UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2025

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 No.)**
200 Minuteman Road Andover, Massachusetts	**01810**
(Address of principal executive offices)	**(Zip Code)**

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

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**

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☒ NO ☐

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant as of the last business day of the registrant's most recently completed second fiscal quarter, June 30, 2025, based on the last reported sale price of the registrant's common stock of $134.01 per share was $4,427 million. As of January 30, 2026, the registrant had 34,302,451 shares of common stock, no par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Definitive Proxy Statement for its 2026 Annual Meeting of Stockholders scheduled to be held on May 20, 2026, which Definitive Proxy will be filed with the Securities and Exchange Commission not later than 120 days after the registrant's fiscal year end of December 31, 2025, are incorporated by reference into Part II and Part III of this Form 10-K.

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K 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 Annual Report on Form 10-K, including statements regarding our future results of operations and financial position, business strategy and plans and our objectives for future operations, are forward-looking statements. The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect," "should," "could," "target," "predict," "seek" and similar expressions are intended to identify forward-looking statements. 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 described in "Item 1A. Risk Factors" in this Annual Report on Form 10-K, 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 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 Annual Report on Form 10-K 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 Annual Report on Form 10-K are made only as of the date of this report and should not be relied upon as predictions of future events. Factors or events that could cause our actual results to differ may emerge from time to time, and we are not able to predict all of them. We undertake no obligation to update any forward-looking statement, whether as a result of new information, future developments, or otherwise, except as may be required by applicable law.

RISK FACTORS SUMMARY

An investment in our common stock involves risks. The following risks, which are discussed more fully in "Item 1A. Risk Factors", and all of the other information contained in this Annual Report on Form 10-K should be considered carefully before investing in our common stock. These risks include, but are not limited to, the following:

- the fluctuation of our financial results from quarter to quarter;
- our ability to attract, train and retain key personnel;
- 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 improve the OCS platform, including by developing the next generation of the OCS products or expanding into new indications, and the development, and potential commercialization of our OCS Kidney device;
- the timing or results of clinical trials for the OCS, including pre- and post-approval studies;
- our ability to sustain profitability;
- 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;
- that we have identified a material weakness in our internal control over financial reporting, and that we may identify additional material weaknesses in the future;
- 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 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 impact of healthcare policy changes, including recently enacted or potential future legislation or administrative actions affecting or reforming the U.S. healthcare system, Organ Procurement and Transplantation Network, or OPTN, or the FDA;
- 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 transplant logistics capabilities to support our NOP to 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;
- 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 or services 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 impact of a shutdown of the U.S. government;
- 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, or the Notes;
- 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 impact of any product recalls or improper use of our products;
- our international expansion plans and the costs related thereto; and
- our estimates regarding revenue, expenses and needs for additional financing.

PART I

Except where the context otherwise requires or where otherwise indicated, the terms "TransMedics," "we," "us," "our," "our company," "the company," and "our business" refer to TransMedics Group, Inc. and its consolidated subsidiaries.

Item 1. Business.

Overview

We are a 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 procurement, OCS perfusion management and transplant logistics services, to provide transplant programs in the United States with a more efficient process to procure donor organs with the OCS. Our transplant 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.

Incidence of end-stage organ failure has been rapidly rising worldwide due to demographic trends that contribute to chronic diseases. Organ transplantation is the treatment of choice for addressing end-stage organ failure due to its positive clinical outcomes and favorable health economics. However, transplant volumes have been significantly restricted by the limitations of cold storage, the standard of care for solid organ transplantation. Cold storage is a rudimentary approach to organ preservation in which a donor organ is flushed with cold pharmaceutical solutions, placed in a plastic bag on top of ice and transported in a cooler. Cold storage subjects organs to significant injury due to a lack of oxygenated blood supply, or ischemia. Further, cold storage does not allow physicians to assess organ viability and lacks the ability to optimize an organ's condition once it has been retrieved from the donor. Time-dependent ischemic injury has been shown to result in short- and long-term post-transplant clinical complications and, together with the inability to assess or optimize organs, contributes to the severe underutilization of donor organs. With the use of cold storage, the majority of lungs and hearts donated after brain death go unutilized, and almost no available lungs and hearts donated after circulatory death are utilized.

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

We developed the NOP to provide additional capabilities to transplant centers for the complicated organ procurement process that often requires resources and logistics beyond a transplant center's existing capabilities and capacity, thereby limiting the number of organs the transplant center may be able to retrieve. Our NOP provides an end-to-end service offering delivering organs from anywhere in the United States on-demand directly to transplant centers leveraging our proprietary OCS technology, trained organ procurement surgeons and clinical specialists, and specially designed and dedicated air and ground transport logistics network. Our end-to-end service offering is necessary to ensure: (i) the successful execution of procuring and delivering healthy organs; (ii) the availability of the necessary surgical and clinical resources; (iii) that the highest transportation safety standards are met; (iv) the sharing of cost efficiencies and reducing cost burden of DCD donors that do not progress to become donors; and (v) the increased access to donor organs that are historically unutilized, all of which combine to make certain that TransMedics is able to provide the highest quality of service to transplant recipients, increasing the likelihood of success in the transplant process for each individual, and ultimately increasing the number of organs transplanted each year in the United States. Our transplant

logistics services include aviation transportation, ground transportation, and other coordination activity that is capable of arranging procurement missions on limited notice and at various hours of the day. Our NOP provides transplant centers with the ability to utilize the OCS to procure and transplant more organs for their patients than they would otherwise be able to do without increasing their own staff.

In August 2023, we acquired Summit Aviation, Inc. and Northside Property Group, LLC, or together Summit. Summit was a charter flight operator based in Bozeman, Montana. The acquisition enabled us to add aircraft transportation services to our NOP and become a comprehensive national provider of donor organ procurement and delivery in the United States. We have also acquired 22 fixed-wing aircraft to transport donor organs as part of the services offered under our NOP. We intend to opportunistically evaluate acquisitions of additional fixed-wing aircraft to enhance our logistics capabilities and support international expansion.

We believe the OCS and the NOP drive significant benefits to all stakeholders in the field of organ transplantation. For patients, we believe the OCS and the NOP provide additional access to life-saving transplants and allow for quicker recovery following transplantation. For hospitals, we believe the OCS and NOP provide a means to increase transplant volume, treat more patients, enhance provider status and improve transplant program economics. Finally, we believe the OCS and NOP provide payors with a more cost-effective treatment for end-stage organ failure and reduces exposure to significant post-transplant complication costs and extended hospital stays.

Our OCS products and NOP services are reimbursed in the United States through existing, standard commercial transplant billing mechanisms. The Medicare program and private payors had been providing reimbursement for the OCS Lung, OCS Heart and OCS Liver during the U.S. pivotal trials and have continued providing reimbursement for our products and services following FDA approval. We are in the process of seeking long-term reimbursement for our products outside of the United States.

Our current corporate headquarters, manufacturing and clinical training facilities are located in Andover, Massachusetts. In January 2026, we entered into an operating lease for premises in Somerville, Massachusetts to serve as our new corporate headquarters. The lease term began in January 2026, and we expect to transition certain of our operations to the Somerville premises on or before January 1, 2028, with the goal of ultimately replacing our existing headquarters in Andover, Massachusetts. We also have a geographically distributed team in the United States supporting our NOP and a designated maintenance hub for our aircraft in Dallas, Texas. We have additional distribution, commercial and research and development operations in Europe. As of December 31, 2025, we had a total of 898 employees worldwide, most of whom were full-time and located in the United States. We generated $605.5 million, $441.5 million and $241.6 million of total revenue during the years ended December 31, 2025, 2024 and 2023, respectively, representing year-over-year growth of 37.1% and 82.7% in 2025 and 2024, respectively. Our business model is characterized by a high level of recurring revenue, which is derived primarily from sales of our single-use, organ-specific disposable sets that are required for each transplant using the OCS as well as services provided to transplant centers by our NOP.

