair Value Measurements

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

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

The carrying values of the Company’s accounts receivable, accounts payable and accrued expenses approximate their fair values due to the short-term nature of these assets and liabilities. The carrying value of the Company’s long-term debt approximates its fair value (a level 2 measurement) at each balance sheet date due to its variable interest rate, which approximates a market interest rate. The Company's 1.50% Convertible Senior Notes due 2028 (the "Notes") are carried at the face value less unamortized debt discount and issuance costs on the consolidated balance sheets, and the fair value of the convertible senior notes is presented at each reporting period for disclosure purposes only.

Segment Information

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

Net Income (Loss) per Share

Basic net income (loss) per common share is computed by dividing the net income (loss) by the weighted average number of shares of common stock outstanding for the period. Diluted net income (loss) per common share is computed by dividing net income (loss) by the weighted average number of shares of common stock outstanding for the period, including potential dilutive common shares assuming the dilutive effect of outstanding common stock equivalents. For periods in which the Company reports a net loss, diluted net loss per common share is the same as basic net loss per common share, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive. The Company reported a net loss attributable to common stockholders for each of the three and nine months ended September 30, 2023 and 2022.

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

	As of September 30,	
	2023	2022
Warrants to purchase common stock	64,440	64,440
Options to purchase common stock	3,191,755	3,309,558
Employee stock purchase plan	9,370	8,886
Restricted stock units	241,167	—
Restricted stock awards	9,772	24,315
Convertible senior notes	4,893,848	—
	8,410,352	3,407,199

3. Marketable Securities and Fair Value Measurements

The Company did not have marketable securities as of September 30, 2023 or December 31, 2022. The Company also did not have assets or liabilities measured at fair value on a recurring basis as of September 30, 2023 or December 31, 2022.

Convertible Senior Notes

As of September 30, 2023, the carrying value of the Notes was $446.4 million (see Note 9) and the estimated fair value of the Notes was $426.2 million. The fair value was determined based on the quoted price of the last trade of the Notes prior to the end of the reporting period in an inactive market, which is considered as Level 2 in the fair value hierarchy.

4. Acquisition of Summit

On August 16, 2023, the Company acquired Summit pursuant to the terms of an equity purchase agreement. Summit is a charter flight operator based in Bozeman, Montana. The acquisition enabled TransMedics to add aircraft transportation services to its NOP and become a comprehensive national provider of donor organ retrieval and delivery in the United States.

The acquisition was accounted for as a purchase of a business under ASC Topic 805, Business Combinations. Under the acquisition method of accounting, the assets and liabilities were recorded as of the acquisition date, at their respective fair values. The preliminary purchase consideration of $14.9 million reflected an upfront cash payment of $18.0 million, net of cash acquired and working capital adjustments.

The Company’s consolidated financial statements reflect the preliminary allocation of the purchase price to the assets and liabilities assumed based on fair value as of the date of the acquisition. The Company's estimate of preliminary purchase consideration is subject to change upon finalizing working capital adjustments. The Company’s preliminary estimate of the fair value of specifically identifiable assets acquired and liabilities assumed as of the date of acquisition is subject to change upon finalizing its valuation analysis. The final determinations, which are expected to be completed by August 2024, may result in changes in the fair value of certain assets and liabilities as compared to these preliminary estimates.

The following tables summarize the preliminary allocation of the purchase price (in thousands):

Assets Acquired and Liabilities Assumed:		
Accounts receivable	$	2,089
Other current assets		1,040
Property, plant and equipment		5,922
Right-of-use asset		288
Intangible assets		2,430
Goodwill		11,673
Total assets acquired		23,442
Accounts payable and other current liabilities		(6,720)
Deferred tax liabilities		(1,540)
Operating lease liabilities		(288)
Total allocation of purchase price consideration, net of cash acquired	$	14,894

Property, plant and equipment consist primarily of flight school aircraft and construction-in-progress related to a commercial aircraft hangar that Summit is in the process of constructing. Flight school aircraft were valued using market comparisons adjusted for aircraft-specific condition. The fair value of construction-in-progress approximated its cost.

Intangible assets consisted primarily of a customer relationship asset of $2.3 million related to flight school revenue and was valued using the multi-period excess earnings method, a form of the income approach. Significant assumptions and estimates utilized in this model include the revenue growth rate, contract renewal probability and the discount rate, and is being amortized to selling, general and administrative over its estimated useful life of 12 years as of the acquisition date on a straight-line basis.

Goodwill was recognized for the excess purchase price over the fair value of the net assets acquired. Goodwill is primarily attributable to the workforce of the acquired business (which is not eligible for separate recognition as an identifiable intangible asset) and anticipated synergies between Summit’s existing business processes and the NOP. Goodwill from the acquisition is included within the Company’s one reporting unit and is included in the Company’s enterprise-level annual review for impairment. Goodwill resulting from the acquisition is not deductible for tax purposes.

Deferred tax liabilities relate to the differences between the fair value recognized in purchase accounting and the tax basis of property, plant and equipment and intangible assets. The net deferred tax liability is a source of income to support the recognition of a portion of our existing deferred tax assets. Therefore, the Company recorded a tax benefit of $1.5 million for the release of a portion of its valuation allowance related to the net deferred tax liabilities recorded in purchase accounting.

The Company incurred total transaction costs of $2.0 million for third-party professional services utilized for the acquisition, which are included in general and administrative costs in the statements of operations. The operating results of the acquired entity have been included in the consolidated financial statements beginning on the acquisition date. Pro forma results of operations for the acquisition have not been presented as they are not material to the Company's consolidated results of operations.

5. Inventory

Inventory consisted of the following (in thousands):

	September 30, 2023	December 31, 2022
Raw materials	$ 18,856	$ 10,939
Work-in-process	3,051	1,876
Finished goods	17,458	7,790
	$ 39,365	$ 20,605

6. Property, Plant and Equipment, Net

Property, plant and equipment, net consisted of the following (in thousands):

	September 30, 2023	December 31, 2022
Transplant aircraft	$ 102,985	$ —
Flight school aircraft	3,484	—
OCS Consoles	13,074	10,878
Manufacturing equipment	5,315	3,721
Computer equipment and software	2,782	2,064
Laboratory equipment	765	671
Office, trade show and training equipment	3,030	2,121
Leasehold improvements	12,917	12,415
Construction-in-progress	4,308	482
	148,660	32,352
Less: Accumulated depreciation and amortization	(17,656)	(13,129)
	$ 131,004	$ 19,223

Depreciation and amortization expense of aircraft is recognized using the straight-line method over the estimated useful life of each asset to its salvage value. The estimated useful lives of aircraft are 10 years for transplant aircraft and five years for flight school aircraft. Residual values estimated for transplant and flight school aircraft are approximately 50% of the original purchase price. Expenditures for repairs and maintenance are charged to expense as incurred.

Construction-in-progress as of September 30, 2023 primarily relates to construction of a commercial aircraft hangar at Bozeman Yellowstone International Airport in Bozeman, Montana.

7. Goodwill and Intangible Assets

The carrying amount of goodwill was $11.7 million as of September 30, 2023 related to the Company's acquisition of Summit. Goodwill is not amortized, but instead is reviewed for impairment at least annually or more frequently when events and circumstances occur indicating that the recorded goodwill may be impaired. To date, the Company has had no impairments to goodwill.

Acquired intangible assets consisted of the following (in thousands):

	Weighted Average Useful Life	September 30, 2023		
		Gross Amount	Accumulated Amortization	Carrying Value
	(in years)			
Customer relationship	12	$ 2,320	$ 24	$ 2,296
Other	12	110	1	109
		$ 2,430	$ 25	$ 2,405

Amortization expense is recorded within selling, general and administrative expense. Future amortization expense of the intangible assets as of September 30, 2023, is expected to be as follows (in thousands):

Year Ending December 31,	
2023 (three months)	$ 49
2024	203
2025	203
2026	203
2027	203
Thereafter	1,544
	$ 2,405

8. Accrued Expenses and Other Current Liabilities

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

	September 30, 2023	December 31, 2022
Accrued payroll and related expenses	$ 15,934	$ 9,812
Accrued transportation costs	4,375	2,581
Accrued research, development and clinical trials expenses	1,261	1,876
Accrued professional fees	2,073	965
Accrued interest	2,683	—
Accrued other	5,325	3,401
	$ 31,651	$ 18,635

9. Long-Term Debt and Financing Arrangements

Convertible Senior Notes

Convertible senior notes consisted of the following (in thousands):

	September 30, 2023
Principal amount of convertible senior notes	$ 460,000
Less: Current portion of convertible senior notes	—
Convertible senior notes, net of current portion	460,000
Debt discount, net of accretion	(13,552)
Convertible senior notes, net of discount and current portion	$ 446,448

On May 11, 2023, the Company issued $460.0 million aggregate principal amount of the Notes, in a private placement to qualified institutional buyers pursuant to Rule 144A under the Securities Act, pursuant to an indenture dated May 11, 2023, by and between the Company and U.S. Bank Trust Company, National Association (the “Indenture”).

The initial conversion price of the Notes is approximately $94.00 per share of common stock, which represents a premium of approximately 32.5% over the closing price of the Company’s common stock on May 8, 2023. The Notes will mature on June 1, 2028, unless earlier repurchased, redeemed or converted. The Company used $52.1 million of the proceeds from the sale of the Notes to fund the cost of entering into capped call transactions, described below. The proceeds from the issuance of the Notes were approximately $393.3 million, net of capped call transaction costs of $52.1 million and initial purchaser discounts and other debt issuance costs totaling $14.6 million.

The Notes bear interest at a rate of 1.50% per year and interest is payable semiannually in arrears on June 1 and December 1 of each year, beginning on December 1, 2023. The initial conversion rate is 10.6388 shares of common stock per $1,000 principal amount of the Notes, which represents an initial conversion price of approximately $94.00 per share of common stock. The conversion rate and conversion price are subject to customary adjustments upon the occurrence of certain events as described in the Indenture.

Before March 1, 2028, noteholders have the right to convert their Notes only upon the occurrence of certain events, including certain corporate events, and during the five business days immediately after any ten consecutive trading days in which the trading price per $1,000 principal amount of Notes is less than ninety eight percent (98%) of the as converted value. Additionally, the noteholder can convert their Notes during any calendar quarter (and only during such calendar quarter), commencing after the calendar quarter ending on September 30, 2023 but before March 1, 2028, provided the last reported sale price of the common stock for at least 20 trading days is greater than or equal to 130% of the conversion price during the 30 consecutive trading days ending on the last trading day of a calendar quarter. From and after March 1, 2028, noteholders may convert their Notes at any time at their election until the close of business on the second scheduled trading day immediately before the maturity date. The Company has the right to elect to settle conversions either in cash, shares or in a combination of cash and shares of its common stock.

Prior to June 8, 2026, the Notes will not be redeemable. On or after June 8, 2026, the Company may redeem for cash all or any portion of the Notes (subject to the partial redemption limitation set forth in the Indenture), at its option, if the last reported sale price of the Company's common stock has been at least 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period (including the last trading day of such period) ending on, and including, the trading day immediately preceding the date on which the Company provides notice of redemption. In addition, calling any Note for redemption will constitute a "Make-Whole Fundamental Change" (as defined in the Indenture) with respect to that Note, in which case the conversion rate applicable to the conversion of that Note will be increased in certain circumstances if it is converted after it is called for redemption.

