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, 2024
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 September 30, 2024, the registrant had 33,561,517 shares of common stock, no par value per share, outstanding.

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements, which reflect our current views 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 any 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 and should not be relied upon as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, 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 will 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 to changes in our expectations.

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

- our ability to maintain profitability on a sustained basis
- our ability to attract, train 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, or NOP™;
- 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, the European Union and other select jurisdictions worldwide;
- our ability to adequately respond to the Food and Drug Administration, or FDA, or other competent authorities, 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 NOP and our ability to maintain and grow our logistics capabilities to support our NOP and reduce dependence on third party transportation, including by means of attracting, training and retaining pilots, and the acquisition, maintenance or replacement of fixed-wing aircraft for our aviation transportation services 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 transportation 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, 2024	December 31, 2023
Assets		
Current assets:		
Cash	$ 330,094	$ 394,812
Accounts receivable	90,128	63,576
Inventory	52,152	44,235
Prepaid expenses and other current assets	20,101	8,031
Total current assets	492,475	510,654
Property, plant and equipment, net	271,739	173,941
Operating lease right-of-use assets	6,943	6,546
Restricted cash	500	500
Goodwill	11,549	11,990
Acquired intangible assets, net	2,202	2,354
Other non-current assets	163	62
Total assets	$ 785,571	$ 706,047
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 13,134	$ 12,717
Accrued expenses and other current liabilities	42,187	38,221
Deferred revenue	2,184	1,961
Operating lease liabilities	2,543	2,035
Total current liabilities	60,048	54,934
Convertible senior notes, net	449,237	447,140
Long-term debt, net	59,294	59,064
Operating lease liabilities, net of current portion	7,072	7,707
Total liabilities	575,651	568,845
Commitments and contingencies (Note 11)		
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; 33,561,517 shares and 32,670,803 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	685,251	641,106
Accumulated other comprehensive loss	(233)	(199)
Accumulated deficit	(475,098)	(503,705)
Total stockholders' equity	209,920	137,202
Total liabilities and stockholders' equity	$ 785,571	$ 706,047

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,	
	2024	2023	2024	2023
Revenue:				
Net product revenue	$ 65,861	$ 47,740	$ 198,918	$ 124,195
Service revenue	42,900	18,690	120,998	36,254
Total revenue	108,761	66,430	319,916	160,449
Cost of revenue:				
Cost of net product revenue	13,246	11,086	41,800	26,950
Cost of service revenue	34,670	14,682	88,048	27,330
Total cost of revenue	47,916	25,768	129,848	54,280
Gross profit	60,845	40,662	190,068	106,169
Operating expenses:				
Research, development and clinical trials	14,266	11,132	39,504	25,294
Acquired in-process research and development expenses	—	27,212	—	27,212
Selling, general and administrative	42,656	30,653	121,712	84,993
Total operating expenses	56,922	68,997	161,216	137,499
Income (loss) from operations	3,923	(28,335)	28,852	(31,330)
Other income (expense):				
Interest expense	(3,617)	(3,590)	(10,838)	(7,186)
Interest income and other income (expense)	3,939	4,996	10,777	7,982
Total other income (expense), net	322	1,406	(61)	796
Income (loss) before income taxes	4,245	(26,929)	28,791	(30,534)
(Provision) benefit for income taxes	(29)	1,507	(184)	1,475
Net income (loss)	$ 4,216	$ (25,422)	$ 28,607	$ (29,059)
Net income (loss) per share:				
Basic	$ 0.13	$ (0.78)	$ 0.86	$ (0.89)
Diluted	$ 0.12	$ (0.78)	$ 0.81	$ (0.89)
Weighted average common shares outstanding:				
Basic	33,441,394	32,614,059	33,108,253	32,474,522
Diluted	35,683,952	32,614,059	35,218,756	32,474,522

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Net income (loss)	$ 4,216	$ (25,422)	$ 28,607	$ (29,059)
Other comprehensive income (loss):				
Foreign currency translation adjustment	4	(42)	(34)	(37)
Total other comprehensive income (loss)	4	(42)	(34)	(37)
Comprehensive income (loss)	$ 4,220	$ (25,464)	$ 28,573	$ (29,096)

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, 2023	32,670,803	$ 641,106	$ (199)	$ (503,705)	$ 137,202
Issuance of common stock upon the exercise of common stock options	113,023	2,547	—	—	2,547
Issuance of common stock in connection with employee stock purchase plan	9,506	638	—	—	638
Vesting of restricted stock units	58,044	—	—	—	—
Stock-based compensation expense	—	6,870	—	—	6,870
Foreign currency translation adjustment	—	—	17	—	17
Net income	—	—	—	12,197	12,197
Balances at March 31, 2024	32,851,376	651,161	(182)	(491,508)	159,471
Issuance of common stock upon the exercise of common stock options	433,398	10,641	—	—	10,641
Vesting of restricted stock units	17,772	—	—	—	—
Issuance of common stock in connection with exercise of warrants	11,735	—	—	—	—
Stock-based compensation expense	—	7,643	—	—	7,643
Foreign currency translation adjustment	—	—	(55)	—	(55)
Net income	—	—	—	12,194	12,194
Balances at June 30, 2024	33,314,281	669,445	(237)	(479,314)	189,894
Issuance of common stock upon the exercise of common stock options	206,275	6,439	—	—	6,439
Issuance of common stock in connection with employee stock purchase plan	21,797	1,423	—	—	1,423
Issuance of restricted common stock	4,160	—	—	—	—
Vesting of restricted stock units	15,004	—	—	—	—
Stock-based compensation expense	—	7,944	—	—	7,944
Foreign currency translation adjustment	—	—	4	—	4
Net income	—	—	—	4,216	4,216
Balances at September 30, 2024	33,561,517	$ 685,251	$ (233)	$ (475,098)	$ 209,920

	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
Purchase 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