Our Competitive Strengths

We believe the continued growth of our company will be driven by the following competitive strengths:

- **Only FDA approved, portable, multi-organ, warm perfusion platform**
  Our Organ Care System is the only FDA approved portable, multi-organ, warm perfusion device on the market. Portability is a critical aspect in reducing the ischemic injury to the organ before transplantation, thereby reducing post-transplant complications and allowing the utilization of more organs for transplant. The multi-organ platform allows for the standardization of use across transplant programs.

- **National OCS Program**
  We developed our NOP to provide transplant programs with a more efficient process to procure donor organs with the OCS. The NOP is designed to support increasing numbers of transplants and extended procurement distances, and provides an alternative to the previous model in which the recipient transplant center sends its team to the donor site for procurement. Our NOP provides a turnkey solution that leverages the technical advantage of the OCS and provides transplant centers with a more efficient way to increase their volume of transplants without significantly increasing resources.

- **Transportation Logistics of the NOP**
  Transporting organs, clinical staff and medical technology in the field of organ transplant is very challenging. Donor organs may become available at almost any hospital at any time. The donor organ must be retrieved and transported to allocated recipients in a timely manner while protecting the organ from ischemic injury. The donor site may not be easily accessible and the distance to travel from donor to recipient may be very long. The expansion of our NOP to provide our own transportation logistics services, including 100% owned and operated private aircraft dedicated to organ procurement, further improves the efficiency of utilizing the NOP as a complete solution for organ procurement.

- **Significant body of strong clinical evidence**
  In order to receive FDA approval for our PMA products, we have conducted clinical trials with large numbers of patient participants, with the results of these trials published in leading medical journals. We also continue to collect clinical data through post-market registries for all of our products and plan to continue to provide the scientific results of these registries to the clinical user community. We expect to continue to build new clinical evidence through new programs to demonstrate the clinical value of product enhancements.

- **Strong relationship with the clinical transplant community**
  The transplant community is highly concentrated in the leading academic medical centers around the world. We have developed strong clinical relationships with many of these centers through their participation in our clinical trials and their commercial utilization of our products and services. In addition, many transplant surgeons at our clinical trial or commercial customer locations may have moved to new centers, bringing their OCS experience with them and allowing our relationships to grow to these new centers.

- **Expertise in transplant reimbursement and billing**
  The OCS has been reimbursed by the Centers for Medicare & Medicaid Services, or CMS, and private insurers during our clinical trials and continues to be reimbursed in the commercial setting. Since our customers have been billing for reimbursement for many years, we have developed a high degree of expertise in the area of transplant reimbursement and appropriate billing of insurers. We provide advice and best practices to our customers in compliance with laws and regulations.

- **Strong research and development capabilities and comprehensive intellectual property portfolio**
  We have a long history and broad experience in the development of warm machine perfusion for organ preservation. During the life of our OCS technology platform we have continued to add technological and usability enhancements to our devices. In the future, we intend to develop newer versions of the technology that continue to improve the ease of use, portability, and capability of the products.

Organ Transplant Therapy Benefits and Challenges

We believe organ transplantation is the most effective treatment for end-stage organ failure in terms of both clinical outcomes and health economics. Organ transplant provides the longest life expectancy and best quality of life compared to other therapies for end-stage organ failure. For example, the therapeutic options for end-stage heart failure include optimum medical management with pharmaceutical treatments, or OMM, mechanical support with a left ventricular assist device, or LVAD, and heart transplantation. Heart transplantation is associated with materially longer survival rates as compared to OMM and LVADs, which are either used as a bridge to transplant or as destination therapy, an alternative to transplant. These improved survival rates, in turn, result in favorable economics for transplantation on the basis of quality-adjusted life years.

However, organ transplant therapy faces two major challenges. First, despite the large and growing incidence of organ failure worldwide, and the significant clinical and economic benefits of organ transplantation, the number of transplants severely lags demand due to the limitations of traditional methods of organ preservation prior to transplantation. Second, a high rate of post-transplant clinical complications needs to be reduced to improve outcomes and lower costs.

The use of cold static storage for preservation of donor organs contributes to these challenges in three ways:

- **Subjects the donor organs to severe time-dependent ischemic injury**

  Cold storage deprives the organs from oxygen, resulting in time dependent injury (ischemia). This injury correlates with post-transplant complications and restricts the viable time for organ procurement and transplant, which limits the time and distance possible between donor and recipient and results in low utilization of the donor pool and limits the number of transplant procedures performed annually.

- **No organ optimization capability**

  Given the non-physiologic environment, cold storage does not allow for any therapeutic interventions to optimize the condition of the donor organs. This further limits utilization of available donor organs for transplantation and could negatively impact post-transplant outcomes. It is well demonstrated that donor organs benefit from some form of optimization to replenish depleted levels of substrates, hormones, and electrolytes that are significantly altered or used up during the donation process.

- **No organ viability assessment capability**

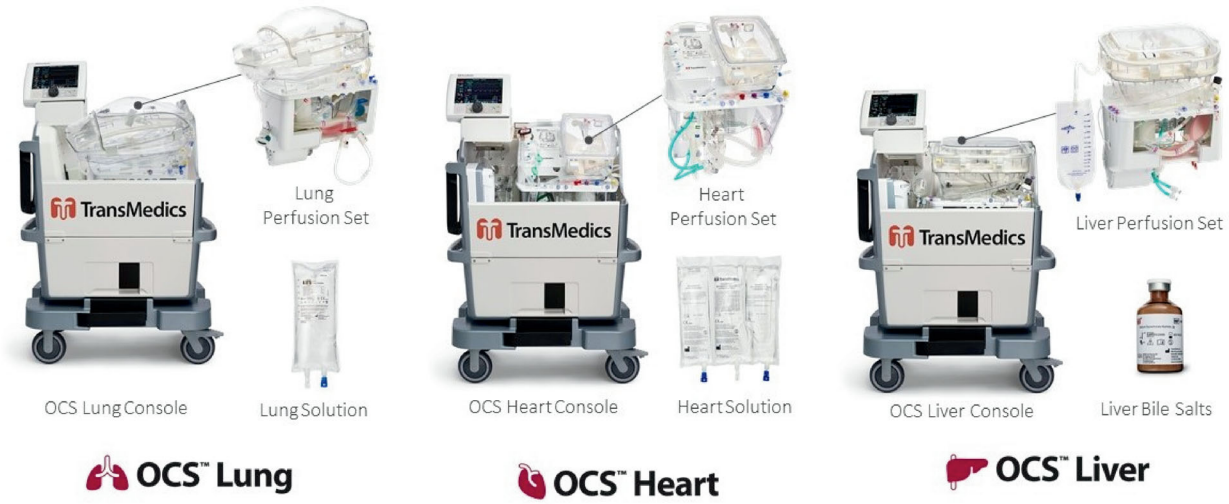
  During cold storage, the organs are not physiologically active, nor functioning; thus, there are no means for evaluating the suitability of these organs for transplantation. This further limits utilization of available organs as donor populations worldwide are growing older and have concomitant risk factors that benefit from sophisticated diagnostic evaluation capabilities to predict whether the donor organ is suitable and safe to transplant.

Our Technology and Solution

We developed the OCS to comprehensively address the major limitations of cold storage. The OCS is a portable organ perfusion, optimization and monitoring system that utilizes our proprietary and customized technology to replicate near-physiologic conditions for donor organs outside of the human body. The OCS was designed to perfuse donor organs with warm, oxygenated and nutrient-enriched blood, while maintaining the organs in a living, functioning state; the lung is breathing, the heart is beating and the liver is producing bile. 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.