The Company accounts for the Notes as a single liability in accordance with ASC 470-20 as the Company concluded that embedded conversion features within the Notes do not meet the requirements for bifurcation. Initial purchaser discounts and other debt issuance costs related to the Notes totaling $14.6 million were recorded by the Company as a debt discount. The debt discount is reflected as a reduction of the carrying value of the Notes on the Company's consolidated balance sheet and is being accreted to interest expense over the term of the Notes using the effective interest method. During the three and nine months ended September 30, 2023, the Company recognized $2.4 million and $3.8 million, respectively, in interest expense related to the 1.50% cash coupon of the Notes and amortization of the debt issuance costs. During the three and nine months ended September 30, 2023, the effective interest rate on the outstanding Notes was approximately 2.1%.

Capped Call Transactions

In connection with the offering of the Notes, the Company entered into privately negotiated capped call transactions (the "Capped Calls") with certain financial institution counterparties (the "Option Counterparties"). The Capped Calls are generally intended to reduce or offset the potential dilution to the common stock upon any conversion of the Notes with such reduction or offset, as the case may be, subject to a cap based on the cap price. For accounting purposes, the Capped Calls are separate transactions, and not part of the terms of the Notes. The Capped Calls are recorded in stockholders' equity and are not accounted for as derivatives. The cost of $52.1 million incurred to purchase the Capped Calls were recorded as a reduction to common stock in the accompanying consolidated balance sheet.

Each of the Capped Calls has an initial strike price of approximately $94.00 per share, subject to certain adjustments, which corresponds to the initial conversion price of the Notes. The Capped Calls have an initial cap price of $141.88 per share, subject to certain adjustments. The Capped Calls cover, subject to anti-dilution adjustments, approximately 4,893,848 million shares of the Company's common stock, which is the same number of shares of the Company's common stock initially underlying the Notes. The Capped Calls are subject to automatic exercise over a 40 trading day period commencing on April 3, 2028, subject to earlier termination under certain circumstances.

Long-term debt

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

	September 30, 2023	December 31, 2022
Principal amount of long-term debt	$ 60,000	$ 60,000
Less: Current portion of long-term debt	—	—
Long-term debt, net of current portion	60,000	60,000
Debt discount, net of accretion	(1,014)	(1,304)
Long-term debt, net of discount and current portion	$ 58,986	$ 58,696

In July 2022, the Company entered into a credit agreement with Canadian Imperial Bank of Commerce ("CIBC"), as amended by the First Amendment to Credit Agreement, dated as of May 8, 2023, by and among the Company and CIBC (the "First Amendment") and the Second Amendment to Credit Agreement, dated as of June 23, 2023, by and among the Company, and CIBC (the "Second Amendment") (as amended, the "CIBC Credit Agreement"), pursuant to which the Company borrowed $60.0 million. In connection with the CIBC Credit Agreement, the Company repaid all amounts due under its previously outstanding credit agreement with OrbiMed Royalty Opportunities II, LP, including $35.0 million of principal repayments and a $1.1 million end of term payment, as well as accrued interest and the OrbiMed Credit Agreement was terminated. Upon repayment of the outstanding amounts, the Company recorded a loss on extinguishment of debt of $0.6 million, which was classified as other expense in the consolidated statements of operations.

On May 8, 2023, the Company entered into the First Amendment, which among other items, allowed for the issuance of the Notes and Capped Calls. On June 23, 2023, the Company entered into the Second Amendment, which among other items, permits the Company to make acquisitions of equity or assets of another entity, subject to the conditions under the Second Amendment, including acquisitions, without further consent of CIBC, up to a maximum amount of $50.0 million for the cash consideration payable in connection with an individual acquisition and a maximum amount of $150.0 million for the total cash consideration payable for all acquisitions made by the Company on or after June 23, 2023. The definition of consolidated adjusted EBITDA was also amended to add a provision for the pro forma effect of any acquisitions that occur during the period. Additionally, pursuant to the Second Amendment, the parties agreed to extend the start of the principal repayment period to July 31, 2026, on which date the Company is obligated to begin repayment of the term loans in equal monthly installments until the maturity date in July 2027.

Borrowings under the CIBC Credit Agreement bear interest at an annual rate equal to either, at the Company's option, (i) the secured overnight financing rate for an interest period selected by the Company, subject to a minimum of 1.50%, plus 2.0% or (ii) 1.0% plus the higher of a) the prime rate subject to a minimum of 4.0% or b) the Federal Funds Effective Rate, plus 0.5%. At the Company's option, the Company may prepay borrowings outstanding under the CIBC Credit Agreement, subject to a prepayment fee of 2.0% of outstanding borrowings if paid prior to 12 months after the closing date, and 1.0% if paid on or after 12 months after the closing date but prior to 24 months after the closing date.

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

All obligations under the CIBC Credit Agreement are guaranteed by the Company and each of its material subsidiaries. All obligations of the Company and each guarantor are secured by substantially all of the Company's and each guarantor's assets, including their intellectual property, subject to certain exceptions. Under the CIBC Credit Agreement, the Company has agreed to customary representations and warranties, events of default and certain affirmative and negative covenants to which it will remain subject until maturity. The financial covenants include, among other covenants, (x) a requirement to maintain a minimum liquidity amount of the greater of either (i) the consolidated adjusted EBITDA loss (or gain) for the trailing four month period (only if EBITDA is negative) and (ii) $10.0 million, and (y) a requirement to maintain total net revenue of at least 75% of the level set forth in the total revenue plan presented to CIBC. As discussed above, the definition of consolidated adjusted EBITDA was amended to include the pro forma effect of acquisitions. The obligations under the CIBC Credit Agreement are subject to acceleration upon the occurrence of specified events of default, including payment default, change in control, bankruptcy, insolvency, certain defaults under other material debt, certain events with respect to governmental approvals (if such events could cause a material adverse change in the Company's business), failure to comply with certain covenants and a material adverse change in the Company's business, operations or financial condition. As of September 30, 2023, the Company was in compliance with all financial covenants of the CIBC Credit Agreement.

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

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

As of September 30, 2023, the stated interest rate applicable to borrowings under the CIBC Credit Agreement was 7.3%. During the three and nine months ended September 30, 2023, the weighted average effective interest rate on outstanding borrowings under the CIBC Credit Agreement was approximately 7.7% and 7.6%, respectively.

10. Stock-Based Compensation

2019 Stock Incentive Plan

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

Shares withheld in payment of the exercise or purchase price of an award or in satisfaction of tax withholding requirements, and the shares covered by a stock appreciation right for which any portion is settled in stock, will reduce the number of shares available for issuance under the 2019 Plan. In addition, the number of shares available for issuance under the 2019 Plan (i) will not be increased by any shares delivered under the 2019 Plan that are subsequently repurchased using proceeds directly attributable to stock option exercises and (ii) will not be reduced by any awards that are settled in cash or that expire, become unexercisable, terminate or are forfeited to or repurchased by TransMedics Group without the issuance of stock under the 2019 Plan. On May 25, 2023, the shareholders of the Company approved the Amended and Restated TransMedics Group, Inc. 2019 Stock Incentive Plan (the "Amended Plan") to among other things, (i) increase the number of shares of the Company's common stock available for issuance thereunder by 1,000,000 shares, (ii) prohibit the payment of dividend or dividend equivalents on a current basis with respect to unvested awards, (iii) extend the expiration date of the Amended Plan until June 1, 2033 and (iv) increase the annual limits on non-employee director compensation. As of September 30, 2023, 1,389,390 shares of common stock were available for issuance under the Amended Plan.

2019 Employee Stock Purchase Plan

Pursuant to the Company's 2019 Employee Stock Purchase Plan (the "2019 ESPP"), certain employees of the Company are eligible to purchase common stock of the Company at a reduced price during offering periods. The 2019 ESPP permits participants to purchase common stock using funds contributed through payroll deductions, subject to the limitations set forth in the Internal Revenue Code, at a purchase price of 85% of the lower of the closing price of the Company's common stock on the first trading day of the offering period or the closing price on the applicable purchase date, which is the final trading day of the applicable offering period. A total of 371,142 shares of the Company's common stock were initially reserved for issuance under the 2019 ESPP. During the nine months ended September 30, 2023, 25,894 shares of common stock were issued under the 2019 ESPP and as of September 30, 2023, 264,559 shares of common stock remained available for issuance.

2021 Inducement Plan

In August 2021, the Company's board of directors approved the TransMedics Group, Inc. Inducement Plan (the "Inducement Plan"). Pursuant to the terms of the Inducement Plan, the Company may grant nonqualified stock options, stock appreciation rights, restricted stock, unrestricted stock, restricted stock unit awards and performance awards to individuals who were not previously employees or directors of the Company or individuals returning to employment after a bona fide period of non-employment with the Company. A total of 1,000,000 shares of the Company's common stock were initially available for issuance under the Inducement Plan. As of September 30, 2023, 290,719 shares of common stock remained available for issuance under the Inducement Plan.

Stock Option Activity

During the nine months ended September 30, 2023, the Company granted options under the 2019 Plan and the Inducement Plan with service-based vesting for the purchase of an aggregate of 473,346 shares of common stock with a weighted average grant-date fair value of $45.49 per share.

Restricted Stock Unit Activity

During the nine months ended September 30, 2023, the Company granted 251,384 restricted stock units under the 2019 Plan and the Inducement Plan with service-based vesting conditions and a weighted-average grant-date fair value of $70.21 per share.

Stock-Based Compensation

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Cost of revenue	$ 112	$ 33	$ 241	$ 89
Research, development and clinical trials expenses	781	394	2,013	1,079
Selling, general and administrative expenses	4,295	2,277	11,813	6,162
	$ 5,188	$ 2,704	$ 14,067	$ 7,330

As of September 30, 2023, total unrecognized compensation cost related to unvested share-based awards was $46.2 million, which is expected to be recognized over a weighted average period of 2.5 years.

11. Asset Acquisition

On August 2, 2023, the Company acquired certain assets related to lung and heart perfusion technology from Bridge to Life Ltd. and its subsidiary Tevosol, Inc., together ("BTL"). The Company intends to further develop these technologies to expand its product offerings and indications for organ transplantation.

The Company accounted for the purchase of BTL as an asset acquisition as substantially all of the fair value of gross assets acquired were concentrated on a single set of identifiable activities consisting of lung and heart perfusion technology, referred to as the in-process research and development ("IPR&D") asset. Due to the stage of development of the IPR&D asset at the date of acquisition, it was not yet probable that there was future economic benefit from this asset. Absent successful clinical results and regulatory approval for the asset applications, there was no alternative future use associated with the asset. Accordingly, the value of the IPR&D asset was expensed as research and development expense in the consolidated statements of operations for the three and nine months ended September 30, 2023. Total IPR&D expense related to this acquisition was $27.2 million.