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,	
	2024	**2023**
Cash flows from operating activities:		
Net income (loss)	$ 28,607	$ (29,059)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization expense	14,078	4,572
Stock-based compensation expense	22,457	14,067
Acquired in-process research and development expenses	—	27,212
Deferred taxes	—	(1,540)
Non-cash interest expense and end of term accretion expense	2,327	1,358
Non-cash lease expense	1,102	728
Unrealized foreign currency transaction (gains) losses	(280)	118
Loss on disposal of fixed assets	17	—
Changes in operating assets and liabilities:		
Accounts receivable	(26,469)	(30,997)
Inventory	(12,490)	(21,029)
Prepaid expenses and other current assets	(6,066)	(2,170)
Other non-current assets	(100)	(54)
Accounts payable	1,742	6,541
Accrued expenses and other current liabilities	5,614	9,257
Deferred revenue	227	765
Operating lease liabilities	(1,626)	(1,101)
Net cash provided by (used in) operating activities	29,140	(21,332)
Cash flows from investing activities:		
Purchases of property, plant and equipment	(116,138)	(110,029)
Purchase of business, net of cash acquired	441	(14,894)
Purchase of in-process research and development assets	—	(27,212)
Net cash used in investing activities	(115,697)	(152,135)
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 common stock upon exercise of stock options	19,627	5,231
Proceeds from issuance of common stock in connection with employee stock purchase plan	2,061	955
Net cash provided by financing activities	21,688	399,494
Effect of exchange rate changes on cash, cash equivalents and restricted cash	151	(99)
Net increase (decrease) in cash, cash equivalents and restricted cash	(64,718)	225,928
Cash, cash equivalents and restricted cash, beginning of period	395,312	201,682
Cash, cash equivalents and restricted cash, end of period	$ 330,594	$ 427,610
Supplemental disclosure of non-cash activities:		
Transfers of inventory to property, plant and equipment	$ 4,588	$ 2,224
Purchases of property, plant and equipment included in accounts payable and accrued expenses	$ 930	$ 1,724
Operating lease liabilities arising from obtaining right-of-use assets	$ 1,499	$ 2,171
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$ 330,094	$ 427,110
Restricted cash	500	500
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	$ 330,594	$ 427,610

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

TRANSMEDICS GROUP, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

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 logistics services, to provide transplant programs in the United States with a more efficient process to procure donor organs with the OCS. The Company's logistics services include aviation transportation, ground transportation and other coordination activity.

On August 16, 2023, the Company acquired Summit Aviation, Inc. and Northside Property Group, LLC (together "Summit"). Summit was a charter flight operator based in Bozeman, Montana. The acquisition enabled TransMedics to add aviation 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 believes that its existing cash of $330.1 million as of September 30, 2024 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. However, the Company in the future 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 when needed, 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. In addition, the Company is subject to risks and uncertainties related to its aviation transportation services, including, but not limited to, compliance with FAA regulations, pilot availability and operational disruptions. These efforts require additional capital, adequate personnel, infrastructure and extensive compliance-reporting capabilities. The Company's research and development may not be successfully completed, adequate protection for the Company's technology may not be obtained, the Company may not obtain necessary government regulatory approval on its expected timeline or at all, and approved products may not prove commercially viable. The Company operates in an environment of rapid change in technology and competition.

The 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, 2023 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, 2024 and results of operations for the three and nine months ended September 30, 2024 and 2023 and cash flows for the nine months ended September 30, 2024 and 2023 have been made. The Company's results of operations for the three and nine months ended September 30, 2024 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2024.

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 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, 2024 and December 31, 2023, the Company had no allowance for credit losses.

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

Fair Value Measurements

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

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

The carrying values of the Company's accounts receivable, accounts payable and accrued expenses approximate their fair values due to the short-term nature of these assets and liabilities. The carrying value of the Company's long-term debt approximates its fair value (a level 2 measurement) at each balance sheet date due to its variable interest rate, which approximates a market interest rate. 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 accompanying consolidated balance sheets, and the fair value of the Notes is presented at each reporting period for disclosure purposes only (see Note 8).

Spare Parts Inventory

Spare parts are used in aviation operations and are generally not for sale. Spare parts inventory is comprised of repairable and expendable spare aircraft parts, which are valued at the lower of cost or net realizable value, using the specific identification method. Storage costs and miscellaneous materials and supplies costs related to inventory or to support flight equipment are expensed as incurred. As of September 30, 2024, spare parts inventory of $2.7 million is included within prepaid expenses and other current assets on the accompanying consolidated balance sheets. The Company had no spare parts inventory as of December 31, 2023. The Company determines, based on the evidence that exists, whether or not it is appropriate to maintain a reserve for excess and obsolete spare parts inventory. The reserve is based on historical experience related to the disposal of inventory due to damage, physical deterioration, obsolescence, or other causes. As of September 30, 2024, the Company had no allowance for spare parts excess and obsolescence.

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.

Foreign Currency Translation

The functional currency of each of the Company's foreign subsidiaries is the currency of the local country. Assets and liabilities of the Company's foreign subsidiaries are translated into U.S. dollars using the period-end exchange rates, and income and expense items are translated into U.S. dollars using average exchange rates in effect during each period. The effects of these foreign currency translation adjustments are included in accumulated other comprehensive income (loss), a separate component of stockholders' equity.

The Company also incurs transaction gains and losses resulting 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. Realized and unrealized foreign currency transaction gains (losses) are included in the consolidated statements of operations as a component of other income (expense). Realized and unrealized gains totaled $0.7 million and $0.3 million for the three and nine months ended September 30, 2024, respectively. Realized and unrealized losses totaled $0.2 million for the three and nine months ended September 30, 2023.

Recently issued accounting pronouncements

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures, which requires public entities to disclose information about their reportable segments' significant expenses and other segment items on an interim and annual basis. Public entities with a single reportable segment are required to apply the disclosure requirements in ASU 2023-07, as well as all existing segment disclosures and reconciliation requirements in ASC 280 on an interim and annual basis. ASU 2023-07 is effective for fiscal years beginning after December 15, 2023, and for interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently assessing the impact of the adoption of this guidance.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which requires public entities, on an annual basis, to provide disclosure of specific categories in their tax rate reconciliations, as well as disclosure of income taxes paid disaggregated by jurisdiction. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently assessing the impact of the adoption of this guidance.

3. Acquisition of Summit

On August 16, 2023, the Company acquired Summit pursuant to the terms of an equity purchase agreement. Summit was a charter flight operator based in Bozeman, Montana. The acquisition enabled TransMedics to add aviation 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. During the three months ended June 30, 2024, the Company recorded a final working capital adjustment of $0.4 million to the purchase price and goodwill, which amount was released to the Company in July 2024. The Company's consolidated financial statements as of September 30, 2024 reflect the final 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 was 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 was subject to change upon finalizing its valuation analysis. During the three months ended December 31, 2023, the Company recorded an adjustment to goodwill of $0.3 million, representing an adjustment to its estimate of the fair value of accounts payable and deferred tax liabilities as of the acquisition date. As of September 30, 2024, the preliminary estimates have been finalized, with no further changes to be recorded to the purchase price or allocation of the purchase price to the assets and liabilities assumed.