The OCS Technology Platform

We developed the OCS, the first and only FDA approved portable, multi-organ, warm perfusion platform, to leverage proprietary core technologies across multiple organs. For each OCS product, we supplement the platform with organ-specific, customized and proprietary technologies. To date, we have developed three OCS products, one for each of lung, heart and liver transplantation. We have initiated the development of OCS Kidney, which is intended to be a smaller platform and include features such as automation and remote monitoring to enable longer preservation time and organ functional assessment. OCS Kidney will leverage our third generation, or Gen-3, multi-organ platform, which is being developed to improve the OCS usability, incorporate new technology, and further facilitate the use of OCS in our NOP.



Each OCS product consists of three primary components customized for each organ:

- **OCS Console:** The OCS Console is a highly portable electromechanical medical device that houses and controls the function of the OCS and is designed to fit in the current workflow for organ transplantation.

- **OCS Perfusion Set:** The OCS Perfusion Set is a sterile, biocompatible single-use disposable set that stores the organ and circulates blood. The OCS Perfusion Set includes all accessories needed to place the organ on the system.

- **OCS Solutions:** The OCS Solutions are a set of nutrient-enriched solutions used with blood to replenish depleted nutrients and hormones needed to optimize the organ's condition outside of the human body.

The OCS technology platform is equipped with the following core technologies that we designed to comprehensively address the limitations of cold storage and improve transplant outcomes:

- **proprietary pulsatile blood pump** to simulate beating heart perfusion in organs outside of the human body;

- **proprietary software-controlled titanium blood warmer** to maintain blood at body temperature while maximizing portability;

- **gas exchanger** to maintain organ oxygenation outside of the human body;

- **customized hemodynamics sensors** to monitor and assess organ function outside of the human body;

- **proprietary software-controlled, miniaturized, electromechanical system with universal power supply and hot-swappable batteries** to maximize portability and travel distance for organ procurement;

- **proprietary wireless monitor and control software** to provide an intuitive user interface for monitoring critical organ function; and

- **customized carbon fiber OCS console structure** to reduce the overall weight of the system and maximize portability.

Key Advantages of the OCS Platform

We believe the OCS platform provides significant benefits relative to cold storage:

- **Significant reduction in ischemia**
  Decreases current time and distance limitations on organ transport while also increasing the previously limited time period for procurement during which high quality transplant outcomes can reliably be obtained. This maximizes organ utilization and enables increased access to organ transplantation, while also meaningfully improving post-transplant outcomes.

- **Enables organ optimization outside of the human body**
  Allows therapeutic optimization of donor organs from the damaging conditions of brain and circulatory death using clinically proven and safe modalities, thus significantly improving donor organ utilization and patient outcomes.

- **Allows for organ viability assessment**
  Enables diagnostic evaluation of the donor organ using currently acceptable clinical standards to evaluate the organ's suitability for transplantation and to maximize the post-transplant outcomes.

We believe that by comprehensively addressing the three limitations of cold static storage, the use of the OCS will allow for increased utilization of donor organs and improve post-transplant outcomes.

Benefits of the OCS Platform for Key Stakeholders

We believe the OCS platform provides significant benefits to key constituents across the transplant continuum.

Value to Patients

We believe the OCS increases patients' access to what we believe is the best treatment option for end-stage organ failure, which results in improved quality of life and longer life expectancy. In addition, we believe improved clinical outcomes from use of the OCS will allow patients to recover more quickly following a transplant.

Value to Providers

We believe the OCS allows providers to improve clinical outcomes and increase the number of patients who receive organ transplants. Improvements in clinical outcomes could enable providers to meet the CMS post-transplant survival metrics required for reimbursement coverage and improve the overall financial profile of their transplant programs. In addition, we believe the increase in transplant volumes enabled by the OCS will help providers achieve "Center of Excellence" designations with payors and thus drive significant revenue growth for their transplant programs.

Value to Payors

We believe organ transplantation is a cost-effective treatment for end-stage organ failure as it provides the longest life expectancy, and better quality of life, compared to other treatments like mechanical support or medical therapy. We believe the OCS will enable payors to benefit from these favorable health economics and limit their exposure to the high cost of severe post-transplantation complications and extended hospital stays.

Our Strategy

We are committed to our goal of transforming organ transplantation with our OCS platform by establishing the OCS as the standard of care for solid organ transplantation and thereby increasing the utilization of donor organs and improving clinical outcomes.

The key elements of our strategy are:

- **Grow the adoption of the OCS at existing transplant center customers and expand the number of centers utilizing OCS and NOP.** We are focused on driving adoption of the OCS and NOP at leading, high volume transplant programs as well as expanding utilization to medium and smaller centers that can utilize OCS and NOP to provide transplants to more patients.

- **Grow our NOP, a turnkey solution to provide outsourced organ procurement, OCS perfusion management and transplant logistics services, to provide transplant programs with a more efficient process to procure donor organs with the OCS.** Our NOP leverages our clinical, logistical and transportation capabilities to provide access to and use of the OCS for transplant centers throughout the United States. Since its inception in 2021, the NOP has accelerated adoption of the OCS, and we believe this program has the potential to maximize utilization of donor organs for transplantation and, by standardizing the quality of use of the OCS, deliver better clinical outcomes.

- **Develop the next generation and Gen-3 OCS technology platforms, including expansion into additional organs, to improve user experience and facilitate our NOP.** In 2025, we introduced next generation OCS improvements in the clinical setting for OCS Lung and OCS Heart through the enrollment of two new clinical trials. The clinical programs are intending to generate new clinical evidence aimed at demonstrating superiority of OCS to static cold storage methods while additionally showing improved donor organ function beyond preservation and enabling safe, reproducible scheduled heart and lung transplants. In addition, we are developing the Gen-3 multi-organ platform to improve the OCS usability, incorporate new technology and automation, and facilitate the use of OCS in our NOP. The OCS Kidney will leverage Gen-3 technology and is intended to be a smaller platform, and include features such as automation and remote monitoring, with the objective of enabling longer preservation time and facilitating functional assessment of donor kidney.

- **Expand internationally in key European countries.** We believe international expansion could represent an additional growth driver for us in the long-term. We have begun to add resources in Europe focused on commercial expansion and market access, including the introduction of NOP in certain regions. In the second half of 2025, we initiated activities related to the expansion of our logistics network in certain European regions to support the offering of our NOP, including infrastructure required for organ transplantation ground transportation services in Italy. We currently conduct research and development activities in Mirandola, Italy and we plan to construct research and development and manufacturing facilities in Italy to further expand our capabilities in Europe.

Commercialization

We commercialize our products through two channels: our NOP and a direct acquisition model. Our NOP enables transplant centers to outsource the organ procurement, OCS perfusion management and transplant logistics process to our trained organ procurement surgeons, clinical specialists and transplant and logistics coordinators while using our OCS products. Our offering allows the transplant center to focus their internal resources on the transplant surgery and patient care. Utilizing our NOP saves the transplant center from investing in additional resources to support higher volumes and longer distance procurements. Since the launch of the NOP in the U.S., our sales of the OCS have primarily been through the NOP.

Our direct acquisition model is provided to transplant centers to train their own teams for organ procurement and OCS perfusion management on the OCS. Customer users are certified on the use of OCS at our training facility. Customers in the direct acquisition channel keep inventory of OCS disposables available and order replenishment as they are used. Through 2025, all of our international customers and a small number of our U.S. customers purchased our OCS products through the direct acquisition model.

Reimbursement

Medicare's reimbursement for organ transplant procedures is well-established and involves two payment mechanisms. The first is the inpatient hospital prospective payment system, which reimburses the transplant hospital for operating costs incurred during the inpatient stay in which the transplant procedure is performed. The payment for this stay is determined by the Medicare Severity-Diagnosis Related Group, or MS-DRG, into which the case is assigned. The second mechanism involves a separate payment, in addition to the MS-DRG-based payment, for organ acquisition costs, which include organ preservation and transportation costs. Medicare reimburses hospitals for allowable organ acquisition costs on a reasonable cost basis. The OCS is reimbursed under this second mechanism.