12. Commitments and Contingencies

Operating Leases

The Company leases office, laboratory and manufacturing space under two non-cancelable operating leases. In June 2023, the Company amended one of its lease agreements to add space, resulting in additional lease payments of approximately $2.6 million over the remaining term of the leases.

There have been no other material changes to the Company's leases during the nine months ended September 30, 2023. For additional information, please read Note 12 *Leases,* to the consolidated financial statements in the Company's Form 10-K for the year ended December 31, 2022.

401(k) Savings Plan

The Company has a defined-contribution savings plan under Section 401(k) of the Internal Revenue Code. This plan covers substantially all employees who meet minimum age and service requirements and allows participants to defer a portion of their compensation on a pre-tax basis. Company contributions to the plan may be made at the discretion of the board of directors. As of December 31, 2022, the Company had not made any contributions to the plan. Effective January 1, 2023, the Company instituted an employer matching program for the 401(k) Plan pursuant to which the Company will match 100% of the first 3% of each participating employee's eligible compensation contributed to the plan and 50% of up to an additional 2% each participating employee's eligible compensation contributed to the plan. For the three and nine months ended September 30, 2023, the Company recorded expense of $0.3 million and $1.0 million, respectively, related to these matching contributions.

Indemnification Agreements

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

The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not currently aware of any indemnification claims and had not accrued any liabilities related to such obligations in its consolidated financial statements as of September 30, 2023 and December 31, 2022.

Unconditional Purchase Commitment

In January 2021, the Company entered into an unconditional $9.5 million purchase commitment, in the ordinary course of business, for goods with specified annual minimum quantities to be purchased through December 2029. The contract is not cancellable without penalty. The remaining purchase commitment as of September 30, 2023 was $7.0 million.

Legal Proceedings

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

13. Segment Reporting and Geographic Data

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

See Note 14 for revenue by country. Long-lived assets by geography are summarized as follows (in thousands):

	September 30, 2023	December 31, 2022
Long-lived assets by country(1):		
United States	$ 130,214	$ 18,568
All other countries	790	655
Total long-lived assets	$ 131,004	$ 19,223

(1) Long-lived assets consist of property, plant and equipment, net of depreciation, which are categorized based on their location of domicile.

14. Revenue

Payments to Customers

The Company has determined that the payments made to the customer for reimbursement of clinical trial materials and customer's costs incurred to execute specific clinical trial protocols related to the Company's OCS products do not provide the Company with a distinct good or service transferred by the customer, and therefore such payments are recorded as a reduction of revenue from the customer in the Company's consolidated statements of operations. The Company records the reduction of revenue in the same period as the revenue is recognized and records a corresponding accrual for its estimate of the payments. As clinical trials reach the closeout phase, the Company updates its accrual estimates with corresponding adjustments to revenue. The net impact of such adjustments were insignificant in each of the three and nine months ended September 30, 2023 and 2022. The Company will continue to update its clinical trial accrual estimates as information related to clinical trial payments is received.

The Company determined that payments made to customers to obtain information related to post-approval studies or existing standard-of-care protocols (i.e., unrelated to the Company's OCS products) meet the criteria to be classified as a cost because the Company receives a distinct good or service transferred by the customer separate from the customer's purchase of the Company's OCS products and the consideration paid to the customer represents the fair value of the distinct good or service received. As a result, such payments made to the customers are recorded as operating expenses. The Company recorded payments made to customers related to post-approval studies and for documentation related to existing standard-of-care protocols of $0.4 million and $0.5 million for the three months ended September 30, 2023 and 2022, respectively, and $0.8 million and $1.0 million for the nine months ended September 30, 2023 and 2022, respectively, as operating expenses.

Summit makes payments to its aircraft management customers who had opted in to Summit's charter program. Summit pays the aircraft owner a fee for the use of the aircraft for charter flight services. The Company determined that fees incurred for the use of aircraft management customers' aircraft 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 Summit's aircraft management services and the consideration to the customer represents the fair value of the distinct good or service received. As a result, such fees are recorded as cost of sales. The Company recorded expense for the use of customers' aircraft of $0.7 million for the three and nine months ended September 30, 2023. As part of the Summit integration, Summit's legacy aircraft management customers are being transitioned to third parties and following this transition, the Company will no longer make such payments to customers.

Disaggregated Revenue

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
OCS Transplant Revenue by country by organ(1)(2):				
United States				
Lung total revenue	$ 3,410	$ 1,438	$ 7,658	$ 6,033
Heart total revenue	15,069	9,304	41,481	18,921
Liver total revenue	41,214	12,543	97,002	30,030
Total United States OCS transplant revenue	59,693	23,285	146,141	54,984
All other countries				
Lung revenue	310	161	964	703
Heart revenue	3,893	2,237	10,803	6,397
Liver revenue	97	—	104	—
Total all other countries OCS transplant revenue	4,300	2,398	11,871	7,100
Total OCS transplant revenue	$ 63,993	$ 25,683	$ 158,012	$ 62,084

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

(2) Service revenue unrelated to OCS transplant, which was $2.4 million for each of the three and nine months ended September 30, 2023 and none for the three and nine months ended September 30, 2022, is not included in this table.

15. Related Party Transactions

Employment of Dr. Amira Hassanein

Dr. Amira Hassanein, who serves as Product Director for the Company's OCS Lung program, is the sister of Dr. Waleed Hassanein, the Company's President and Chief Executive Officer and a member of the Company's board of directors. The Company paid Dr. Amira Hassanein approximately $0.1 million in total compensation for each of the three months ended September 30, 2023 and 2022, for her services as an employee. The Company paid Dr. Amira Hassanein approximately $0.3 million in total compensation for each of the nine months ended September 30, 2023 and 2022, for her services as an employee.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the year ended December 31, 2022, as filed with the SEC on February 27, 2023 ("2022 Form 10-K"). Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Item 1A. Risk Factors" section of this Quarterly Report on Form 10-Q and the "Item 1A. Risk Factors" section of our 2022 Form 10-K, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

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

We designed the OCS to be a platform that allows us to leverage core technologies across products for multiple organs. To date, we have developed three OCS products, one for each of heart, lung and liver transplantations, making the OCS the only FDA approved, portable, multi-organ, warm perfusion technology platform. All three of our products, OCS Heart, OCS Lung and OCS Liver, have received Pre-Market Approval, or PMA, from the Food and Drug Administration, or FDA for both organs donated after brain death, or DBD organs, and organs donated after circulatory death, or DCD organs.

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

Since our inception, we have incurred significant operating losses. Our ability to generate revenue sufficient to achieve profitability will depend on the successful further development and commercialization of our products. We generated total revenue of $160.4 million and incurred a net loss of $29.1 million for the nine months ended September 30, 2023. We generated total revenue of $93.5 million and incurred a net loss of $36.2 million for the year ended December 31, 2022. As of September 30, 2023, we had an accumulated deficit of $507.7 million. We expect to continue to incur net losses for the foreseeable future as we focus on growing commercial sales of our products in both the United States and select non-U.S. markets, including growing our commercial team, which will pursue increasing commercial sales of our OCS products; growing our NOP, including by maintaining and growing our aviation capabilities to support our NOP to reduce dependence on third party transportation, including by means of the acquisition of fixed-wing aircraft or other acquisitions, joint ventures or strategic investments; scaling our manufacturing and sterilization operations; developing the next generation OCS; continuing research, development and clinical trial efforts; seeking regulatory clearance for new products and product enhancements, including additional indications or other organs, in both the United States and select non-U.S. markets; and operating as a public company. As a result, we will need substantial additional funding for expenses related to our operating activities, including selling, general and administrative expenses and research, development and clinical trials expenses.

Because of the numerous risks and uncertainties associated with product development, commercialization and regulations of our industry, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve or maintain profitability. Until such time, if ever, as we can generate substantial revenue sufficient to achieve profitability, we expect to finance our operations through a combination of equity offerings, debt financings and strategic alliances. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms or at all. If we are unable to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back or discontinue the further development and commercialization efforts of one or more of our products, or may be forced to reduce or terminate our operations. In March 2023, the U.S. Department of Health and Human Services' Health Resources and Services Administration, or HRSA, announced initiatives designed to improve the Organ Procurement and Transplantation network, or OPTN, including its intent to solicit contract proposals to manage the OPTN, which is currently operated by the United Network for Organ Sharing, or UNOS, under a contract that expires in September 2023. Additionally, on July 25, 2023 and July 27, 2023, the U.S. House of Representatives and U.S. Senate, respectively, passed the Securing the U.S. Organ Procurement and Transplantation Network Act, which expressly authorizes HRSA to award multiple grants, contracts or cooperative agreements to support the operation of the OPTN and specifies that the OPTN shall be operated through awards that are distinct from awards made to support the organization tasked with supporting the networks' board of directors. The impact that the HRSA initiatives and the U.S. Organ Procurement and Transplantation Network Act may have on our business, including on our NOP, is uncertain at this time.

In May 2023, we issued and sold $460.0 million in aggregate principal amount of our 1.50% Convertible Senior Notes due 2028, or the Notes, in a private placement to qualified institutional buyers pursuant to Rule 144A under the Securities Act. The Notes were issued pursuant to an indenture, dated May 11, 2023. The Notes bear interest at a rate of 1.50% per year, payable semi-annually in arrears on June 1 and December 1 of each year, beginning on December 1, 2023. The Notes will mature on June 1, 2028, unless earlier converted, redeemed or repurchased.

As of September 30, 2023, we had cash of $427.1 million. We believe that our cash will be sufficient for us to fund our operating expenses, capital expenditure requirements and debt service payments for at least 12 months following the filing of our Quarterly Report on Form 10-Q. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See "—Liquidity and Capital Resources".

Strategic Transactions

On August 16, 2023, we acquired Summit Aviation, Inc. and Northside Property Group, LLC, or together Summit. Summit is a charter flight operator based in Bozeman, Montana. The acquisition enabled us to add aircraft transportation services to our NOP and become a comprehensive national provider of donor organ retrieval and delivery in the United States.

In separate transactions during the three months ended September 30, 2023, we have acquired eight fixed-wing aircraft to transport donor organs as part of the services offered under our NOP. We intend to acquire additional fixed-wing aircraft as we scale our fleet of aircraft to reduce our dependence on third party transportation providers.

On August 2, 2023, we acquired certain assets related to lung and heart perfusion technology from Bridge to Life Ltd. and its subsidiary Tevosol, Inc., or together BTL. We intend to further develop these technologies to expand our product offerings and indications for organ transplantation.

Economic Impacts and COVID-19

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

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

The COVID-19 pandemic, including efforts to contain the spread of the coronavirus, has impacted, and may continue to impact, our business, financial condition, operating results and cash flows, including as a result of the impact of new variants or spikes in infection rates. Continued impacts to our business as a result of COVID-19 may include decreased overall frequency of transplant procedures; disruptions to our manufacturing operations and supply chain; labor shortages; decreased productivity and unavailability of materials or components; limitations on our employees' and customers' ability to travel, and delays in product installations, trainings or shipments to and from other affected countries and within the United States.