The following table summarizes the 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		11,549
Total assets acquired		23,318
Accounts payable and other current liabilities		(6,917)
Deferred tax liabilities		(1,660)
Operating lease liabilities		(288)
Total allocation of purchase price consideration, net of cash acquired	$	14,453

Property, plant and equipment consisted primarily of flight school aircraft and construction-in-progress related to a commercial aircraft hangar that Summit was in the process of constructing at the date of acquisition. 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. Intangible assets are being amortized on a straight-line basis to selling, general and administrative over their estimated useful lives of 12 years as of the acquisition date.

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 existing deferred tax assets. Therefore, the Company recorded a tax benefit of $1.7 million in 2023 for the release of a portion of its valuation allowance related to the net deferred tax liabilities recorded in purchase accounting.

4. Inventory

Inventory consisted of the following (in thousands):

	September 30, 2024	December 31, 2023
Raw materials	$ 28,047	$ 25,823
Work-in-process	4,889	3,806
Finished goods	19,216	14,606
	$ 52,152	$ 44,235

5. Property, Plant and Equipment, Net

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

	September 30, 2024	December 31, 2023
Transplant aircraft	$ 238,062	$ 141,855
Flight school aircraft	3,717	3,484
OCS Consoles	18,444	14,491
Manufacturing equipment	9,373	6,898
Computer equipment and software	3,708	3,021
Laboratory equipment	2,685	1,875
Office, trade show and training equipment	4,601	4,006
Leasehold improvements	22,657	13,354
Construction-in-progress	3,732	6,250
	306,979	195,234
Less: Accumulated depreciation and amortization	(35,240)	(21,293)
	$ 271,739	$ 173,941

During the three and nine months ended September 30, 2024, total depreciation and amortization expense was $5.1 million and $13.9 million, respectively. During the three and nine months ended September 30, 2023, total depreciation and amortization expense was $1.9 million and $4.5 million, respectively. Construction-in-progress as of December 31, 2023 primarily related to construction of a commercial aircraft hangar at Bozeman Yellowstone International Airport in Bozeman, Montana. The aircraft hangar was placed in service in June 2024 and is included in leasehold improvements as of September 30, 2024. The Company is depreciating the aircraft hangar over 28.5 years. Substantially all of the Company's property, plant and equipment are held in the United States. The Company capitalized costs associated with the development of internal use software of $1.1 million and $1.6 million in the three and nine months ended September 30, 2024, respectively, which costs are included in construction-in-progress.

6. Goodwill and Intangible Assets

The carrying amount of goodwill was $11.5 million and $12.0 million as of September 30, 2024 and December 31, 2023, respectively, and related to the Company’s acquisition of Summit. The change in goodwill during the nine months ended September 30, 2024 is a result of final working capital adjustments to the purchase price 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):

		September 30, 2024		
	Weighted Average Useful Life (in years)	Gross Amount	Accumulated Amortization	Carrying Value
Customer relationship	12	$ 2,320	$ 218	$ 2,102
Other	12	110	10	100
		$ 2,430	$ 228	$ 2,202

	Weighted Average Useful Life	December 31, 2023		
		Gross Amount	Accumulated Amortization	Carrying Value
	(in years)			
Customer relationship	12	$ 2,320	$ 73	$ 2,247
Other	12	110	3	107
		$ 2,430	$ 76	$ 2,354

Amortization expense is recorded within selling, general and administrative expense. Amortization expense was $0.1 million and $0.2 million for the three and nine months ended September 30, 2024, respectively and less than $0.1 million for the three and nine months ended September 30, 2023. Future amortization expense of the intangible assets as of September 30, 2024 is expected to be as follows (in thousands):

Year Ending December 31,	
2024 (three months)	$ 51
2025	203
2026	203
2027	203
2028	203
Thereafter	1,339
	$ 2,202

7. Accrued Expenses and Other Current Liabilities

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

	September 30, 2024	December 31, 2023
Accrued payroll and related expenses	$ 20,766	$ 20,300
Accrued transportation costs	3,511	4,381
Accrued research, development and clinical trials expenses	3,287	1,771
Accrued other	14,623	11,769
	$ 42,187	$ 38,221

8. Long-Term Debt and Financing Arrangements

Convertible Senior Notes

The Notes consisted of the following (in thousands):

	September 30, 2024	December 31, 2023
Principal amount of convertible senior notes	$ 460,000	$ 460,000
Less: Current portion of convertible senior notes	—	—
Convertible senior notes, net of current portion	460,000	460,000
Debt discount, net of accretion	(10,763)	(12,860)
Convertible senior notes, net of discount and current portion	$ 449,237	$ 447,140

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. 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.

During the three and nine months ended September 30, 2024, the Company recognized $2.4 million and $7.3 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 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, 2024 and 2023, the effective interest rate on the outstanding Notes was approximately 2.1%. As of September 30, 2024, the estimated fair value of the Notes was $848.7 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.

A conditional conversion feature of the Notes was triggered on June 30, 2024, as the last reported sale price of the Company's common stock was greater than or equal to 130% of the conversion price of the Notes for at least 20 trading days during the period of 30 consecutive trading days ending on and including the last trading day of the quarter ended June 30, 2024, and the Notes therefore became convertible at the noteholders' election in the calendar quarter ended September 30, 2024. This conditional conversion feature was triggered again on September 30, 2024, and the Notes therefore are convertible at the noteholders' election in the calendar quarter ending December 31, 2024. If this condition or another conversion condition is met in the future, the Notes may again become convertible, otherwise the Notes will be convertible at the noteholders' election from March 1, 2028 through the close of business on the second scheduled trading day immediately before the maturity date.

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 was recorded as a reduction to common stock in the accompanying consolidated balance sheets.

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 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, 2024	December 31, 2023
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	(706)	(936)
Long-term debt, net of discount and current portion	$ 59,294	$ 59,064

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"), the Second Amendment to Credit Agreement, dated as of June 23, 2023, by and among the Company and CIBC (the "Second Amendment") and the Third Amendment to Credit Agreement, dated as of November 9, 2023, by and among the Company and CIBC (the "Third Amendment") (as amended, the "CIBC Credit Agreement"), pursuant to which the Company borrowed $60.0 million.

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 1.0% if paid on or after 12 months after the closing date but prior to 24 months after the closing date.

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), as defined, for the trailing four month period (only if EBITDA is negative) and (ii) $10.0 million, and (y) a requirement to maintain total net revenue of at least 75% of the level set forth in the total revenue plan presented to CIBC. The obligations under the CIBC Credit Agreement are subject to acceleration upon the occurrence of specified events of default, including payment default, change in control, bankruptcy, insolvency, certain defaults under other material debt, certain events with respect to governmental approvals (if such events could cause a material adverse change in the Company's business), failure to comply with certain covenants and a material adverse change in the Company's business, operations or financial condition. As of September 30, 2024, 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.