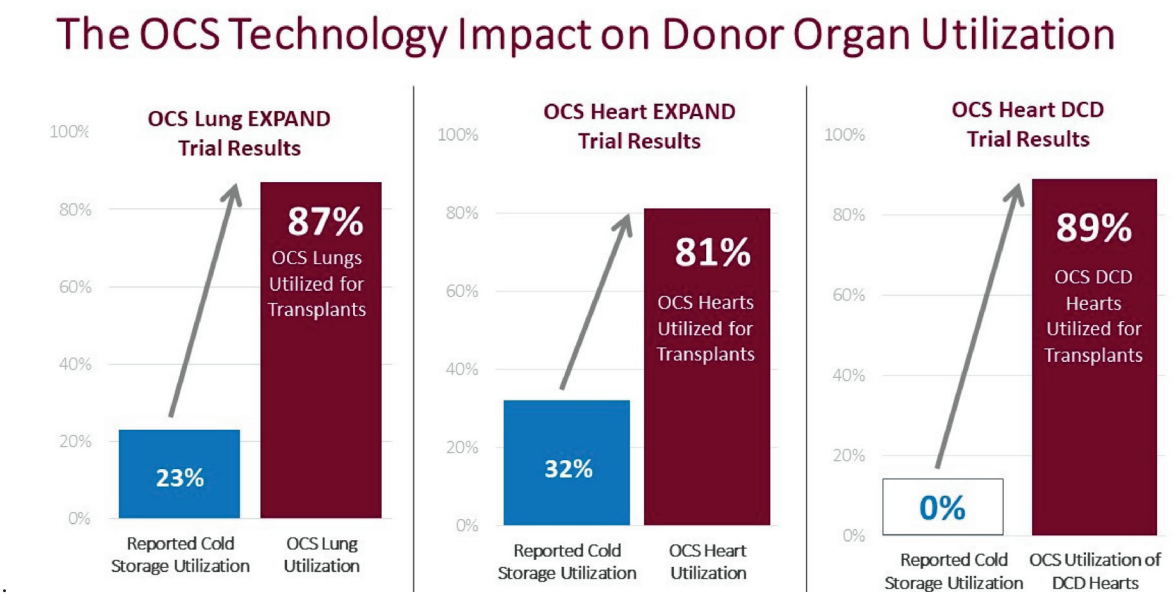
For Medicaid transplant recipients, reimbursement to a transplant hospital for the incurred cost of the OCS is determined based on the applicable state Medicaid program. Some states establish a global payment for the transplant and organ acquisition costs, and some states have separate payments for the inpatient stay based on the MS-DRG system and for organ acquisition costs. Private insurers typically have agreements as to how they reimburse for the transplant costs and the organ acquisition costs, which may be through a global payment for both, or a payment for the transplant and a separate mechanism for paying for organ acquisition costs. Nearly half of U.S. lung, heart and liver transplants are covered under the Medicare and Medicaid programs, with the remainder being reimbursed through private payors.

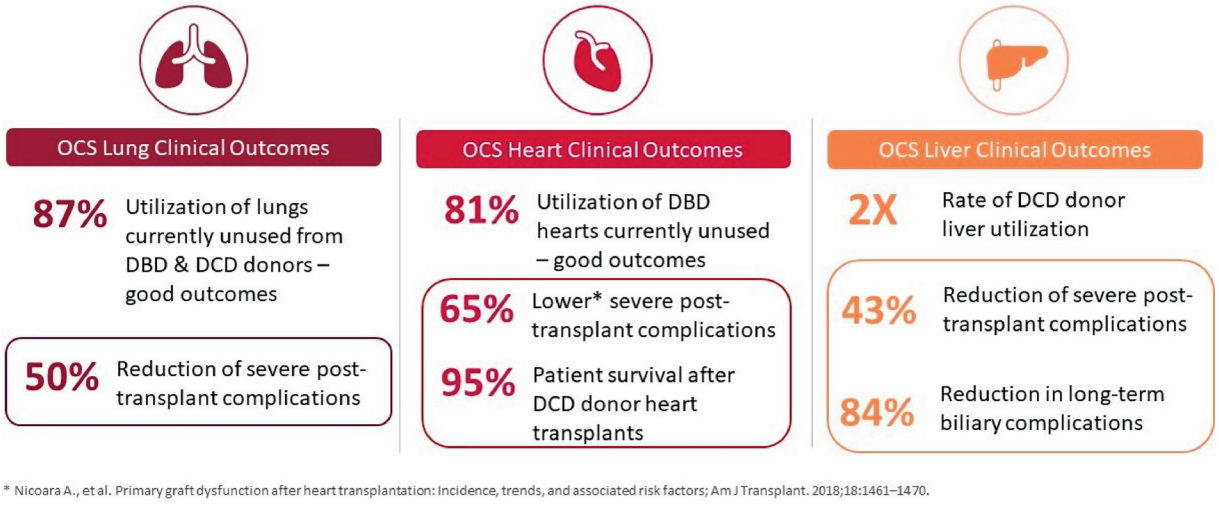
Medicare and private payors provided reimbursement for the OCS Lung, OCS Heart and OCS Liver during the U.S. pivotal trials and have provided reimbursement for the OCS Lung, OCS Heart and OCS Liver following their FDA approvals. This has established a history of billing precedent. We believe these established methods will continue to facilitate commercial reimbursement for the OCS Lung, OCS Heart and OCS Liver. Reimbursement outside of the United States follows a similar overall structure; however, reimbursement decisions are required in each individual country and may require national health systems to review and approve OCS reimbursement for each organ-specific product. Currently, there are a few areas of national reimbursement for use of OCS for transplant. Most notably, reimbursement is in place in the UK and the Netherlands for DCD heart transplant. However, most national healthcare systems do not reimburse transplant centers for the use of the OCS and additional reimbursement in international markets may require us to undertake additional clinical studies. Some international hospitals using the OCS currently pay for the OCS from their hospital budget or charitable funds. We are in the process of seeking long-term reimbursement for our OCS products in several jurisdictions.

Clinical Evidence

The lead transplant surgeons at transplant centers are clinically focused and rely primarily on clinical evidence to drive changes in their practice of organ transplantation. We have developed a substantial body of global clinical evidence to support our FDA PMA approvals and PMA submissions for the OCS for lung, heart and liver transplantation. Many of these clinical trials and studies have been published in peer-reviewed clinical journals. Our clinical trials have evaluated the use of the OCS for transplantation of organs that meet the current criteria for organ transplantation, as well as organs that would otherwise go unutilized from DBD and DCD donors. We believe the results of our clinical trials across lung, heart and liver transplantation may support the potential of the OCS in improving clinical outcomes and increasing utilization of available donor organs.

The results of our clinical trials are summarized in the images below.





* Nicoara A., et al. Primary graft dysfunction after heart transplantation: Incidence, trends, and associated risk factors; Am J Transplant. 2018;18:1461–1470.