Components of Our Results of Operations

Revenue

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

We generate service revenue by providing outsourced organ retrieval, OCS organ management services and organ transportation under our NOP in the United States. Commencing with the acquisition of Summit and the purchase of fixed-wing transplant aircraft we anticipate increased service revenue from our transportation offering.

Prior to the acquisition, Summit derived its revenue primarily from charter flight services. To a lesser extent, Summit also derived revenue from providing flight school training, managing aircraft and other related services. As part of the Summit integration, we are transitioning Summit's charter flight and aircraft management customers to third parties and following this transition we do not anticipate generating revenue from charter flights or aircraft management services. We are continuing to offer flight school training services. During the three and nine months ended September 30, 2023, service revenue of $2.4 million, including $1.6 million of charter flight and aircraft management services and $0.8 million of flight school training revenue, is from Summit's legacy operations and is unrelated to the NOP and organ transplant.

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

When a customer order includes disposable sets and any of our NOP services, we have determined that the disposable sets and services constitute separate performance obligations and we recognize revenue as the disposable sets and services are each delivered to the customer.

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

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

Through September 30, 2023, all of our sales outside of the United States have been commercial sales (unrelated to any clinical trials). Our sales in the EU are dependent on obtaining and maintaining the CE Mark certifications for each of our OCS products. As required by the EU Medical Devices Regulation (Regulation 2017/745), or the MDR, we received recertification of the CE Mark in September 2022 for each of the OCS Heart and OCS Lung systems, which includes the OCS Console, the OCS disposables, and the OCS solution additives. We also received the recertification of the CE Mark in September 2022 for the OCS Liver Console and disposables. We received the CE Mark for the OCS Liver combined with our solution additives under the MDR in May 2023, with an effective date of April 2023. In addition, we received a Class II Medical Device License from Health Canada for our OCS Liver combined with our solution additives in October 2023 to complement our existing Health Canada licenses for OCS Heart and OCS Lung.

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

Cost of Revenue, Gross Profit and Gross Margin

Cost of net product revenue consists of costs of components of our OCS Consoles and disposable sets, costs of direct materials, labor and the manufacturing overhead that directly supports production and depreciation of OCS Consoles loaned to customers. When we loan an OCS Console to a customer for its use free of charge, we capitalize as property, plant and equipment the cost of our OCS Console and depreciate it over its five-year estimated useful life. Included in the cost of OCS disposable sets are the costs of our OCS Lung, OCS Heart and OCS Liver Solutions. Cost of service revenue primarily consists of labor and overhead that directly support organ retrieval and OCS organ management services and transportation costs, including aircraft depreciation, aircraft costs, fuel, crew travel, maintenance and third-party flight costs that support organ delivery. We expect that cost of revenue will increase or decrease in absolute dollars primarily as, and to the extent that, our revenue increases or decreases. For the three months ended September 30, 2023, cost of service revenue also included approximately $2.3 million of costs related to charter flight and aircraft management services and flight school training revenue, from Summit's legacy operations, which is unrelated to the NOP and organ transplant.

Gross profit is the amount by which our revenue exceeds our cost of revenue in each reporting period. We calculate gross margin as gross profit divided by revenue. Our gross margin has been and will continue to be affected by a variety of factors, primarily production volumes, the cost of components and direct materials, manufacturing overhead costs, direct labor, the cost of services provided under the NOP and the selling price of our OCS products and NOP services.

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

Operating Expenses

Research, Development and Clinical Trials Expenses

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

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

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

Acquired In-Process Research and Development Expenses

Acquired in-process research and development expenses, or IPR&D, consist of the acquisition value of transactions that do not qualify as a business combination and that do not have an alternative future use.

Selling, General and Administrative Expenses

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

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

Other Income (Expense)

Interest Expense

Interest expense consists of interest expense associated with outstanding borrowings under our loan agreements as well as the amortization of debt discounts associated with such agreements. In July 2022, we entered into a credit agreement with Canadian Imperial Bank of Commerce, or CIBC, under which we borrowed $60.0 million. At that time, we repaid the remaining $35.0 million of principal that had been outstanding under our prior credit agreement with OrbiMed Royalty Opportunities II, LP, or OrbiMed. In May 2023, we issued and sold $460.0 million in aggregate principal amount of our 1.50% Convertible Senior Notes due 2028.

Other Income (Expense), Net

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

Results of Operations

Comparison of the Three Months Ended September 30, 2023 and 2022

The following table summarizes our results of operations for the three months ended September 30, 2023 and 2022:

	Three Months Ended September 30,		
	2023	2022	Change
		(in thousands)	
Revenue:			
Net product revenue	$ 47,740	$ 21,299	$ 26,441
Service revenue	18,690	4,384	14,306
Total revenue	66,430	25,683	40,747
Cost of revenue:			
Cost of net product revenue	11,086	4,231	6,855
Cost of service revenue	14,682	3,337	11,345
Total cost of revenue	25,768	7,568	18,200
Gross profit	40,662	18,115	22,547
Operating expenses:			
Research, development and clinical trials	11,132	6,808	4,324
Acquired in-process research and development expenses	27,212	—	27,212
Selling, general and administrative	30,653	16,851	13,802
Total operating expenses	68,997	23,659	45,338
Loss from operations	(28,335)	(5,544)	(22,791)
Other income (expense):			
Interest expense	(3,590)	(787)	(2,803)
Other income (expense), net	4,996	(1,076)	6,072
Total other income (expense), net	1,406	(1,863)	3,269
Loss before income taxes	(26,929)	(7,407)	(19,522)
(Provision) benefit for income taxes	1,507	(19)	1,526
Net loss	$ (25,422)	$ (7,426)	$ (17,996)

Revenue

OCS transplant-related revenue consisted of:

	Three Months Ended September 30,		
	2023	2022	Change
		(in thousands)	
OCS Transplant Revenue by country by organ:			
United States			
Lung total revenue	$ 3,410	$ 1,438	$ 1,972
Heart total revenue	15,069	9,304	5,765
Liver total revenue	41,214	12,543	28,671
Total United States OCS transplant revenue	59,693	23,285	36,408
All other countries			
Lung total revenue	310	161	149
Heart total revenue	3,893	2,237	1,656
Liver total revenue	97	—	97
Total all other countries OCS transplant revenue	4,300	2,398	1,902
Total OCS transplant revenue	$ 63,993	$ 25,683	$ 38,310

We also had service revenue unrelated to OCS transplant of $2.4 million, including $1.6 million of charter flight and aircraft management services and $0.8 million of flight school training revenue, from Summit's legacy operations for the three months ended September 30, 2023.

Revenue from customers in the United States related to OCS transplant was $59.7 million in the three months ended September 30, 2023 and increased by $36.4 million compared to the three months ended September 30, 2022, primarily due to higher sales volumes of our disposable sets for livers, hearts and lungs. Revenue for each organ in the table above includes net product revenue from sales of disposable sets as well as service revenue for organ retrieval, OCS organ management services and organ transportation services under the NOP in the United States. Revenue from customers who participated in our NOP accounted for approximately 98% and 90% of total OCS transplant revenue from customers in the United States for the three months ended September 30, 2023 and 2022, respectively. Increases in net product revenue and NOP service revenue in the United States were primarily as a result of increased utilization of our NOP.

Revenue from customers outside the United States was $4.3 million in the three months ended September 30, 2023 and increased by $1.9 million compared to the three months ended September 30, 2022. Revenue outside of the United States increased for the three months ended September 30, 2023 compared to the three months ended September 30, 2022 due primarily to increased sales volume of OCS Heart disposable sets.

Cost of Revenue, Gross Profit and Gross Margin

Cost of net product revenue increased by $6.9 million in the three months ended September 30, 2023 compared to the three months ended September 30, 2022. Cost of service revenue increased by $11.3 million from $3.3 million in the three months ended September 30, 2022 to $14.7 million in the three months ended September 30, 2023 as we experienced increased utilization of the NOP, which launched in late 2021. Gross profit increased by $22.5 million in the three months ended September 30, 2023 compared to the three months ended September 30, 2022. Cost of service revenue also included approximately $2.3 million of costs related to charter flight and aircraft management services and flight school training revenue, from Summit's legacy operations, which is unrelated to the NOP and organ transplant.

Gross margin from net product revenue was 77% and 80% for the three months ended September 30, 2023 and 2022, respectively. Gross margin from net product revenue decreased primarily as a result of increasing manufacturing capacity, increased costs of certain parts and consumables, and scrap costs. Gross margin from service revenue was 21% and 24% for the three months ended September 30, 2023 and 2022, respectively, and consisted primarily of organ retrieval and OCS organ management services under our NOP, and to a lesser extent NOP transportation services. Gross margin from service revenue decreased during the three months ended September 30, 2023 as compared to the three months ended September 30, 2022 as increased costs relating to the introduction of transportation services and the integration of Summit were mostly offset by efficiencies as a result of the increased utilization of our NOP. Gross margin from service revenue also included charter revenue and costs from Summit's legacy customers, which had lower margins and will not be recurring.

Operating Expenses

Research, Development and Clinical Trials Expenses

	Three Months Ended September 30,		
	2023	2022	Change
		(in thousands)	
Personnel related (including stock-based compensation expense)	$ 4,318	$ 2,351	$ 1,967
Laboratory supplies and research materials	2,764	1,581	1,183
Consulting and third-party testing	1,713	815	898
Clinical trials costs	504	630	(126)
Facility related and other	1,833	1,431	402
Total research, development and clinical trials expenses	$ 11,132	$ 6,808	$ 4,324

Total research, development and clinical trials expenses increased by $4.3 million from $6.8 million in the three months ended September 30, 2022 to $11.1 million in the three months ended September 30, 2023. Personnel related costs increased by $2.0 million due primarily to increased headcount to support development efforts for our next generation OCS program and overall compensation increases. Personnel related costs included stock-based compensation expense of $0.8 million and $0.4 million for the three months ended September 30, 2023 and 2022, respectively. Laboratory supplies and research materials costs increased by $1.2 million primarily due to increased supplies and materials used for development of our next generation OCS. Consulting and third-party testing costs increased by $0.9 million due to development efforts for our next generation OCS program and digital tools by our external development consultants.

Acquired In-Process Research and Development Expenses

IPR&D in 2023 was related to the acquisition of certain assets related to lung and heart perfusion technology from BTL.

Selling, General and Administrative Expenses

	Three Months Ended September 30,		
	2023	2022	Change
	(in thousands)		
Personnel related (including stock-based compensation expense)	$ 18,146	$ 9,961	$ 8,185
Facility related, NOP support and other	6,425	4,263	2,162
Professional and consultant fees	5,588	1,789	3,799
Tradeshows and conferences	494	838	(344)
Total selling, general and administrative expenses	$ 30,653	$ 16,851	$ 13,802

Total selling, general and administrative expenses increased by $13.8 million from $16.9 million in the three months ended September 30, 2022 to $30.7 million in the three months ended September 30, 2023 due to increases in personnel related costs, facility related, NOP support and other costs, and professional and consultant fees. Personnel related costs increased by $8.2 million primarily due to the continued expansion of our team to support the growth in our business, as well as an increase in stock-based compensation expense of $2.0 million, due primarily to additional grants to new and existing employees. Facility related, NOP support and other costs increased by $2.2 million due primarily to increased costs related to the expansion of the NOP and increased recruiting and facilities costs due to the growth in our business. Professional and consultant fees increased by $3.8 million due to transaction costs related to our acquisitions of $2.0 million, higher legal fees related to the business growth and additional investment in digital tools to support the NOP.