During the three and nine months ended September 30, 2024, the Company recognized $1.2 million and $3.6 million, respectively, in interest expense related to the CIBC borrowings. During the three and nine months ended September 30, 2023, the Company recognized $1.2 million and $3.4 million, respectively, in interest expense related to the CIBC borrowings. During the three and nine months ended September 30, 2024, the weighted average effective interest rate on outstanding borrowings under the CIBC Credit Agreement was approximately 7.7% and 7.8%, respectively. 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. As of September 30, 2024, the stated interest rate applicable to borrowings under the CIBC Credit Agreement was 7.2%.

9. 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 ("RSUs"), unrestricted stock, unrestricted stock units, and other stock-based awards to employees, directors, and consultants of the Company and its subsidiaries. The number of shares of common stock of TransMedics Group initially available for issuance under the 2019 Plan

was 3,428,571 shares, plus the number of shares underlying awards under the previously outstanding 2014 Stock Incentive Plan (the "2014 Plan"), not to exceed 1,595,189 shares, that expire or are terminated, surrendered, or cancelled without the delivery of shares, are forfeited to or repurchased by TransMedics Group or otherwise become available again for grant. Since the effectiveness of the Company's 2019 Plan in April 2019, no 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, 2024, 866,112 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, 2024, 31,303 shares of common stock were issued under the 2019 ESPP and as of September 30, 2024, 233,256 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, RSUs 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. On November 2, 2023, the Company's Board of Directors approved an increase of 500,000 to shares available under the Inducement Plan. As of September 30, 2024, 551,558 shares of common stock remained available for issuance under the Inducement Plan.

Stock Option Activity

During the nine months ended September 30, 2024, the Company granted options under the 2019 Plan and the Inducement Plan with service-based vesting for the purchase of an aggregate of 356,247 shares of common stock with a weighted average grant-date fair value of $57.59 per share.

Restricted Stock Unit Activity

During the nine months ended September 30, 2024, the Company granted 238,352 RSUs under the 2019 Plan and the Inducement Plan with service-based vesting conditions and a weighted-average grant-date fair value of $90.49 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,	
	2024	2023	2024	2023
Cost of revenue	$ 383	$ 112	$ 1,123	$ 241
Research, development and clinical trials expenses	1,077	781	3,078	2,013
Selling, general and administrative expenses	6,484	4,295	18,256	11,813
	$ 7,944	$ 5,188	$ 22,457	$ 14,067

As of September 30, 2024, total unrecognized compensation cost related to unvested share-based awards was $65.4 million, which is expected to be recognized over a weighted average period of 2.2 years.

10. Net Income (Loss) per Share

Basic net income (loss) per common share is computed by dividing the net income (loss) by the weighted average number of shares of common stock outstanding for the period. Diluted net income (loss) per common share is computed by dividing net income (loss) by the weighted average number of shares of common stock outstanding for the period, including potential dilutive common shares assuming the dilutive effect of outstanding stock awards, using the treasury stock method, and outstanding convertible notes, using the if-converted method.

A reconciliation of the numerators and the denominators of the basic and dilutive net income (loss) per common share computations are as follows (in thousands, except share and per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Numerator:				
Net income (loss)	$ 4,216	$ (25,422)	$ 28,607	$ (29,059)
Denominator:				
Weighted average basic common shares outstanding	33,441,394	32,614,059	33,108,253	32,474,522
Effect of dilutive securities:				
Options to purchase common stock	1,975,523	—	1,895,962	—
Restricted stock units	266,861	—	202,800	—
Warrants to purchase common stock	—	—	4,635	—
Restricted stock awards	174	—	4,270	—
Employee stock purchase plan	—	—	2,836	—
Weighted average dilutive common shares outstanding	35,683,952	32,614,059	35,218,756	32,474,522
Net income (loss) per share:				
Basic	$ 0.13	$ (0.78)	$ 0.86	$ (0.89)
Diluted	$ 0.12	$ (0.78)	$ 0.81	$ (0.89)

The Company excluded the following potential common shares, presented based on weighted average shares outstanding, from the computation of diluted net income (loss) per share because including them would have had an anti-dilutive effect:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Convertible senior notes	4,893,848	4,893,848	4,893,848	2,554,089
Options to purchase common stock	37,035	3,201,994	323,905	3,225,282
Employee stock purchase plan	16,310	18,739	13,584	14,522
Restricted stock units	1,002	233,418	3,949	171,306
Restricted stock awards	317	12,709	106	18,008
Warrants to purchase common stock	—	14,440	—	14,440
	4,948,512	8,375,148	5,235,392	5,997,647

11. Commitments and Contingencies

Operating Leases

The Company leases office, laboratory and manufacturing space under two non-cancelable operating leases. There have been no material changes to the Company's leases during the nine months ended September 30, 2024. 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, 2023.

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. Effective January 1, 2023, the Company instituted an employer matching program for the 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, 2024, the Company recorded expense of $0.9 million and $2.5 million, respectively, related to these matching contributions. 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 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, 2024 and December 31, 2023.

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, 2024 was $6.0 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.

12. Revenue

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,	
	2024	2023	2024	2023
OCS transplant revenue by country by organ(1)(2):				
United States				
Lung total revenue	$ 3,726	$ 3,410	$ 12,675	$ 7,658
Heart total revenue	24,525	15,069	71,922	41,481
Liver total revenue	76,671	41,214	220,636	97,002
Total United States OCS transplant revenue	104,922	59,693	305,233	146,141
All other countries				
Lung revenue	182	310	1,590	964
Heart revenue	2,401	3,893	9,800	10,803
Liver revenue	—	97	—	104
Total all other countries OCS transplant revenue	2,583	4,300	11,390	11,871
Total OCS transplant revenue	$ 107,505	$ 63,993	$ 316,623	$ 158,012

(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 $1.3 million and $3.3 million for the three and nine months ended September 30, 2024, respectively, and $2.4 million for the three and nine months ended September 30, 2023, is not included in this table.

Significant Customers

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, 2024 and 2023, no customer accounted for more than 10% of revenue. As of September 30, 2024 and December 31, 2023, no customer accounted for more than 10% of accounts receivable.

Payments to Customers

In connection with its clinical trials, the Company makes payments to customers for reimbursement of clinical trial materials and customer's costs incurred to execute specific clinical trial protocols related to the Company's OCS products, which are recorded as a reduction of revenue. For each of the three and nine months ended September 30, 2024 and 2023, the net impact of adjustments to revenue for such payments were insignificant.