OCS Clinical Trial Overview Table

	OCS Lung		OCS Heart			OCS Liver
Trial Name	**INSPIRE**	**EXPAND Lung**	**PROCEED II**	**EXPAND Heart/CAP**	**DCD Heart/CAP**	**PROTECT/CAP**
Objective	Compare OCS to Cold Storage	Improve Utilization	Compare OCS to Cold Storage	Improve Utilization	Improve Utilization and Compare OCS to Cold Storage	Compare OCS to Cold Storage
Number of Patients	320	79	128	150	270	374
Summary Outcomes	Met primary effectiveness endpoint 50% Reduction in post-transplant complications Reduction of injurious ischemic time	Did not meet primary effictiveness endpoint Significant increase in utilization to 87% Good one year survival Reduction in PGD3	Met primary effectiveness endpoint Reduction of injurious ischemic time Post-hoc observational analysis, graft-related deaths were similar in both groups, overall deaths were higher in OCS Group	Met primary effectiveness endpoint Signficant increase in utilization to 81% Good one year survival 65% Lower incidence of PGD	Met primary effectiveness endpoint Significant increase in utilization to 89% Good 1 year survival (94%)	Met primary effectiveness endpoint 43% reduction in early allograft dysfunction 74% reduction of ischemic biliary complications at one year Utilization - 98% Good 1 year survival
Length of Follow-up Post-Transplantation	24 months	12 months	30 days	12 months	12 months	24 months
Number of Centers	21 U.S. and international	8 U.S. and international	10 U.S. and international	9 U.S.	25 U.S.	20 U.S.
Publication	Warnecke et al., Lancet Respiratory Medicine, April 2018	Loor et al., Lancet Respiratory Medicine, August 2019	Ardehali et al., The Lancet Journal, April 2015	Schroder et al., JACC: Heart Failure, January 2024	Schroder et al., NEJM, June 2023	Markmann et al., JAMA Surgery, January 2022

Next-Generation OCS Trials

In August 2025 and January 2026, we received FDA approval under Investigational Device Exemptions, or IDEs, to initiate multi-part, prospective clinical trials for next-generation versions of our OCS Heart and OCS Lung systems, respectively. The OCS Heart trial, referred to as the ENHANCE Heart trial, was initiated in the fourth quarter of 2025 and is designed to evaluate the performance of a next-generation OCS Heart platform under extended perfusion conditions and to further assess clinical outcomes relative to static cold storage in certain donor populations. The ENHANCE Heart trial is structured as a multi-center, two-part clinical study and is expected to enroll more than 650 heart transplant recipients across participating centers. Enrollment in the ENHANCE Heart trial is expected to occur over multiple years, with data available following the completion of each respective part of the trial.

The OCS Lung DENOVO trial is intended to evaluate the performance of the modified OCS Lung system and may allow for claims of superiority on the label compared to static cold storage. The DENOVO Lung trial is expected to enroll transplant recipients who meet protocol-defined eligibility criteria. Enrollment is expected to commence following site activation and regulatory readiness, with clinical data anticipated to become available on a staged basis during the enrollment and follow-up period.

These trials are intended to support potential future regulatory submissions for our next generation OCS Heart and Lung Systems, including PMA supplements, and may enable expanded indications for use of our OCS Heart system.

Intellectual Property

Patents and Trade Secrets

We rely on a combination of patent, trademark, copyright, trade secret and other intellectual property laws, nondisclosure and assignment of inventions agreements and other measures to protect our intellectual property. Our patent portfolio includes patents and patent applications that we own or license from third parties.

As of December 31, 2025, our owned and licensed patent portfolio consisted of approximately 451 issued patents and pending patent applications worldwide, including in the United States, Australia, Europe, Canada, China, Israel, New Zealand and Japan. Our owned portfolio includes patents and applications related to one or more of the OCS Lung, OCS Heart, OCS Liver and solutions. In the United States, our owned portfolio includes about 47 issued patents and 14 pending applications. Outside the United States, our owned portfolio includes about 331 issued patents and 57 pending applications. Issued patents in our portfolio are expected to expire between 2026 and 2043, excluding any potential additional patent term for patent term adjustments or patent term extensions, if applicable. If granted, the pending U.S. and foreign patent applications in our portfolio are expected to expire between 2026 and 2043, excluding any potential additional patent term for patent term adjustments or patent term extensions, if applicable.

As of December 31, 2025, our patent portfolio relating to the OCS Lung or lung transplantation technology includes families comprised of patents and patent applications with claims that are generally directed to certain methods and systems for preserving a lung ex vivo using both perfusion and ventilation. Such patents are issued in the United States, Austria, Australia, Belgium, Brazil, Canada, China, Czech Republic, Denmark, Europe, France, Germany, Ireland, Israel, Italy, Japan, Hong Kong, Netherlands, New Zealand, Spain, Sweden, and United Kingdom, and patent applications are pending in the United States, Australia, Canada, China, Europe, Hong Kong, Israel, Japan and under the Patent Cooperation Treaty. These patents, and any patents issued from pending patent applications, are expected to expire in 2043, excluding any potential additional patent term for patent term adjustments or patent term extensions, if applicable.

As of December 31, 2025, our patent portfolio relating to the OCS Heart or heart transplantation technology includes families comprised of patents and patent applications with claims that are generally directed to certain methods and systems for preserving a heart ex vivo. Such patents are issued in the United States, Austria, Australia, Belgium, Brazil, Canada, China, Czech Republic, Denmark, Europe, France, Germany, Hong Kong, Ireland, Israel, Italy, Japan, Netherlands, New Zealand, Spain, Sweden, and United Kingdom, and patent applications are pending in the United States, Australia, Brazil, Canada, China, Europe, Israel, Japan, and New Zealand. These patents, and any patents issued from pending patent applications, are expected to expire in 2039, excluding any potential additional patent term for patent term adjustments or patent term extensions, if applicable. Patent term extension for one patent relating to the OCS Heart, U.S. Patent No. 7,651,835, was granted on July 2, 2025, extending the patent term to expire on March 13, 2032.

As of December 31, 2025, our patent portfolio relating to the OCS Liver or liver transplantation technology includes a family of issued and pending patent applications with claims that are generally directed to certain systems, including perfusion circuits for perfusing a liver ex vivo. Such patents are issued in the United States, Austria, Australia, Belgium, Canada, China, Czech Republic, Denmark, Europe, France, Germany, Hong Kong, Ireland, Israel, Italy, Japan, Netherlands, New Zealand, Spain, Sweden, and United Kingdom, and applications are pending in the United States, Australia, Canada, Israel and Japan. This patent and any patents issued from pending patent applications are expected to expire in 2035, excluding any potential additional patent term for patent term adjustments or patent term extensions, if applicable. Patent term extension for one patent relating to the OCS Liver, U.S. Patent No. 10,076,112, was granted on June 24, 2025, extending the patent term to expire on September 28, 2035.

As of December 31, 2025, our patent portfolio relating to the OCS Solutions or other solutions for transplantation systems includes families comprised of patents and patent applications with claims that are generally directed to compositions of certain perfusion fluids. Such patents are issued in the United States, Austria, Australia, Belgium, Brazil, Canada, China, Czech Republic, Denmark, Europe, France, Germany, Hong Kong, Ireland, Israel, Italy, Japan, Netherlands, New Zealand, Spain, Sweden and United Kingdom, and patent applications are pending in the United States, Canada, China, Europe and Hong Kong. These patents, and any patents issued from pending patent applications, are expected to expire in 2035, excluding any potential additional patent term for patent term adjustments or patent term extensions, if applicable.

The term of individual patents depends on the legal term for patents in the countries in which they are granted. In most countries, including the United States, the patent term is generally 20 years from the earliest filing date of a non-provisional patent application in the applicable country. Patents may not be issued from any of our pending applications and, if patents are issued, they may not be of sufficient scope or strength to provide meaningful protection for our technology. Notwithstanding the scope of the patent protection available to us, a competitor could develop methods or devices that are not covered by our patents. Furthermore, numerous U.S. and foreign issued patents and patent applications owned by third parties exist in the fields in which we are developing products. Because patent applications can take many years to issue, there may be applications unknown to us, which applications may later result in issued patents that our existing or future products or proprietary technologies may be alleged to infringe.