Other Income (Expense)

Interest Expense

Interest expense was $3.6 million and $0.8 million for the three months ended September 30, 2023 and 2022, respectively. The increase was due primarily to interest expense on the $460.0 million principal amount of the Notes, which were issued in May 2023. Interest expense also increased due to an increase in the variable interest rate of the CIBC loan, which is based on the prime rate.

Other Income (Expense), Net

Other income (expense), net for the three months ended September 30, 2023 and 2022 included interest income of $5.2 million and $0.4 million, respectively, from interest earned on invested cash balances. Other income (expense), net also included $0.2 million and $0.9 million of realized and unrealized foreign currency transactions losses during the three months ended September 30, 2023 and 2022, respectively.

(Provision) Benefit for Income Taxes

We recorded a tax benefit of $1.5 million for the release of a portion of our valuation allowance related to the net deferred tax liabilities recorded in purchase accounting. As part of the allocation of the purchase price of Summit, we recorded deferred tax liabilities for the differences between the fair value recognized in purchase accounting and the tax basis of property, plant and equipment and intangible assets. The net deferred tax liability is a source of income to support the recognition of a portion of our existing deferred tax assets. Therefore, we released the same amount of our valuation allowance. We maintain a valuation allowance on our overall net deferred tax asset as we deem it more likely than not that the net deferred tax asset will not be realized.

Comparison of the Nine Months Ended September 30, 2023 and 2022

The following table summarizes our results of operations for the nine months ended September 30, 2023 and 2022:

	Nine Months Ended September 30,		
	2023	2022	Change
		(in thousands)	
Revenue:			
Net product revenue	$ 124,195	$ 54,160	$ 70,035
Service revenue	36,254	7,924	28,330
Total revenue	160,449	62,084	98,365
Cost of revenue:			
Cost of net product revenue	26,950	11,689	15,261
Cost of service revenue	27,330	5,826	21,504
Total cost of revenue	54,280	17,515	36,765
Gross profit	106,169	44,569	61,600
Operating expenses:			
Research, development and clinical trials	25,294	21,056	4,238
Acquired in-process research and development expenses	27,212	—	27,212
Selling, general and administrative	84,993	48,171	36,822
Total operating expenses	137,499	69,227	68,272
Loss from operations	(31,330)	(24,658)	(6,672)
Other income (expense):			
Interest expense	(7,186)	(2,719)	(4,467)
Other income (expense), net	7,982	(2,087)	10,069
Total other income (expense), net	796	(4,806)	5,602
Loss before income taxes	(30,534)	(29,464)	(1,070)
(Provision) benefit for income taxes	1,475	(47)	1,522
Net loss	$ (29,059)	$ (29,511)	$ 452

Revenue

OCS-related revenue consisted of:

	Nine Months Ended September 30,		
	2023	2022	Change
		(in thousands)	
OCS Transplant Revenue by country by organ:			
United States			
Lung total revenue	$ 7,658	$ 6,033	$ 1,625
Heart total revenue	41,481	18,921	22,560
Liver total revenue	97,002	30,030	66,972
Total United States OCS transplant revenue	146,141	54,984	91,157
All other countries			
Lung total revenue	964	703	261
Heart total revenue	10,803	6,397	4,406
Liver total revenue	104	—	104
Total all other countries OCS transplant revenue	11,871	7,100	4,771
Total OCS transplant revenue	$ 158,012	$ 62,084	$ 95,928

We also had service revenue unrelated to OCS transplant of $2.4 million, including $1.6 million of charter flight and aircraft management services and $0.8 million of flight school training revenue, from Summit's legacy operations for the nine months ended September 30, 2023.

Revenue from customers in the United States related to OCS transplant was $146.1 million in the nine months ended September 30, 2023 and increased by $91.2 million compared to the nine months ended September 30, 2022, primarily due to higher sales volumes of our OCS Liver and OCS Heart disposable sets. Revenue for each organ in the table above includes net product revenue from sales of disposable sets as well as service revenue for organ retrieval, OCS organ management services and organ transportation services under the NOP in the United States. Revenue from customers who participated in our NOP accounted for approximately 96% and 85% of total revenue from customers in the United States for the nine months ended September 30, 2023 and 2022, respectively. Revenue from sales of OCS Liver disposable sets and NOP services in the United States increased by $67.0 million due primarily to higher sales volumes of OCS Liver disposable sets resulting from the commercialization of the OCS Liver product and the expansion and increased utilization of our NOP. Revenue from sales of OCS Heart disposable sets and organ retrieval and NOP services in the United States increased by $22.6 million also primarily as a result of the commercialization of the OCS Heart product as well as the expansion and increased utilization of the NOP.

Revenue from customers outside the United States was $11.9 million in the nine months ended September 30, 2023 and increased by $4.8 million compared to the nine months ended September 30, 2022. Revenue outside of the United States increased for the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022 due primarily to increased sales volume of OCS Heart disposable sets.

Cost of Revenue, Gross Profit and Gross Margin

Cost of net product revenue increased by $15.3 million in the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022. Cost of service revenue increased by $21.5 million from $5.8 million in the nine months ended September 30, 2022 to $27.3 million in the nine months ended September 30, 2023 as we expanded and increased utilization of the NOP, which launched in late 2021. Gross profit increased by $61.6 million in the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022. Cost of service revenue also included approximately $2.3 million of costs related to charter flight and aircraft management services and flight school training revenue, from Summit's legacy operations, which is unrelated to the NOP and organ transplant.

Gross margin from net product revenue was 78% for each of the nine months ended September 30, 2023 and 2022, respectively. Gross margin from service revenue was 25% and 26% for the nine months ended September 30, 2023 and 2022, respectively, and consisted primarily of organ retrieval and OCS organ management services under our NOP. Service revenue gross margin during the nine months ended September 30, 2023, included the introduction of transportation services and the purchase and integration of Summit in the third quarter of 2023. Service revenue gross margin during the nine months ended September 30, 2022 included our initial launch of the NOP program and did not include a full period of our NOP service offering.

Operating Expenses

Research, Development and Clinical Trials Expenses

	Nine Months Ended September 30,		
	2023	2022	Change
		(in thousands)	
Personnel related (including stock-based compensation expense)	$ 10,553	$ 6,851	$ 3,702
Laboratory supplies and research materials	5,221	4,209	1,012
Consulting and third-party testing	3,795	4,448	(653)
Clinical trials costs	973	1,738	(765)
Facility related and other	4,752	3,810	942
Total research, development and clinical trials expenses	$ 25,294	$ 21,056	$ 4,238

Total research, development and clinical trials expenses increased by $4.2 million from $21.1 million in the nine months ended September 30, 2022 to $25.3 million in the nine months ended September 30, 2023. Personnel related costs increased by $3.7 million due primarily to increased headcount to support development efforts for our next generation OCS program and overall compensation increases. Personnel related costs included stock-based compensation expense of $2.0 million and $1.1 million for the nine months ended September 30, 2023 and 2022, respectively. Laboratory supplies and research materials costs increased by $1.0 million primarily due to our increased need for supplies and materials used for development of our next generation OCS. Consulting and third-party testing costs decreased by $0.7 million, due to timing of development efforts for our next generation OCS program by our external development consultants. Clinical trial costs decreased by $0.8 million due to the timing of pre-approval and post-approval clinical trials.

Acquired In-Process Research and Development Expenses

IPR&D in 2023 was related to the acquisition of certain assets related to lung and heart perfusion technology from BTL.

Selling, General and Administrative Expenses

	Nine Months Ended September 30,		
	2023	2022	Change
		(in thousands)	
Personnel related (including stock-based compensation expense)	$ 48,419	$ 27,557	$ 20,862
Facility related, NOP support and other	20,465	12,118	8,347
Professional and consultant fees	12,863	6,018	6,845
Tradeshows and conferences	3,246	2,478	768
Total selling, general and administrative expenses	$ 84,993	$ 48,171	$ 36,822

Total selling, general and administrative expenses increased by $36.8 million from $48.2 million in the nine months ended September 30, 2022 to $85.0 million in the nine months ended September 30, 2023 due to increases in personnel related costs, facility related, NOP support and other costs, professional and consultant fees and tradeshow and conferences costs. Personnel related costs increased by $20.9 million primarily due to the continued expansion of our team to support the growth in our business, as well as an increase in stock-based compensation expense of $5.7 million, due primarily to additional grants to new and existing employees. Facility related, NOP support and other costs increased by $8.3 million due to increased costs to support the expansion of our NOP and increased recruiting and facilities costs due to the growth in our business. Professional and consultant fees increased by $6.8 million due to transaction costs related to our acquisitions of $2.0 million, higher legal fees related to the business growth and additional investment in digital tools to support the NOP.

Other Income (Expense)

Interest Expense

Interest expense was $7.2 million and $2.7 million for the nine months ended September 30, 2023 and 2022, respectively. The increase was due primarily to interest expense for our $460.0 million principal amount of the Notes, which were issued in May 2023. Interest expense also increased due to an increase in the principal amount of the CIBC loan outstanding compared to the principal that had been outstanding under our prior credit agreement with OrbiMed, partially offset by the lower average interest rate for our indebtedness under the CIBC Credit Agreement.

Other Income (Expense), Net

Other income (expense), net for the nine months ended September 30, 2023 and 2022 included interest income of $8.1 million and $0.4 million, respectively, from interest earned on invested cash balances. Other income (expense), net included $0.2 million and $1.9 million of realized and unrealized foreign currency transactions losses during the nine months ended September 30, 2023 and 2022, respectively. Other expense, net for the nine months ending September 30, 2022 also included a loss on extinguishment of debt of $0.6 million.

(Provision) Benefit for Income Taxes

We recorded a tax benefit of $1.5 million for the release of a portion of our valuation allowance related to the net deferred tax liabilities recorded in purchase accounting. As part of the allocation of the purchase price of Summit, we recorded deferred tax liabilities for the differences between the fair value recognized in purchase accounting and the tax basis of property, plant and equipment and intangible assets. The net deferred tax liability is a source of income to support the recognition of a portion of our existing deferred tax assets. Therefore, we released the same amount of our valuation allowance. We maintain a valuation allowance on our overall net deferred tax asset as we deem it more likely than not that the net deferred tax asset will not be realized.

Liquidity and Capital Resources

Since our inception, we have incurred significant operating losses. To date, we have funded our operations primarily with proceeds from borrowings under loan agreements, proceeds from the issuance of our convertible senior notes, proceeds from the sale of common stock in our public offerings and revenue from clinical trials and commercial sales of our OCS products and NOP services. On May 11, 2023, we issued $460.0 million aggregate principal amount of the Notes, in a private placement to qualified institutional buyers pursuant to Rule 144A under the Securities Act. The total net proceeds from the sale of the Notes, after deducting debt issuance costs of $14.6 million, and purchases of Capped Calls of $52.1 million, were $393.3 million. At September 30, 2023, our principal source of liquidity was cash of $427.1 million.