The Company also makes payments to customers to obtain information related to post-approval studies or existing standard-of-care protocols unrelated to the Company's OCS products and records such payments as operating expenses. For the three and nine months ended September 30, 2024, the Company recorded $1.8 million and $4.5 million, respectively, of operating expense related to these costs. For the three and nine months ended September 30, 2023, the Company recorded $0.4 million and $0.8 million, respectively, of operating expense related to these payments.

13. 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, 2024 and 2023 for her services as an employee, and $0.3 million in total compensation for each of the nine months ended September 30, 2024 and 2023.

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, 2023, as filed with the SEC on February 27, 2024 (the "2023 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 2023 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 NOP, an innovative turnkey solution to provide outsourced organ retrieval, OCS organ management and logistics services, to provide transplant programs in the United States with a more efficient process to procure donor organs with the OCS. In 2023, we enhanced our NOP offering with the addition of a logistics team to expand our transportation logistics capabilities. Our logistics services include aviation transportation, ground transportation, and other coordination activity. 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 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 issuance of our 1.50% convertible senior notes due 2028, or the Notes, proceeds from the sale of common stock in our public offerings, and revenue from commercial sales of our OCS products and NOP services and clinical trials.

From our inception through December 31, 2023, we incurred significant operating losses. Our ability to generate revenue sufficient to achieve sustained profitability will depend on the continued growth in customer utilization of our products and services. We generated total revenue of $108.8 million and $319.9 million, and net income of $4.2 million and $28.6 million, for the three and nine months ended September 30, 2024, respectively. We generated total revenue of $241.6 million and incurred a net loss of $25.0 million for the year ended December 31, 2023. As of September 30, 2024, we had an accumulated deficit of $475.1 million. We expect our operating and capital expenditures will continue to increase 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 logistics capabilities, including hiring training and retaining pilots to scale our aviation transportation, to support our NOP and reduce dependence on third party transportation, including by means of the acquisition, maintenance or replacement 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.

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 on an annual basis. Until such time, if ever, as we can generate substantial revenue sufficient to achieve sustained profitability, we may 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 will have to delay, scale back or discontinue the further development and commercialization efforts of one or more of our products, or may be forced to 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 expired in March 2024. Additionally, in September 2023, the Securing the U.S. Organ Procurement and Transplantation Network Act was signed into law and 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. In September 2024, HRSA began awarding contracts aimed at supporting these initiatives. 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.

Economic Impacts

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.

Components of Our Results of Operations

Revenue

We generate net product revenue primarily from sales of our single-use, organ-specific disposable sets used on our organ-specific OCS Consoles. To a lesser extent, we also generate product revenue from the sale of OCS Consoles to customers and the implied rental of OCS Consoles loaned to customers at no charge. For each new transplant procedure, customers purchase an additional OCS disposable set for use on the customer's existing organ-specific OCS Console. We also generate service revenue by providing outsourced organ retrieval, OCS organ management and logistics services under our NOP in the United States. With the acquisition of Summit, the purchase of fixed-wing transplant aircraft and the addition of a logistics team, we anticipate increased service revenue from our logistics services.

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 have transitioned Summit's charter flight and aircraft management customers to third parties. We do not anticipate generating revenue from charter flights or aircraft management and related services. We are continuing to offer flight school training services. During the three and nine months ended September 30, 2024, service revenue of $1.3 million and $3.3 million, respectively, consisting primarily of flight school training revenue is from Summit's legacy operations and is unrelated to the NOP and organ transplant. 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 OCS transplant-related 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 logistics services under our NOP, and an OCS Console, whether sold or loaned to the customer.

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 Conformité Européene mark, or CE Mark, certifications for each of our OCS products. As required by Regulation (EU) 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 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. 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 and logistics costs, including labor costs for pilots, aircraft depreciation, aircraft costs, fuel, crew travel, maintenance and third-party flight costs and ground transportation that support organ delivery. Cost of service revenue for the three and nine months ended September 30, 2024 also includes $0.7 million and $2.4 million, respectively, of costs from Summit's legacy operations unrelated to the NOP and organ transplant. Cost of service revenue for the three and nine months ended September 30, 2023 also includes $2.3 million of costs from Summit's legacy operations unrelated to the NOP and organ transplant.

Gross profit is the amount by which revenue exceeds cost of revenue in each reporting period and gross margin is gross profit divided by revenue. Our overall gross margin will be impacted by the relative mix of product and service revenue, as product and service revenue have different margin profiles, and we expect our overall gross margin will decrease as service revenue increases as a proportion of overall revenue in 2024 as compared to 2023. Product and service gross margins are also 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 overall cost of revenue will increase or decrease in absolute dollars primarily as, and to the extent that, our revenue increases or decreases. 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 product gross margin. We also expect to see modest improvements in the future in our services gross margin 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, and recruiting and temporary service fees related to such personnel;
- expenses incurred in connection with the clinical trials of our products, including under agreements with third parties, such as consultants, contractors and data management organizations;
- the cost of maintaining and improving our product designs, including the testing of materials and parts used in our products;

- laboratory supplies and research materials; and
- facilities, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities and insurance.

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

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of salaries and related costs, including stock-based compensation, for personnel in our commercial team and personnel in executive, marketing, finance and administrative functions, and recruiting and temporary service fees for such personnel. 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.

Selling, general and administrative expenses also include direct and allocated facility-related costs, costs to support 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.

Other Income (Expense)

Interest Expense

Interest expense consists of interest expense associated with outstanding borrowings under our loan agreement and our Notes 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. In May 2023, we issued and sold $460.0 million in aggregate principal amount of our Notes.

Interest Income and Other Income (Expense)

Interest income and other income (expense) 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 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, 2024 and 2023

The following table summarizes our results of operations for the three months ended September 30, 2024 and 2023:

	Three Months Ended September 30,		
	2024	2023	Change
		(in thousands)	
Revenue:			
Net product revenue	$ 65,861	$ 47,740	$ 18,121
Service revenue	42,900	18,690	24,210
Total revenue	108,761	66,430	42,331
Cost of revenue:			
Cost of net product revenue	13,246	11,086	2,160
Cost of service revenue	34,670	14,682	19,988
Total cost of revenue	47,916	25,768	22,148
Gross profit	60,845	40,662	20,183
Operating expenses:			
Research, development and clinical trials	14,266	11,132	3,134
Acquired in-process research and development expenses	—	27,212	(27,212)
Selling, general and administrative	42,656	30,653	12,003
Total operating expenses	56,922	68,997	(12,075)
Income (loss) from operations	3,923	(28,335)	32,258
Other income (expense):			
Interest expense	(3,617)	(3,590)	(27)
Interest income and other income (expense)	3,939	4,996	(1,057)
Total other expense, net	322	1,406	(1,084)
Income (loss) before income taxes	4,245	(26,929)	31,174
(Provision) benefit for income taxes	(29)	1,507	(1,536)
Net income (loss)	$ 4,216	$ (25,422)	$ 29,638