There has been substantial litigation regarding patent and other intellectual property rights in the medical device industry. In the future, we may need to engage in litigation to enforce patents issued or licensed to us, to protect our trade secrets or know-how, to defend against claims of infringement of the rights of others or to determine the scope and validity of the proprietary rights of others. Litigation could be costly and could divert our attention from other functions and responsibilities. Adverse determinations in litigation could subject us to significant liabilities to third parties, could require us to seek licenses from third parties and could prevent us from manufacturing, selling or using the OCS, any of which could severely harm our business.

For more information, see “Item 1A. Risk Factors—Risks Related to Our Intellectual Property” in this Annual Report on Form 10-K.

Competition

Competition in organ preservation for transplantation can be classified into two main segments: (1) cold storage and cold perfusion technologies and (2) warm perfusion technologies. In both cold storage and cold perfusion, the organs are not functioning and are metabolically inactive. The characteristics of cold storage and cold perfusion described above significantly limit donor organ utilization and are a primary driver of post-transplant complications. Supply of cold storage and cold perfusion products is fragmented with a number of companies mainly providing undifferentiated flush and perfusion solutions or temperature controlled cold storage devices.

Warm perfusion preservation for solid organ transplant is an emerging alternative designed to address the limitations of cold storage and cold perfusion. In warm perfusion, the organs are functioning and metabolically active. We are aware of only two other companies providing warm perfusion systems, OrganOx Limited, which was acquired by Terumo Corporation in October 2025, and XVIVO Perfusion AB, both of which offer single-organ warm perfusion systems for the liver and lung, respectively. We also compete with other cold preservation devices in this industry, such as those from Paragonix Technologies, Inc., which was acquired by Getinge in September 2024.

We believe that our principal competitive factors include:

- strong clinical evidence from large trials demonstrating safety, effectiveness and clinical benefits;
- superior technology;
- our NOP, including clinical service and transplant logistics services;
- regulatory approvals for broad clinical indications of use;
- ease of integration into current organ procurement workflow, including system portability across all modes of transportation;
- platform capabilities designed to support multiple organ transplant programs;
- brand recognition among leading transplant programs worldwide;
- established clinical relationships and a core of committed clinical users;
- commercial reimbursement; and
- sophisticated clinical training and support program to users worldwide.

Research, Development and Clinical Trial Operations

Our research, development and clinical trial operations function is focused on developing the next generation and Gen-3 OCS, including development of OCS products for additional organs; improving incrementally the technology and manufacturing efficiency of our current platform; expanding the body of clinical evidence supporting the use of the OCS platform through pre-market clinical trials, post-market registries and scientific publications; developing applications to expand the access and use of the data generated from the OCS; and conducting research to investigate new clinical applications and uses for the OCS platform.

The function includes a dedicated clinical trial team that has trial management, data collection and biostatistics expertise. Additionally, our product engineering function consists of multi-disciplinary engineering teams that have electrical, mechanical, systems and software engineering expertise. Finally, our regulatory function includes a team with both U.S. and international medical device regulatory expertise and is supported by senior ex-FDA regulatory advisors and outside legal counsel. For the years ended December 31, 2025, 2024 and 2023 our research, development and clinical trials expenses were $69.1 million, $56.0 million and $36.1 million, respectively.

Manufacturing and Supply Chain Operations

We design and assemble our OCS Consoles and disposable OCS Perfusion Sets at our facility in Andover, Massachusetts. We utilize two assembly shifts and we have the ability to add additional shifts to the cleanroom to further increase production capacity. We manufacture our sterilized disposable OCS Perfusion Sets in an ISO class 7 cleanroom. We plan to move into our new corporate headquarters on or before January 1, 2028, and the new facility is expected to provide additional manufacturing and assembly space and infrastructure to support our operations over time. We may continue to utilize certain functions of our existing facility in connection with our operations. We believe the capacity of these facilities is sufficient to cover the next several years of forecasted demand. We rely on third parties to sterilize our products prior to sale.

We source many of the components for the OCS Console and OCS Perfusion Sets from third-party suppliers that are required to manufacture and test them according to our specifications. We purchase some of the components of the OCS Console and OCS Perfusion Set from single-source suppliers and, in a few cases, sole-source suppliers.

We source the OCS Solutions using our proprietary formulas from third-party suppliers. Fresenius is our single-source supplier of OCS Solutions for the OCS Lung and OCS Heart. Our agreement with Fresenius for the supply of OCS Lung Solution had an original term through April 2024 and was automatically extended for an extension term through April 2026. Upon expiration of the extension term, the agreement will continue to extend for subsequent periods of 24 months each, unless terminated by either party at least 12 months prior to the end of the then-current extension term. We may also terminate this agreement with 12 months' notice if we request that Fresenius qualifies a second manufacturing plant or qualifies a reputable third party to manufacture the OCS Lung Solution and Fresenius fails to respond to this request. Our agreement with Fresenius includes an obligation to meet certain annual minimum purchase commitments based upon rolling order forecasts that we provided to Fresenius in accordance with this agreement. Our agreement with Fresenius for the supply of OCS Heart Solution has one-year evergreen terms, terminable by either party at least 12 months prior to the end of the then-current term.

Our supply chain and operations team includes supply chain procurement and planning, production and test employees, sustaining engineers, manufacturing engineers and field service technicians.

Product Regulation

Our OCS products and our operations are subject to extensive regulation by the FDA and other federal and state authorities in the United States, as well as comparable international authorities including, but not limited to, those in the European Union.

Our products are subject to regulation as medical devices under the Federal Food, Drug and Cosmetic Act, or FDCA, as implemented and enforced by the FDA. The FDA regulates the development, design, non-clinical and clinical research, manufacturing, safety, effectiveness, labeling, packaging, storage, installation, servicing, recordkeeping, premarket clearance or approval, adverse event reporting, advertising, promotion, marketing and distribution, and import and export of medical devices to ensure that medical devices distributed domestically are safe and effective for their intended uses and otherwise meet the requirements of the FDCA.

In addition to U.S. regulations, we are subject to a variety of regulations in the European Union and other countries, governing medical devices, clinical investigations and commercial sales and distribution of our products. Regardless of whether we have or are required to obtain FDA clearance or approval for a product, we will be required to obtain the relevant authorizations/approvals before commencing clinical trials/investigations and to obtain the necessary authorizations, approvals or certifications of our products under the comparable regulatory authorities of countries outside of the United States before we can commence clinical trials/investigations or commercialize our products in those countries. In the European Union, the manufacturer of a medical device must affix a Conformité Européene mark, or CE mark, after the device in question has successfully passed a conformity assessment to establish its safety and device characteristics. The CE mark allows the device to be placed on the market anywhere in the EU and additional Member States of the European Economic Area, or EEA, (i.e., Norway, Lichtenstein and Iceland). The CE mark is also recognized in Turkey and, for a limited transitional period following the UK's withdrawal from the European Union, referred to as Brexit, in the United Kingdom.

The authorization/approval processes for devices outside the European Union will vary from country to country and the time may be longer or shorter than that required for FDA clearance or approval or CE marking.