Cash Flows

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

	Nine Months Ended September 30,	
	2023	2022
	(in thousands)	
Net cash used in operating activities	$ (21,332)	$ (41,782)
Net cash provided by (used in) investing activities	(152,135)	57,277
Net cash provided by financing activities	399,494	164,862
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(99)	(1,475)
Net increase in cash, cash equivalents and restricted cash	$ 225,928	$ 178,882

Operating Activities

During the nine months ended September 30, 2023, operating activities used $21.3 million of cash, primarily resulting from our net loss of $29.1 million and net cash used by changes in our operating assets and liabilities of $38.8 million, partially offset by net non-cash charges of $46.5 million, which included an IPR&D charge of $27.2 million. Net cash used by changes in our operating assets and liabilities for the nine months ended September 30, 2023 consisted primarily of an increase in accounts receivable of $31.0 million, an increase in inventory of $21.0 million and an increase in prepaid expenses and other current assets of $2.2 million, partially offset by an increase in accounts payable and accrued expenses and other current liabilities of $15.8 million.

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

Investing Activities

During the nine months ended September 30, 2023, net cash used in investing activities of $152.1 million consisted of purchases of property, plant and equipment of $110.0 million, including $103.0 million of transplant-related aircraft purchases, the purchase of IPR&D assets from BTL for $27.2 million and the purchase of Summit for $14.9 million, net of cash received.

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

Financing Activities

During the nine months ended September 30, 2023, net cash provided by financing activities of $399.5 million consisted of net proceeds from the issuance of our Notes of $445.4 million, partially offset by payments of $52.1 million for associated capped calls, proceeds from the issuance of common stock upon exercise of stock options of $5.2 million and proceeds from the issuance of common stock in connection with the 2019 Employee Stock Purchase Plan of $1.0 million.

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

Convertible Senior Notes

On May 11, 2023, we issued $460.0 million aggregate principal amount of the Notes, in a private placement to qualified institutional buyers pursuant to Rule 144A under the Securities Act, pursuant to an indenture dated May 11, 2023, by and between us and U.S. Bank Trust Company, National Association, or the Indenture.

The initial conversion price of the Notes is approximately $94.00 per share of common stock, which represents a premium of approximately 32.5% over the closing price of our common stock on May 8, 2023. The Notes will mature on June 1, 2028, unless earlier repurchased, redeemed or converted. We used $52.1 million of the proceeds from the sale of the Notes to fund the cost of entering into capped call transactions, described below. The proceeds from the issuance of the Notes were approximately $393.3 million, net of capped call transaction costs of $52.1 million and initial purchaser discounts and other debt issuance costs totaling $14.6 million. The Notes bear interest at a rate of 1.50% per year and interest is payable semiannually in arrears on June 1 and December 1 of each year, beginning on December 1, 2023. The initial conversion rate is 10.6388 shares of common stock per $1,000 principal amount of the Notes, which represents an initial conversion price of approximately $94.00 per share of common stock. The conversion rate and conversion price are subject to customary adjustments upon the occurrence of certain events as described in the Indenture.

Before March 1, 2028, noteholders have the right to convert their Notes only upon the occurrence of certain events, including certain corporate events, and during the five business days immediately after any ten consecutive trading days in which the trading price per $1,000 principal amount of Notes is less than ninety eight percent (98%) of the as converted value. Additionally, the noteholder can convert their Notes during any calendar quarter (and only during such calendar quarter), commencing after the calendar quarter ending on September 30, 2023 but before March 1, 2028, provided the last reported sale price of the common stock for at least 20 trading days is greater than or equal to 130% of the conversion price during the 30 consecutive trading days ending on the last trading day of a calendar quarter. From and after March 1, 2028, noteholders may convert their Notes at any time at their election until the close of business on the second scheduled trading day immediately before the maturity date. We have the right to elect to settle conversions either in cash, shares or in a combination of cash and shares of our common stock.

Prior to June 8, 2026, the Notes will not be redeemable. On or after June 8, 2026, we may redeem for cash all or any portion of the Notes (subject to the partial redemption limitation set forth in the Indenture), at our option, if the last reported sale price of our common stock has been at least 130% of the conversion price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period (including the last trading day of such period) ending on, and including, the trading day immediately preceding the date on which we provide notice of redemption. In addition, calling any Note for redemption will constitute a “Make-Whole Fundamental Change” (as defined in the Indenture) with respect to that Note, in which case the conversion rate applicable to the conversion of that Note will be increased in certain circumstances if it is converted after it is called for redemption.

Long-Term Debt

In July 2022, we entered into a credit agreement with CIBC as amended by the First Amendment to Credit Agreement, dated as of May 8, 2023, by and among the Company and CIBC, or the First Amendment, and the Second Amendment to Credit Agreement, dated as of June 23, 2023, by and among the Company and CIBC, or the Second Amendment, pursuant to which we borrowed $60.0 million, referred to herein as the CIBC Credit Agreement. We used proceeds of the CIBC Credit Agreement to repay all amounts due under our credit agreement with OrbiMed, which was entered into in June 2018.

On May 8, 2023, we entered into the First Amendment, which among other items, allowed for the issuance of the Notes and capped call transactions. On June 23, 2023, we entered into the Second Amendment, which among other items, permits us to make acquisitions of equity or assets of another entity, subject to the conditions under the Second Amendment, including acquisitions, without further consent of CIBC, up to a maximum amount of $50.0 million for the cash payable in connection with an individual acquisition and a maximum amount in aggregate of $150.0 million for the total cash consideration payable for all acquisitions made by the Company on or after June 23, 2023. The definition of consolidated adjusted EBITDA was also amended to add a provision for the pro forma effect of any acquisitions that occur during the period. Additionally, pursuant to the Second Amendment, we and CIBC agreed to extend the start of the principal repayment period to July 31, 2026, on which date we are obligated to begin repayment of the term loans in equal monthly installments until the maturity date in July 2027.

Borrowings under the CIBC Credit Agreement bear interest at an annual rate equal to either, at our option, (i) the secured overnight financing rate for an interest period selected by us, subject to a minimum of 1.50%, plus 2.0% or (ii) 1.0% plus the higher of a) the prime rate, subject to a minimum of 4.0% or b) the Federal Funds Effective Rate, plus 0.5%. At our option, we may prepay borrowings outstanding under the CIBC Credit Agreement, subject to a prepayment fee of 2.0% of outstanding borrowings if paid prior to 12 months after the closing date, and 1.0% if paid after 12 months but prior to 24 months after the closing date.

All obligations under the CIBC Credit Agreement are guaranteed by us and each of our material subsidiaries. All obligations of us and each guarantor are secured by substantially all of our and each guarantor's assets, including their intellectual property, subject to certain exceptions. Under the CIBC Credit Agreement, we have agreed to customary representations and warranties, events of default and certain affirmative and negative covenants to which we will remain subject until maturity. The financial covenants include, among other covenants, (x) a requirement to maintain a minimum liquidity amount of the greater of either (i) the consolidated adjusted EBITDA loss (or gain) for the trailing four month period (only if EBITDA is negative) and (ii) $10.0 million, and (y) a requirement to maintain total net revenue of at least 75% of the level set forth in the total revenue plan presented to CIBC. As discussed above, the definition of consolidated adjusted EBITDA was amended to include the pro forma effect of acquisitions. The obligations under the CIBC Credit Agreement are subject to acceleration upon the occurrence of specified events of default, including payment default, change in control, bankruptcy, insolvency, certain defaults under other material debt, certain events with respect to governmental approvals (if such events could cause a material adverse change in our business), failure to comply with certain covenants and a material adverse change in our business, operations or financial condition. As of September 30, 2023, we were in compliance with all covenants of the CIBC Credit Agreement.

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

Funding Requirements

As we continue to pursue and increase commercial sales of our OCS products, we expect our costs and expenses to increase in the future, particularly as we expand our commercial team, grow our NOP, scale our manufacturing and sterilization operations, continue research, development and clinical trial efforts, seek regulatory approval for new products and product enhancements, including new indications, both in the United States and in select non-U.S. markets, and seek greater control of air and ground transport for our NOP. For example, if the demand for our products exceeds our existing manufacturing and sterilization capacity, our ability to fulfill orders would be limited until we have sufficiently expanded such operations. In addition, following the closing of our IPO, we have incurred and expect to continue to incur additional costs associated with operating as a public company. The timing and amount of our operating and capital expenditures will depend on many factors, including:

- the amount of net product revenue generated by sales of our OCS Consoles, OCS disposable sets and other products that may be approved in the United States and select non-U.S. markets, revenue generated by our services, and growth of the NOP;
- the costs and expenses of expanding our U.S. and non-U.S. sales and marketing infrastructure and our manufacturing operations;
- the extent to which our OCS products are adopted by the transplant community;

- the ability of our customers to obtain adequate reimbursement from third-party payors for procedures performed using the OCS products;
- the degree of success we experience in commercializing our OCS products for additional indications;
- the costs, timing and outcomes of post-approval studies or any future clinical studies and regulatory reviews, including to seek and obtain approvals for new indications for our OCS products;
- the emergence of competing or complementary technologies or procedures;
- the number and types of future products we develop and commercialize;
- the cost of development of the next generation OCS;
- the costs associated with building our commercial operations, including the NOP;
- the costs associated with maintaining and growing our aviation capabilities, including by means of the acquisition of fixed-wing aircraft or other acquisitions, joint ventures or strategic investments;
- the cost of maintaining, replacing or acquiring additional fixed-wing aircraft;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims; and
- the level of our selling, general and administrative expenses.

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

We may need to raise additional funding, which might not be available on favorable terms or at all. See “Item 1A. Risk Factors—Risks Related to Our Financial Position and Need for Additional Capital” in our 2022 Form 10-K.

Material Contractual Obligations

On May 11, 2023, we issued $460.0 million aggregate principal amount of Notes due 2028. The Notes bear interest at a rate of 1.50% per year, payable semi-annually in arrears on June 1 and December 1 of each year, beginning on December 1, 2023. The Notes will mature on June 1, 2028, unless earlier converted, redeemed or repurchased.

In June 2023, we amended one of our lease agreements to lease additional space, resulting in additional lease payments of approximately $2.6 million over the remaining term of the leases. As of September 30, 2023, approximately $0.6 million of the additional lease payments will be payable in the next twelve months.

In connection with our acquisition of Summit we have a construction contract for the completion of a commercial aircraft hangar at Bozeman Yellowstone International Airport in Bozeman, Montana. We anticipate we will incur approximately $5.0 million to $6.0 million over the next six months to complete construction of the hangar.

We intend to acquire additional fixed-wing aircraft as we scale our fleet of aircraft. During the three months ended September 30, 2023, we have acquired eight transplant-related fixed-wing aircraft with an aggregate purchase price of $103.0 million and we plan to acquire additional aircraft in the next twelve months.