Revenue

OCS transplant-related revenue consisted of:

	Three Months Ended September 30,		
	2024	2023	Change
		(in thousands)	
OCS transplant revenue by country by organ:			
United States			
Lung total revenue	$ 3,726	$ 3,410	$ 316
Heart total revenue	24,525	15,069	9,456
Liver total revenue	76,671	41,214	35,457
Total United States OCS transplant revenue	104,922	59,693	45,229
All other countries			
Lung total revenue	182	310	(128)
Heart total revenue	2,401	3,893	(1,492)
Liver total revenue	—	97	(97)
Total all other countries OCS transplant revenue	2,583	4,300	(1,717)
Total OCS transplant revenue	$ 107,505	$ 63,993	$ 43,512

We also had service revenue unrelated to OCS transplant of $1.3 million for the three months ended September 30, 2024, which consisted primarily of flight school training revenue from Summit's legacy operations, and service revenue unrelated to OCS transplant of $2.4 million for the three months ended September 30, 2023, 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.

Revenue from customers in the United States related to OCS transplant was $104.9 million in the three months ended September 30, 2024 and increased by $45.2 million compared to the three months ended September 30, 2023, due to higher sales volumes of our OCS Liver, OCS Heart and OCS Lung disposable sets and increased usage of the NOP. 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 and logistics services under the NOP in the United States. Establishing the NOP, which launched in late 2021, has allowed us to broaden our customer base and increase utilization of the OCS in organ transplantation. Substantially all of our customers in the United States now participate in the NOP. By adding logistics to our NOP offering in late 2023, we have been able to further increase product and service revenue.

Revenue from customers outside the United States was $2.6 million and $4.3 million for the three months ended September 30, 2024 and 2023, respectively.

Cost of Revenue, Gross Profit and Gross Margin

Cost of net product revenue increased by $2.2 million in the three months ended September 30, 2024 compared to the three months ended September 30, 2023. Cost of service revenue increased by $20.0 million in the three months ended September 30, 2024 compared to the three months ended September 30, 2023 as we increased utilization of the NOP. Gross profit increased by $20.2 million in the three months ended September 30, 2024 compared to the three months ended September 30, 2023.

Overall gross margin was 56% and 61% for the three months ended September 30, 2024 and 2023, respectively. The decrease in gross margin from 2023 to 2024 was driven primarily by the relative increase in service revenue, which has a lower gross margin than product revenue. Gross margin from net product revenue was 80% and 77% for the three months ended September 30, 2024 and 2023, respectively. Gross margin from net product revenue increased from the three months ended September 30, 2023 to the three months ended September 30, 2024 primarily due to higher volume of product sales. Gross margin from service revenue was 19% and 21% for the three months ended September 30, 2024 and 2023, respectively, and consisted primarily of organ retrieval, OCS organ management and logistics services under our NOP. Gross margin from service revenue decreased during the three months ended September 30, 2024 as compared to the three months ended September 30, 2023 primarily due to investments in our NOP network, including aviation-related expenditures, to prepare for future growth.

Operating Expenses

Research, Development and Clinical Trials Expenses

	Three Months Ended September 30,		
	2024	2023	Change
		(in thousands)	
Personnel related (including stock-based compensation expense)	$ 5,462	$ 4,577	$ 885
Laboratory supplies and research materials	3,085	2,764	321
Consulting and third-party services	3,859	1,772	2,087
Clinical trials costs	182	504	(322)
Facility related and other	1,678	1,515	163
Total research, development and clinical trials expenses	$ 14,266	$ 11,132	$ 3,134

Total research, development and clinical trials expenses increased by $3.1 million from $11.1 million in the three months ended September 30, 2023 to $14.3 million in the three months ended September 30, 2024. Personnel related costs increased by $0.9 million primarily due 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 $1.1 million and $0.8 million for the three months ended September 30, 2024 and 2023, respectively. Consulting and third-party services costs increased by $2.1 million due to development efforts by our external development consultants for our next generation OCS program, other product development and digital tools.

Acquired In-Process Research and Development Expenses

Acquired IPR&D expenses in the three months ended September 30, 2023 of $27.2 million were related to the acquisition of certain assets related to lung and heart perfusion technology from Bridge to Life Ltd. and its subsidiary Tevosol, Inc., or together BTL.

Selling, General and Administrative Expenses

	Three Months Ended September 30,		
	2024	2023	Change
		(in thousands)	
Personnel related (including stock-based compensation expense)	$ 28,188	$ 19,138	$ 9,050
Professional and consultant fees	4,086	5,588	(1,502)
NOP support	3,558	2,366	1,192
Tradeshows and conferences	353	543	(190)
Facility related and other	6,471	3,018	3,453
Total selling, general and administrative expenses	$ 42,656	$ 30,653	$ 12,003

Total selling, general and administrative expenses increased by $12.0 million from $30.7 million in the three months ended September 30, 2023 to $42.7 million in the three months ended September 30, 2024 due primarily to increases in personnel related costs, facility related and other costs and NOP support costs. Personnel related costs increased by $9.1 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 $2.2 million, due primarily to additional grants to new and existing employees. NOP support costs increased by $1.2 million due primarily to increased utilization of the NOP and our efforts to prepare for further growth. Facility related and other costs increased by $3.5 million due primarily to increased costs associated with post-approval studies as well as information technology infrastructure costs and depreciation and amortization expense due to the growth in our business. These increases were partially offset by decreases in professional and consultant fees and tradeshows and conferences expenses. Professional and consultant fees decreased by $1.5 million due primarily to transaction costs incurred in the three months ended September 30, 2023 of $2.0 million related to our Summit acquisition and decreased legal fees, partially offset by increased fees in the three months ended September 30, 2024 related to information technology and other enterprise solutions costs to support the growth in our business.

Other Income (Expense)

Interest Expense

Interest expense was $3.6 million for each of the three months ended September 30, 2024 and 2023 and consisted of interest expense on the $460.0 million principal amount of the Notes that carry a 1.5% interest rate and interest expense on the $60.0 million principal amount of the CIBC loan that carries a variable interest rate, which was 7.2% as of September 30, 2024.

Interest Income and Other Income (Expense)

Interest income and other income (expense) for the three months ended September 30, 2024 and 2023 included interest income of $3.3 million and $5.2 million, respectively, from interest earned on cash balances. Other income (expense) for the three months ended September 30, 2024 and 2023 also included $0.7 million of realized and unrealized foreign currency transactions gains and $0.2 million of realized and unrealized foreign currency transactions losses, respectively.