FDA Premarket Clearance and Approval Requirements

Unless an exemption applies, each medical device commercially distributed in the United States requires either FDA clearance of a 510(k) premarket notification, approval of a PMA or issuance of a de novo classification order. Under the FDCA, medical devices are classified into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent and regulatory controls needed to ensure its safety and effectiveness. Class I includes devices with the lowest risk to the patient and/or the user and are those for which safety and effectiveness can be reasonably assured by adherence to the FDA's general controls for medical devices, which include compliance with the applicable portions of the Quality Management System Regulation, or QMSR (that recently replaced the Quality System Regulation (QSR), facility registration and product listing, reporting of adverse medical events and device malfunctions, and truthful and non-misleading labeling, advertising, and promotional materials. Class II devices are subject to the FDA's General Controls and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. These special controls can include performance standards, post-market surveillance, patient registries and FDA guidance documents. While most Class I devices are exempt from the 510(k) premarket notification requirement, manufacturers of most Class II devices are required to submit to the FDA a

premarket notification under Section 510(k) of the FDCA requesting a substantial equivalence determination that provides permission to commercially distribute the device. The FDA's permission to commercially distribute a device subject to a 510(k) premarket notification is generally known as 510(k) clearance. Under the 510(k) process, the manufacturer must submit to the FDA a premarket notification demonstrating that the device is "substantially equivalent" to either a device that was legally marketed prior to May 28, 1976, the date upon which the Medical Device Amendments of 1976 were enacted, or a device that was reclassified from Class III to Class II or I, or another commercially available device that was cleared through the 510(k) process or that was granted marketing authorization through the de novo classification process under section 513(f)(2) of the FDCA, or a 510(k) exempt device. We received 510(k) clearance for the OCS Lung Solution for cold flush, storage and transportation of donor lungs in July 2021, for the OCS Lung Donor Flush Set in November 2022, and for the OCS Heart Leukocyte Reducing Filter in October 2023.

Devices deemed by the FDA to pose the greatest risks, such as life-sustaining, life-supporting and many implantable devices, or devices that have been found not substantially equivalent to a legally marketed Class I or Class II predicate device, are placed in Class III, requiring approval of a PMA.

Each of our OCS warm perfusion products is a Class III device. We have received a PMA for each of the following:

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

PMA Pathway

Class III devices require an approved PMA before they can be marketed. The PMA process is more demanding than the 510(k) premarket notification process. In a PMA, the manufacturer must demonstrate that the device is safe and effective, and the PMA must be supported by extensive data, including data from preclinical studies and human clinical trials. The PMA must also contain a full description of the device and its components, a full description of the methods, facilities and controls used for manufacturing, and proposed labeling. If the FDA accepts the application for review, it has 180 days under the FDCA to complete its review of a PMA, although in practice, the FDA's review generally takes one year, or even longer, from the time the PMA application is submitted to the FDA until an approval is obtained. An advisory committee of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may not accept the panel's recommendation. In addition, the FDA will generally conduct a preapproval inspection of the applicant or its third-party manufacturers' manufacturing facility or facilities to ensure compliance with the QMSR and, in some cases, will audit the applicant and clinical sites as part of its Bioresearch Monitoring program.

During the PMA review, the FDA assesses whether the data and information in the PMA constitute valid scientific evidence to support a determination that there is a reasonable assurance that the device is safe and effective for its intended use(s) based on the proposed labeling. The FDA may approve a PMA with post-approval conditions intended to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution, and collection of long-term follow-up data from patients in the clinical study that supported a PMA or requirements to conduct additional clinical studies post-approval. The FDA may condition a PMA approval on some form of post-market surveillance when deemed necessary to protect the public health or to provide additional safety and effectiveness data for the device in a larger population or for a longer period of use. Failure to comply with the conditions of approval can result in material adverse enforcement action, including withdrawal of the approval. Certain changes to an approved device, such as changes in manufacturing facilities, methods, or quality control procedures, or changes in the design or performance specifications, which affect the safety or effectiveness of the device, require submission and approval of a PMA supplement. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may not require as extensive clinical data or the convening of an advisory committee. Certain other changes to an approved device require the submission and approval of a new PMA, such as when the design change causes a different intended use, mode of operation, and technical basis of operation, or when the design change is so significant that a new generation of the

device will be developed, and the data that were submitted with the original PMA are not applicable for the change in demonstrating a reasonable assurance of safety and effectiveness.

Clinical Trials

Clinical trials are almost always required to support a PMA application and may be necessary to support PMA supplements for additional indications or modified versions of a marketed device product. All clinical investigations of investigational devices to determine safety and effectiveness must be conducted in accordance with the FDA's IDE regulations that govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of study review and approval, informed consent, recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a "significant risk" to human health, as defined by the FDA, the FDA requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical trials. To be approved, an IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. If the FDA determines that there are deficiencies or other concerns with an IDE for which it requires modification, the FDA may permit a clinical trial to proceed under a conditional approval. Acceptance of an IDE application for review does not guarantee that the FDA will allow the IDE to become effective and, if it does become effective, the FDA may or may not determine that the data derived from the trials support the safety and effectiveness of the device to support marketing approval or clearance, or to warrant the continuation of clinical trials. An IDE supplement must be submitted to, and approved by, the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study plan or the rights, safety or welfare of human subjects. Non-significant risk device studies do not require submission of an IDE application to FDA.

In the United States, the study must be approved by, and conducted under the oversight of, an Institutional Review Board, or IRB. The IRB is responsible for the initial and continuing review of the study and may pose additional requirements for the conduct of the study.

During a study, the sponsor is required to comply with the applicable FDA requirements, including, for example, trial monitoring, selecting clinical investigators and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims for them. After a trial begins, we, the FDA or the IRB could suspend or terminate a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits or protocol violations.

Post-market Regulation

After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include:

- establishment registration and device listing with the FDA;
- QMSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling and marketing regulations, which require that promotion is truthful, not misleading, fairly balanced and provide adequate directions for use and that all claims are substantiated, and also prohibit the promotion of products for unapproved or "off-label" uses and impose other restrictions on labeling;
- approval of a PMA supplement for certain modifications to PMA-approved devices that affect the safety or effectiveness of the device, or clearance of a new 510(k) premarket notification for modifications to 510(k) cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of the device;
- medical device reporting regulations, which require that a manufacturer report to the FDA information that reasonably suggests a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;
- correction and removal reporting regulations, which require that manufacturers report to the FDA field corrections and product removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;

- complying with the federal law and regulations requiring Unique Device Identifiers on devices and also requiring the submission of certain information about each device to the FDA's Global Unique Device Identification Database;
- the FDA's recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations if the FDA finds that there is a reasonable probability that the device would cause serious, adverse health consequences or death; and
- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device.

Our manufacturing processes are required to comply with the applicable portions of the QMSR, which cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices intended for human use. The QMSR also requires, among other things, maintenance of records and documentation to meet the requirements of the QMSR. The QMSR recently replaced the QSR to harmonize and modernize the regulatory requirements for devices in the U.S. with those used by regulatory authorities in other jurisdictions, primarily through incorporating by reference the international standard specific for medical device quality management systems set by the International Organization for Standardization ISO 13485:2016.

As a manufacturer, our facilities, records and manufacturing processes are subject to periodic scheduled or unscheduled inspections by the FDA. Our failure to maintain compliance with the QMSR or other applicable regulatory requirements could result in the shutdown of, or restrictions on, our manufacturing operations and the recall or seizure of our products. The discovery of previously unknown problems with any of our products, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or off-label by a physician in the practice of medicine, could result in restrictions on the device, including the removal of the product from the market or voluntary or mandatory device recalls.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that we failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, which may result in any of the following sanctions:

- warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;
- recalls, withdrawals, or administrative detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for approvals of PMAs of new products or modified products;
- withdrawing a PMA approval that has already been granted;
- refusal to grant export permits or certificates for our products; or
- criminal prosecution.

Regulation of Medical Devices in the European Union

In the European Union, our products are regulated as medical devices. Regulation of medical devices in the European Union is harmonized through Regulation (EU) 2017/745, or the MDR, which repealed and replaced Directive 93/42/EEC on medical devices, or the MDD, with effect from May 26, 2021.

The national competent authorities in each member state oversee and enforce compliance with the standards set out in the MDR against relevant economic operators (including device manufacturers, importers, authorized representatives and distributors). Under the MDR, national competent authorities can inform other national competent authorities, the European Commission and Notified Bodies, as applicable, of certain non-compliances.