Other than as disclosed above, there have been no material changes to our cash requirements from those disclosed in our 2022 Form 10-K.

Critical Accounting Policies and Significant Judgments and Estimates

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

There have been no material changes to our critical accounting policies and estimates from those disclosed in our consolidated financial statements and the related notes and other financial information included in our 2022 Form 10-K except for our new accounting policies listed below and described in Note 2 to our consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q:

- Business Combinations
- Asset Acquisitions
- Goodwill and Acquired Intangible Assets

Recently Issued Accounting Pronouncements

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

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

We are exposed to changes in interest rates and foreign currency exchange rates because we finance certain operations through variable rate debt instruments, hold investments and denominate our transactions in a variety of foreign currencies. Changes in these rates may have an impact on future cash flow and earnings. We manage these risks through normal operating and financing activities. There has been no material change in the foreign currency exchange risk or interest rate risk discussed in "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our 2022 Form 10-K other than as disclosed below.

Convertible Senior Notes

In May 2023, we issued the Notes with an aggregate principal amount of $460.0 million. In connection with the issuance of the Notes, we entered into privately negotiated capped call transactions with certain counterparties. The Capped Calls are expected generally to offset the potential dilution to our common stock as a result of any conversion of the Notes. The Notes have a fixed annual interest rate of 1.50%. Accordingly, we do not have interest rate exposure on the Notes.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our President and Chief Executive Officer and our Chief Financial Officer (our principal executive officer and principal financial and accounting officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2023. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2023, our President and Chief Executive Officer and our Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three months ended September 30, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We are not currently subject to any material legal proceedings.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. For a detailed discussion of the risks that affect our business, please refer to the section titled “Item 1A. Risk Factors” in our 2022 Form 10-K and additional risks below.

Risks Related to our Operations and Business

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

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

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

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

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

We may not fully realize the anticipated benefits of our completed or future acquisitions, joint ventures, and strategic investments, such transactions may expose us to additional risks.

On August 2, 2023, we acquired certain assets related to lung and heart perfusion technology from Bridge to Life Ltd. and its subsidiary Tevosol, Inc., or together Bridge to Life. In addition, on August 16, 2023, we acquired Summit, an aviation business. We have separately acquired eight fixed-wing aircraft during the three months ended September 30, 2023, and intend to acquire additional fixed-wing aircraft, that will be operated as part of our NOP. Utilization of these acquired assets and integration of Summit, may be complex, costly and time consuming and we may face unanticipated issues, expenses and liabilities. We may not successfully or profitably utilize newly acquired assets or integrate, operate, maintain and manage any newly acquired operations or employees. Further development of the assets we acquired from Bridge to Life, or the Bridge to Life Assets, will require extensive clinical development, management of nonclinical, clinical and manufacturing activities. In addition, we may decide that only certain of the acquired technology is useful for the next generation of the OCS, or that integration of the acquired technology is not feasible or is too costly. We also may face challenges integrating Summit into our organization. We have never provided aviation services and will depend on the management team of Summit for the successful operation and integration into our NOP services offering. Even if we are able to utilize the Bridge to Life Assets and integrate Summit or any other acquired assets or businesses successfully, we may not realize the expected benefits of the transactions. These are the Company's first acquisitions, and we may need to invest in additional business processes and systems to support the Summit integration or to utilize the Bridge to Life Assets. Such additional costs may offset the financial benefits that may be realized from the acquisitions. We also may suffer the loss of key employees, customers and strategic partners of Summit or any future acquired company and it may be difficult to implement our corporate culture. There also may be increased risk due to integrating financial reporting and internal control systems of Summit. We may review additional acquisition, joint ventures and strategic investment opportunities to expand our current product offerings, increase the size and geographic scope of our operations or otherwise offer growth and operating efficiency opportunities. There can be no assurance that we will be able to identify suitable candidates or consummate future transactions on favorable terms. If required, the financing for future transactions could result in an increase in our indebtedness, dilute the interests of our shareholders or both. The purchase price for some acquisitions or joint ventures interests may include additional amounts to be paid in cash in the future, a portion of which may be contingent on the achievement of certain future operating results of the acquired business. If the performance of any such acquired business or joint venture exceeds such operating results, then we may incur additional charges and be required to pay additional amounts. Our failure to successfully utilize any acquired assets, complete the integration of any acquired business, achieve the long-term plan for such assets or businesses, as well as any other adverse consequences associated with our acquisition and investment activities, could have an adverse effect on our business. Any acquisition may also disrupt our ongoing business, divert resources, increase our expenses, and distract our management from our ongoing operations.

The availability of pilots to the airline and private aviation industries is limited and may negatively affect our operations and financial condition. Increases in our labor costs adversely affect our business, results of operations and financial condition.

Our pilots are subject to stringent pilot qualification and crew member flight training standards, or FAA Qualification Standards, which among other things require minimum flight time for pilots, mandate strict rules to minimize pilot fatigue and require periodic recertification. These requirements limit the availability of qualified pilot candidates and increases pilot salaries and related labor costs. Pilot shortages result in increased labor costs, which result in an increase in our operating expenses. Such requirements also impact pilot scheduling, work hours and the number of pilots required to be employed for our operations. Further, in recent years, the airline industry has experienced significant volatility in pilot attrition, including volatility resulting from pilot wage and bonus increases at other industry participants, the growth of cargo, low-cost and ultra-low-cost airlines, and more pilots reaching retirement age. If our attrition rates are higher than our ability to hire and retain replacement pilots, our operations and financial results would be adversely affected.

In addition, our operations and financial condition may be negatively impacted if we are unable to train pilots in a timely manner. Due to an industry-wide shortage of qualified pilots, driven by the flight hours requirements under the FAA Qualification Standards, including any special requirements related to certain types of aircraft, and attrition resulting from the hiring needs of other industry participants, pilot training timelines have significantly increased and stressed the availability of flight simulators, instructors and related training equipment. The training of our pilots may not be accomplished in a cost-efficient manner or in a manner timely enough to support our operational needs.

Due to the nature of our NOP services offering, which may require flight routes to various locations across the United States and often on short notice, we may not have access to a qualified pilot at the departure location. We may rely on commercial airlines to fly our pilots to the departure location. An inability to have pilots located in departure locations when necessary may cause us to delay or cancel a flight and could adversely affect our reputation, business, results of operation and financial condition.

We are exposed to operational disruptions due to maintenance.

Our aircraft fleet requires regular maintenance work, which may cause operational disruption. Failure to perform timely maintenance and repairs results in aircraft being underutilized which could have an adverse impact on our business, financial condition and results of operations. On occasion, airframe manufacturers and/or regulatory authorities require mandatory or recommended modifications to be made across a particular fleet which may mean having to ground a particular type of aircraft. This may cause operational disruption to, and impose significant costs on, us. Furthermore, our operations in remote locations, where delivery of components and parts or transportation of maintenance personnel could take a significant period of time, could result in delays in our ability to maintain and repair our aircraft. Any such delays may pose a risk to our business, financial condition and results of operations. Moreover, as our aircraft base increases and our fleet ages, our maintenance costs could potentially increase and we may be unable to manage the composition of our fleet in a manner that reduces costs due to the availability and prices for replacement aircraft and parts.

Significant increases in fuel costs could have a material adverse effect on our business, financial condition and results of operations.

Fuel is essential to the operation of our aircraft and to our ability to carry out our aircraft operations. Fuel costs are a key component of our operating expenses for our aircraft operations. A significant increase in fuel costs may impact our flight activity and otherwise negatively impact our revenue, operating expenses and results of operations. In addition, potential increased environmental regulations that might require new fuel sources (e.g., sustainable aviation fuel) could lead to increased costs.

Significant reliance on aircraft manufactured by a single company and spare parts poses risks to our business and prospects.

As part of our services offered under our NOP, we have acquired a fleet of fixed-wing aircraft. All of the aircraft we currently operate are the product of a single manufacturer. Parts and services from this manufacturer are subject to their product and workmanship warranties. If this manufacturer fails to adequately fulfill its obligations towards us or experiences interruptions or disruptions in production or provision of services due to, for example, bankruptcy, natural disasters, labor strikes or disruption of its supply chain we may experience a significant delay in the delivery of or fail to receive previously ordered aircraft and parts, which would adversely affect our revenue and results of operations and could jeopardize our ability to meet the demands of our customers. Although we could choose to operate aircraft of other manufacturers or increase our reliance on third-party operators, such a change would involve substantial expense to us and could disrupt our business activities.

As part of our business strategy, we rely on Pratt & Whitney aircraft engines to power our owned aircraft, and we may enter into program agreements covering certain of our aircraft related to engine maintenance and overhauls for certain aircraft in our fleet. If Pratt & Whitney fails to adequately fulfill its obligations towards us or experiences interruptions or disruptions in production or provision of services due to, for example, bankruptcy, natural disasters, labor strikes or disruption of its supply chain, we may experience a significant delay in the delivery of or fail to receive previously ordered aircraft engines and parts, which would adversely affect our revenue and profitability and could jeopardize our ability to meet the demands of our customers. In addition, if we fail to meet our obligations or are otherwise in default under the program agreements, our access to aircraft engines and parts may become limited, which could adversely impact our business, operations, cash flow, financial condition and liquidity.

Our insurance may become too difficult or expensive to obtain. If we are unable to maintain sufficient insurance coverage, it may materially and adversely impact our results of operations and financial position.

Hazards are inherent in the operation of aircraft and may result in loss of life and property, potentially exposing us to substantial liability claims arising from the operation of aircraft. We carry insurance customary for the operation of aircraft. Insurance underwriters are required by various federal and state regulations to maintain minimum levels of reserves for known and expected claims. However, underwriters may not have adequate reserves to fund existing and future claims. The number of accidents, as well as the number of insured losses within the aviation and aerospace industries, and the impact of general economic conditions on underwriters may result in increases in premiums above the rate of inflation. To the extent that our existing insurance carriers are unable or unwilling to provide us with sufficient insurance coverage, and if insurance coverage is not available from another source (for example, a government entity), our insurance costs may increase and may result in our being in breach of regulatory requirements or contractual arrangements requiring that specific insurance be maintained, which may have a material adverse effect on our business, financial condition and results of operations.

The operation of aircraft is often affected by factors beyond our control including: air traffic congestion at airports; airport slot restrictions; air traffic control inefficiencies; increased and changing security measures; changing regulatory and governmental requirements; new or changing travel-related taxes; any of which could have a material adverse effect on our business, results of operations and financial condition.

Our aircraft operations are affected by factors beyond our control, including air traffic congestion at airports, airport slot restrictions, air traffic control inefficiencies and staffing shortages, increased and changing security measures, changing regulatory and governmental requirements, and new or changing travel-related taxes. Factors that cause flight delays could prevent us from effectively transporting organs in a timely manner, which could have a material adverse effect on our business, results of operations and financial condition.