Comparison of the Nine Months Ended September 30, 2024 and 2023

The following table summarizes our results of operations for the nine months ended September 30, 2024 and 2023:

	Nine Months Ended September 30,		
	2024	2023	Change
		(in thousands)	
Revenue:			
Net product revenue	$ 198,918	$ 124,195	$ 74,723
Service revenue	120,998	36,254	84,744
Total revenue	319,916	160,449	159,467
Cost of revenue:			
Cost of net product revenue	41,800	26,950	14,850
Cost of service revenue	88,048	27,330	60,718
Total cost of revenue	129,848	54,280	75,568
Gross profit	190,068	106,169	83,899
Operating expenses:			
Research, development and clinical trials	39,504	25,294	14,210
Acquired in-process research and development expenses	—	27,212	(27,212)
Selling, general and administrative	121,712	84,993	36,719
Total operating expenses	161,216	137,499	23,717
Income (loss) from operations	28,852	(31,330)	60,182
Other income (expense):			
Interest expense	(10,838)	(7,186)	(3,652)
Interest income and other income (expense)	10,777	7,982	2,795
Total other income (expense), net	(61)	796	(857)
Income (loss) before income taxes	28,791	(30,534)	59,325
(Provision) benefit for income taxes	(184)	1,475	(1,659)
Net income (loss)	$ 28,607	$ (29,059)	$ 57,666

Revenue

OCS transplant-related revenue consisted of:

	Nine Months Ended September 30,		
	2024	2023	Change
		(in thousands)	
OCS transplant revenue by country by organ:			
United States			
Lung total revenue	$ 12,675	$ 7,658	$ 5,017
Heart total revenue	71,922	41,481	30,441
Liver total revenue	220,636	97,002	123,634
Total United States OCS transplant revenue	305,233	146,141	159,092
All other countries			
Lung total revenue	1,590	964	626
Heart total revenue	9,800	10,803	(1,003)
Liver total revenue	—	104	(104)
Total all other countries OCS transplant revenue	11,390	11,871	(481)
Total OCS transplant revenue	$ 316,623	$ 158,012	$ 158,611

We also had service revenue unrelated to OCS transplant of $3.3 million for the nine months ended September 30, 2024, which consisted primarily of flight school training revenue from Summit's legacy operations and service revenue unrelated to OCS transplant of $2.4 million for the nine months ended September 30, 2023, 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.

Revenue from customers in the United States related to OCS transplant was $305.2 million in the nine months ended September 30, 2024 and increased by $159.1 million compared to the nine months ended September 30, 2023, due to higher sales volumes of our OCS Liver, OCS Heart and OCS Lung disposable sets and increased usage of the NOP. 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 and logistics services under the NOP in the United States. Establishing the NOP, which launched in late 2021, has allowed us to broaden our customer base and increase utilization of the OCS in organ transplantation. Substantially all of our customers in the United States now participate in the NOP. By adding logistics to our NOP offering in late 2023, we have been able to further increase product and service revenue.

Revenue from customers outside the United States was $11.4 million and $11.9 million in the nine months ended September 30, 2024 and 2023, respectively.

Cost of Revenue, Gross Profit and Gross Margin

Cost of net product revenue increased by $14.9 million in the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023. Cost of service revenue increased by $60.7 million in the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023 as we increased utilization of the NOP. Gross profit increased by $83.9 million in the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023.

Overall gross margin was 59% and 66% for the nine months ended September 30, 2024 and 2023, respectively. The decrease in gross margin from 2023 to 2024 was driven primarily by the relative increase in service revenue, which has a lower gross margin than product revenue. Gross margin from net product revenue was 79% and 78% for the nine months ended September 30, 2024 and 2023, respectively. Gross margin from service revenue was 27% and 25% for the nine months ended September 30, 2024 and 2023, respectively, and consisted primarily of organ retrieval, OCS organ management and logistics services under our NOP. The increase in gross margin from services was due primarily to improved efficiency in our NOP service model as a result of the addition of our logistics offering and increased scale.

Operating Expenses

Research, Development and Clinical Trials Expenses

	Nine Months Ended September 30,		
	2024	2023	Change
	(in thousands)		
Personnel related (including stock-based compensation expense)	$ 16,204	$ 11,078	$ 5,126
Laboratory supplies and research materials	9,332	5,221	4,111
Consulting and third-party services	8,504	4,032	4,472
Clinical trials costs	452	973	(521)
Facility related and other	5,012	3,990	1,022
Total research, development and clinical trials expenses	$ 39,504	$ 25,294	$ 14,210

Total research, development and clinical trials expenses increased by $14.2 million from $25.3 million in the nine months ended September 30, 2023 to $39.5 million in the nine months ended September 30, 2024. Personnel related costs increased by $5.1 million primarily due 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 $3.1 million and $2.0 million for the nine months ended September 30, 2024 and 2023, respectively. Laboratory supplies and research materials costs increased by $4.1 million from the nine months ended September 30, 2023 to the nine months ended September 30, 2024, primarily due to our increased need for supplies and materials used for development of our next generation OCS and other product development. Consulting and third-party services costs increased by $4.5 million due to development efforts by our external development consultants for our next generation OCS program, other product development and digital tools. Facility related and other costs increased by $1.0 million from the nine months ended September 30, 2023 to the nine months ended September 30, 2024 due primarily to the increased costs of supporting a larger group of research and development personnel and their development efforts.

Acquired In-Process Research and Development Expenses

Acquired IPR&D expenses in the nine months ended September 30, 2023 of $27.2 million were 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,		
	2024	2023	Change
		(in thousands)	
Personnel related (including stock-based compensation expense)	$ 79,567	$ 51,176	$ 28,391
Professional and consultant fees	12,636	12,863	(227)
NOP support	9,101	8,642	459
Tradeshows and conferences	3,218	3,543	(325)
Facility related and other	17,190	8,769	8,421
Total selling, general and administrative expenses	$ 121,712	$ 84,993	$ 36,719

Total selling, general and administrative expenses increased by $36.7 million from $85.0 million in the nine months ended September 30, 2023 to $121.7 million in the nine months ended September 30, 2024 due primarily to increases in personnel related costs and facility related and other costs. Personnel related costs increased by $28.4 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 $6.4 million, due primarily to additional grants to new and existing employees. Facility related and other costs increased by $8.4 million due primarily to increased costs associated with post-approval studies and information technology infrastructure costs, and depreciation and amortization expense due to the growth in our business. Professional and consultant fees decreased due primarily to transaction costs incurred in the nine months ended September 30, 2023 of $2.0 million related to our Summit acquisition and decreased legal fees, partially offset by increased fees in the nine months ended September 30, 2024 related to information technology and other enterprise solutions costs to support the growth in our business.