In the United States, the federal government singularly controls all U.S. airspace, and aviation operators are completely dependent on the FAA to operate that airspace in a safe, efficient and affordable manner. The air traffic control system, which is operated by the FAA, in the U.S., faces challenges in managing the growing demand for U.S. air travel. U.S. air-traffic controllers often rely on outdated technologies that routinely overwhelm the system and compel aviation operators to fly inefficient, indirect routes resulting in delays and increased operational cost. For example, in January 2023, the FAA experienced an unexpected technical system outage that resulted in all domestic commercial air traffic being temporarily grounded for several hours, which adversely impacted airlines and private aviation industry operators during the duration of the outage. There have also been recent instances where understaffing of certain U.S. air traffic control systems have led to flight delays and cancellations, and resulted in significant costs to aviation operators. These instances are capable of repetition and may harm our business and results of operations in the future.

In addition, discussions regarding privatization of the U.S. air traffic control system are ongoing, which could adversely affect our business. Further, implementation of the Next Generation Air Transport System by the FAA could result in changes to aircraft routings and flight paths that could lead to increased noise complaints and lawsuits, resulting in increased costs.

The operation of aircraft is subject to various risks, and failure to maintain an acceptable safety record may have an adverse impact on our ability to obtain and retain customers.

The operation of aircraft is subject to various risks, including catastrophic disasters, crashes, mechanical failures and collisions, which may result in loss of life, personal injury and/or damage to property, plant and equipment. We may experience accidents in the future. These risks could endanger the safety of our personnel, third-parties, equipment, viability of donor organs and other property (both ours and that of third-parties), as well as the environment. If any of these events were to occur, we could experience loss of revenue, termination of customer contracts, higher insurance rates, litigation, regulatory investigations and enforcement actions (including potential grounding of our fleet and suspension or revocation of our operating authorities) and damage to our reputation and customer relationships. In addition, to the extent an accident occurs with an aircraft we operate or charter, we could be held liable for resulting damages, which may involve claims from injured passengers, and survivors of deceased passengers and property owners. The amount of our insurance coverage may not be adequate to cover such losses, or we may be forced to bear substantial losses from such events, regardless of our insurance coverage. Moreover, any aircraft accident or incident, even if fully insured, and whether involving us or other private aircraft operators, could create a public perception that we are less safe or reliable than other private aircraft operators, which could cause our customers to lose confidence in us.

We incur considerable costs to maintain the quality of (i) our safety program, (ii) our training programs and (iii) our fleet of aircraft. These costs may increase. If we are unable to maintain an acceptable safety record, we may not be able to retain existing customers and employees or attract new customers and employees, which could have a material adverse effect on our business, financial condition and results of operations. Failure to comply with regulatory requirements related to the maintenance of our aircraft and associated operations may result in enforcement actions, including revocation or suspension of our operating authorities in the United States.

Our aircraft operations are subject to significant governmental regulation and changes in government regulations imposing additional requirements and restrictions on our aircraft operations could increase our operating costs and result in service delays and disruptions.

All interstate air carriers, including us, are subject to regulation by the DOT, the FAA and other governmental agencies. The laws enforced by these agencies impose substantial costs on us, may reduce air travel demand, and also may restrict the manner in which we conduct our business now or in the future, resulting in a material adverse effect on our operations. We also incur substantial costs in maintaining our current certifications and otherwise complying with the laws to which we are subject. An adverse decision by a federal agency may have a material adverse effect on our operations, such as an FAA decision to ground, or require time consuming inspections of or maintenance on, all or any of our aircraft. Our business may also be affected if government agencies shut down for any reason or if there is significant automation or another operational disruption, such as those attributed to air traffic control or weather.

In addition, we are subject to restrictions imposed by federal law on foreign ownership of U.S. airlines and oversight by the DOT in maintaining our status as a U.S. Citizen (as such term is set forth in Title 49, U.S. Code, Section 40102 and administrative interpretations thereof issued by the DOT or its predecessor or successors, or as the same may be from time to time amended). A failure to comply with or changes to these restrictions may materially adversely affect our business.

Revocation of permits, approvals, authorizations and licenses.

Our aircraft operations require a variety of federal, state and local permits, approvals, authorizations and licenses. Our aircraft operations are subject to regulations and requirements and may be adversely affected if we are unable to comply with existing regulations or requirements or if changes in applicable regulations or requirements occur.

Our aircraft maintenance costs will increase as our fleet ages.

Our aircraft maintenance costs will increase as our fleet ages. Currently, most of the parts on our aircraft are under multi-year warranties, but many of these warranties will expire in the coming years. If any maintenance provider with whom we have a flight hour agreement fails to perform or honor such agreements, we could incur higher interim maintenance costs until we negotiate new agreements. Any unexpected increase in maintenance costs may negatively impact our financial position and results of operations.

Prior to our acquisitions to facilitate our aircraft operations, we had no experience operating aircraft ourselves, and we may not be able to achieve the anticipated benefits of our acquisitions or further expansion of our aircraft operations.

Prior to our acquisitions to facilitate our aircraft operations, we had no experience operating aircraft ourselves, and we depend on the management team of Summit and additional employees we may hire for the successful operation of aviation services and the integration into our NOP services offering. The management teams must work together to comply with applicable laws and regulations and to manage our growing NOP logistics network. The operation of aircraft is a highly regulated activity and one that involves unique risks, including those described above, which we have not needed to manage previously. We may not successfully manage these risks or profitably utilize, integrate, operate, maintain and manage our newly acquired aircraft, employees and other aircraft operations.

If we fail to retain the existing management of Summit, or if we fail to successfully manage our aircraft operations or growing logistics network, our ability to realize the anticipated benefits of the acquisition of Summit or expansion of our NOP may be adversely affected.

Risks Related to Our Convertible Senior Notes

Servicing our 1.50% convertible senior notes due 2028 requires a significant amount of cash, and we may not have sufficient cash flow to pay our debt.

In May 2023, we issued $460.0 million aggregate principal amount of the Notes, pursuant to that certain indenture dated as of May 11, 2023, between us as issuer, and U.S. Bank Trust Company, National Association, as trustee. Our ability to make scheduled payments of the principal of, to pay interest on, or to refinance our indebtedness, including the Notes, depends on our future performance, which is subject to many factors, including, economic, financial, competitive and other, beyond our control. If our business does not generate cash flow from operations sufficient to service our debt and make necessary capital expenditures and we may therefore be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance the Notes, which mature in 2028, will depend on the capital markets and our financial condition at such times. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations, and limit our flexibility in planning for and reacting to changes in our business.

We may not have the ability to raise the funds necessary to repurchase the Notes as required upon a fundamental change, and our future debt may contain limitations on our ability to repurchase the Notes.

Holders of the Notes will have the right to require us to repurchase their Notes for cash upon the occurrence of a fundamental change at a fundamental change repurchase price equal to 100% of the principal amount of the Notes to be repurchased, plus accrued and unpaid interest, if any. A fundamental change may also constitute an event of default or prepayment under, and result in the acceleration of the maturity of, our then-existing indebtedness. We cannot guarantee that we will have sufficient financial resources, or will be able to arrange financing, to pay the fundamental change repurchase price in cash with respect to any Notes surrendered by holders for repurchase upon a fundamental change. In addition, restrictions under our then existing credit facilities or other indebtedness, if any, may not allow us to repurchase the Notes upon a fundamental change. Our failure to repurchase the Notes upon a fundamental change when required would result in an event of default with respect to the Notes which could, in turn, constitute a default under the terms of our other indebtedness, if any. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and repurchase the Notes.

Capped call transactions entered into in connection with the Notes may impact the value of our common stock.

In connection with the Notes, we entered into capped call transactions (the “Capped Call Transactions”) with certain financial institutions. The Capped Call Transactions are expected to generally reduce the potential dilution upon conversion of the Notes into shares of our common stock.

In connection with establishing their initial hedges of the Capped Call Transactions, these financial institutions or their respective affiliates may have entered into various derivative transactions with respect to our common stock and/or purchased our common stock. The financial institutions, or their respective affiliates, may modify their hedge positions by entering into or unwinding various derivatives with respect to our common stock and/or purchasing or selling our common stock or other securities of ours in secondary market transactions prior to the maturity of the Notes. This activity may have an impact on the value of our common stock.

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

None.

Item 5. Other Information.

During our fiscal quarter ended September 30, 2023, certain of our directors and officers (as defined in Rule 16a-1(f) under the Exchange Act) entered into contracts, instructions or written plans for the purchase or sale of our securities that are intended to satisfy the conditions specified in Rule 10b5-1(c) under the Exchange Act for an affirmative defense against liability for trading in securities on the basis of material nonpublic information. We refer to these contracts, instructions, and written plans as "Rule 10b5-1 trading plans" and each one as a "Rule 10b5-1 trading plan."

We describe the material terms of these Rule 10b5-1 trading plans in the table below.

Rule 10b5-1 Trading Plans

Director/Officer	Action and Date of Action	Commencement of Trading Period	Scheduled Termination of Trading Period [1]	Security Covered	Maximum Number of Securities to be Purchased or Sold Pursuant to the Rule 10b5-1 Trading Plan [2]	Covers Purchase Or Sale
Waleed Hassanein, M.D., Chief Executive Officer	Adoption 6-Sep-23	16-Jan-24	31-Dec-24	Common Stock	171,000	Sale
Tamer Khayal, Chief Commercial Officer	Adoption 6-Sep-23	16-Jan-24	15-Jan-25	Common Stock	139,727 [3]	Sale
Edward Basile, Director	Adoption 6-Sep-23	6-Feb-24	31-Dec-24	Common Stock	27,814	Sale
Stephen Gordon, Chief Financial Officer	Adoption 14-Sep-23	1-Jan-24	31-Dec-24	Common Stock	77,060	Sale

(1) The plans are subject to earlier termination under certain circumstances specified in the plans, including upon the sale or purchase (as applicable) of all shares subject to the plan and upon either party to a plan giving notice of termination within the time prescribed under the plan.

(2) Subject to adjustments for stock splits, stock combinations, stock dividends and other similar changes to our common stock.

(3) Pursuant to the plan, Mr. Khayal may also sell up to 24,776 additional shares of common stock if such shares of common stock remain unsold pursuant to existing 10b5-1 plans entered into by Mr. Khayal and certain of his affiliates upon the termination of such plans and up to 4,359 shares of common stock underlying RSUs that may vest on February 20, 2024, subject to Mr. Khayal's continued service to the Company as of such date . As of the date of this report, there were 24,776 shares that remained unsold pursuant to such existing plans.

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: November 8, 2023

TRANSMEDICS GROUP, INC.

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

Date: November 8, 2023

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

Exhibit 31.1

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

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

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

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

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

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

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

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

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

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

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

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

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

Date: November 8, 2023

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

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

Exhibit 31.2

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

I, Stephen Gordon, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 8, 2023

/s/ Stephen Gordon

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

Exhibit 32.1

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

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of TransMedics Group, Inc. (the "Company") for the period ended September 30, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Waleed Hassanein, M.D., President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

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

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

Date: November 8, 2023

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

Exhibit 32.2

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

AS ADOPTED PURSUANT TO

SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of TransMedics Group, Inc. (the "Company") for the period ended September 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Stephen Gordon, Chief Financial Officer, Treasurer and Secretary of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

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

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

Date: November 8, 2023

By: /s/ Stephen Gordon

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