Other Income (Expense)

Interest Expense

Interest expense was $10.8 million and $7.2 million for the nine months ended September 30, 2024 and 2023, 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 Income and Other Income (Expense)

Interest income and other income (expense) for the nine months ended September 30, 2024 and 2023 included interest income of $10.5 million and $8.1 million, respectively, from interest earned on our cash balances. Other income (expense) included $0.3 million of realized and unrealized foreign currency transactions gains and $0.2 million of realized and unrealized foreign currency transactions losses during the nine months ended September 30, 2024 and 2023, respectively.

Liquidity and Capital Resources

From our inception through December 31, 2023, we 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 Notes, proceeds from the sale of common stock in our public offerings and revenue from commercial sales of our OCS products and NOP services and clinical trials. 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, 2024, our principal source of liquidity was cash of $330.1 million.

Cash Flows

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

	Nine Months Ended September 30,	
	2024	2023
	(in thousands)	
Net cash provided by (used in) operating activities	$ 29,140	$ (21,332)
Net cash used in investing activities	(115,697)	(152,135)
Net cash provided by financing activities	21,688	399,494
Effect of exchange rate changes on cash, cash equivalents and restricted cash	151	(99)
Net increase (decrease) in cash, cash equivalents and restricted cash	$ (64,718)	$ 225,928

Operating Activities

During the nine months ended September 30, 2024, operating activities provided $29.1 million of cash, primarily resulting from net income of $28.6 and net non-cash charges of $39.7 million, partially offset by net cash used by changes in our operating assets and liabilities of $39.2 million. Net cash used by changes in our operating assets and liabilities for the nine months ended September 30, 2024 consisted primarily of an increase in accounts receivable of $26.5 million, an increase in inventory of $12.5 million and an increase in prepaid expenses and other current assets of $6.1 million, partially offset by an increase in accounts payable and accrued expenses and other current liabilities of $7.4 million.

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.

Investing Activities

During the nine months ended September 30, 2024, net cash used in investing activities of $115.7 million consisted primarily of purchases of property, plant and equipment, including an increase of $96.2 million in transplant aircraft. We also received $0.4 million for the final settlement of the Summit purchase price working capital adjustments.

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.

Financing Activities

During the nine months ended September 30, 2024, net cash provided by financing activities of $21.7 million consisted of proceeds from the issuance of common stock upon exercise of stock options of $19.6 million and proceeds from the issuance of common stock in connection with the 2019 Employee Stock Purchase Plan of $2.1 million.

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.

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. 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.

A conditional conversion feature of the Notes was triggered on June 30, 2024, as the last reported sale price of our common stock was greater than or equal to 130% of the conversion price of the Notes for at least 20 trading days during the period of 30 consecutive trading days ending on and including the last trading day of the quarter ended June 30, 2024, and the Notes therefore became convertible at the noteholders' election in the calendar quarter ended September 30, 2024. This conditional conversion feature was triggered again on September 30, 2024, and the Notes therefore are convertible at the noteholders' election in the calendar quarter ending December 31, 2024. If this condition or another conversion condition is met in the future, the Notes may again become convertible, otherwise the Notes will be convertible at the noteholders' election from March 1, 2028 through the close of business on the second scheduled trading day immediately before the maturity date.

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, the Second Amendment to Credit Agreement, dated as of June 23, 2023, by and among the Company and CIBC, or the Second Amendment, and the Third Amendment to Credit Agreement, dated as of November 9, 2023, by and among the Company and CIBC, or the Third Amendment, pursuant to which we borrowed $60.0 million, referred to herein as the CIBC Credit Agreement.

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 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), as defined, for the trailing four month period (only if EBITDA is negative) and (ii) $10.0 million, and (y) a requirement to maintain total net revenue of at least 75% of the level set forth in the total revenue plan presented to CIBC. The obligations under the CIBC Credit Agreement are subject to acceleration upon the occurrence of specified events of default, including payment default, change in control, bankruptcy, insolvency, certain defaults under other material debt, certain events with respect to governmental approvals (if such events could cause a material adverse change in our business), failure to comply with certain covenants and a material adverse change in our business, operations or financial condition. As of September 30, 2024, we were 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, 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. The timing and amount of our operating and capital expenditures will depend on many factors, including:

- the amount of 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 maintaining and improving our commercial operations, including the NOP;
- the costs associated with maintaining and growing our logistics capabilities, including by means of attracting, training and retaining pilots, and the acquisition, maintenance, or replacement of fixed-wing aircraft for our aviation transportation services or other acquisitions, joint ventures or strategic investments;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims; and
- the level of our selling, general and administrative expenses.

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

We may need to raise additional funding, which might not be available on favorable terms or at all. See "Item 1A. Risk Factors—Risks Related to Our Financial Position and Need for Additional Capital" in our 2023 Form 10-K.

Material Contractual Obligations

There have been no material changes to our cash requirements from those disclosed in our 2023 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 2023 Form 10-K.

Recently Issued Accounting Pronouncements

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to changes in interest rates and foreign currency exchange rates because we finance certain operations through variable rate debt instruments 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 2023 Form 10-K.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our President and Chief Executive Officer and our Chief Financial Officer (our principal executive officer and principal financial and accounting officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2024. 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, 2024, 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, 2024 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 2023 Form 10-K.

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

None.

Item 5. Other Information.

During our fiscal quarter ended September 30, 2024, 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
Stephen Gordon, Chief Financial Officer	Adoption 16-Sep-24	15-Dec-24	31-Dec-25	Common Stock	58,401 (3)	Sale
James R. Tobin 2012 Trust	Adoption 8-Aug-24	7-Nov-24	7-Nov-25	Common Stock	40,000	Sale

(1) Each plan is subject to earlier termination under certain circumstances specified in the plan, 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. Gordon may sell up to 8,401 additional shares of common stock underlying RSUs that may vest on February 20, 2025 and February 23, 2025, subject to Mr. Gordon's continued service to the Company as of such date.

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 with Embedded Linkbase Documents
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: October 29, 2024

TRANSMEDICS GROUP, INC.

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

Date: October 29, 2024

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: October 29, 2024

/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: October 29, 2024

/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, 2024, 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: October 29, 2024

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, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Stephen Gordon, Chief Financial Officer and Treasurer 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: October 29, 2024

By: /s/ Stephen Gordon

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