Under the MDR, a medical device placed on the market in the European Union must meet the applicable General Safety and Performance Requirements, or GSPRs, laid down in Annex I of the MDR. Similar to the U.S. system, medical devices are classified into one of four classes based on risk: I, IIa, IIb and III, with class I representing the lowest risk products and class III the highest risk products. One of the most fundamental GSPRs is that a medical device must be designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients, or the safety and health of users and others (provided that any risks posed are acceptable when weighted against the benefits). In addition, the GSPRs include (but are not limited to) that the device must achieve the performances intended by the manufacturer, be designed, manufactured and packaged in a suitable manner and the manufacturer must establish, implement, document and maintain a risk management plan. The European Commission has adopted various standards applicable to medical devices, referred to as harmonized standards. While not mandatory, compliance with these harmonized standards is often viewed as the easiest way to satisfy the GSPRs as a practical matter. Compliance with a harmonized standard developed to implement a GSPR also creates a rebuttable presumption that the device satisfies that essential requirement. To date, the European Commission has harmonized certain standards, including, for example, standards of sterilization, biological evaluation, the quality management system, *etc.* but will continue to harmonize more standards going forward.

To demonstrate compliance with the GSPRs, medical device manufacturers must undergo a conformity assessment procedure, the specifics of which vary according to the type of medical device and its classification. Conformity assessment procedures involve an assessment of available clinical evidence, literature data for the product and post-market experience in respect of similar products already marketed.

For all medical devices other than low risk devices (*i.e.*, Class I non-sterile, non-measuring devices), a conformity assessment procedure requires the intervention of a notified body. Notified bodies are independent organizations which audit and examine a product’s technical dossier and the manufacturer's quality system. If satisfied that the relevant medical device conforms to the relevant GSPRs, the notified body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then affix the CE mark to the device, which allows the device to be placed on the market throughout the European Union (and by extension the European Economic Area). Once the device has been placed on the market in the European Union, the manufacturer must comply with requirements for reporting incidents and field safety corrective actions associated with its use. The notified body has ongoing audit rights and must be notified of all significant changes to the device.

All of our medical devices that were previously certified under the MDD, including OCS Heart, OCS Lung, and OCS Liver systems, which includes the OCS Console, the OCS disposables, and the OCS solution additives, have been recertified under the MDR.

Clinical Investigations

Clinical evidence is required for the conformity assessment of most medium and high risk devices. In some cases, a clinical investigation may be required to support the CE marking of a device. All clinical investigations involving medical devices must comply with the relevant requirements of the MDR, EU member state requirements, and current good clinical practices defined in harmonized standards and guidance documents. Clinical investigations for medical devices cannot proceed without a positive opinion of an ethics committee and notification to the relevant national competent authorities. Both national competent authorities and ethics committees also require the submission of serious adverse event reports during a study and may request a copy of the final study report.

Post-marketing Requirements

In the European Union, we are currently required to comply with strict post-marketing obligations. These include obligations to have in place quality management, post-market surveillance and vigilance systems. These requirements include that the manufacturer must report to the relevant national competent authorities (a) any serious incident involving devices made available on the EU market and (b) any field safety corrective action (i) in respect of devices made available on the EU market or (ii) undertaken in a third country in relation to a device made available on the EU market if the reason for such action is not limited to the device made available in the third country. Additionally, the manufacturer of high risk devices must submit periodic safety update reports to its notified body and manufacturers of lower risk devices must maintain periodic safety update reports as part of the technical documentation for their products.

National competent authorities in the European Union also closely monitor the marketing programs implemented by device companies. The MDR prohibits making misleading claims, including promoting the product for or suggesting a use that is not part of its intended purpose. However, the obligations that companies must fulfill concerning premarketing approval of promotional material vary among member states of the European Union as beyond that requirement, advertising and promotion law for medical devices is not harmonized in the European Union.

Regulations Applicable to Transport of Organs Intended for Transplantation

In the European Union, Directive 2010/53/EU sets out certain standards which the EU member states should apply in respect of procurement, preservation and transport of organs intended for transplantation. While we are not directly affected by this directive, our EU customers are, and our products may either help or impede their compliance with this Directive.

Regulation of Medical Devices in the United Kingdom

The Medicines and Healthcare products Regulatory Agency, or the MHRA, is responsible for regulating the UK medical devices market. The MHRA performs market surveillance of medical devices on the UK market and is able to take decisions over the marketing and supply of devices in the UK. The MHRA is also responsible for the designation and monitoring of UK approved bodies (the equivalent of EU notified bodies).

Since May 26, 2021, the MDR has applied throughout the EU and Northern Ireland. As the MDR took effect after the UK left the European Union, it was not retained in UK law and therefore does not apply in Great Britain (England, Wales and Scotland). It applies in Northern Ireland under the terms of the Northern Ireland Protocol.

In the United Kingdom medical devices are regulated under the Medical Devices Regulations 2002 (SI 2002 No 618, as amended), or the UK MDR, which give effect to the MDD and associated EU legislation which has since been repealed and replaced in the European Union by the MDR.

This means that the route to market of medical devices in Great Britain is based on the requirements derived from pre-existing directly applicable EU legislation prior to the UK's exit from the EU. Despite the MDR not applying in Great Britain, the UK MDR provides a transitional period that allows manufacturers to place devices CE marked under the MDR on the market in Great Britain potentially up until June 30, 2030.

Since January 1, 2021 (when the Brexit transition period ended), there have been a number of changes, introduced to the UK MDRs, which regulate how medical devices are placed on the market in Great Britain. These include:

- a Great Britain-specific pathway to market which involves product marking with the UKCA mark, potentially involving a UK Approved Body, depending on the class of device;
- an obligation to register all medical devices, including in vitro diagnostic medical devices, or IVDs, custom-made devices and systems or procedure packs, with the MHRA before they are placed on the Great Britain market; and
- an obligation on medical device manufacturers based outside the UK who wish to place a device on the Great Britain market to appoint a single UK Responsible Person for all devices who will act on their behalf to carry out specified tasks, such as registration. We have appointed a UK Responsible Person for our devices in the UK.

The UK Government recently adopted new post-market surveillance legislation (through amendments to the UK MDR) and plans to adopt further changes to pre-market medical device regulation in 2026. The UK Government also plans to consult on the indefinite recognition of the CE mark for medical devices placed on the market in Great Britain.

Clinical Investigations

In order to demonstrate compliance with the essential requirements of the UK MDR and the GSPRs of the MDR, and in order to justify the application of UKCA/CE/CE UKNI marking, it will sometimes be necessary for the manufacturer of the device to provide clinical data with which to substantiate claims made for that device. This may involve the need for a specifically designed clinical investigation to:

- verify that under normal conditions of use the performance characteristics of the device are those intended by the manufacturer; and
- determine any undesirable side-effects and to assess whether these are acceptable risks when weighed against the intended performance of the device.

If such an investigation is necessary, and will be conducted in the UK, the manufacturer must submit a notification to the MHRA before the investigation is due to begin, and such a clinical investigation may only proceed provided no grounds for objection are raised by the MHRA within the statutory review time constraint. The manufacturer must also obtain ethics committee approval for the investigation.

Post-marketing Requirements

Once a medical device has been placed on the UK market, the manufacturer is required to submit vigilance reports to the MHRA when certain incidents occur in the UK that involve their device. They must also take appropriate safety action when required. The manufacturer must also ensure their device meets appropriate standards of safety and performance for as long as it is in use. The advertising and marketing of medical devices is governed in the UK primarily by self-regulatory codes of practice.

The MHRA Enforcement of Medical Device Regulations in the UK

To ensure that medical devices placed on the market and put into service in the UK meet applicable regulatory requirements the MHRA will:

- conduct risk-based assessments of all allegations of non-compliance brought to their attention;
- monitor the activity of UK Approved Bodies designated by MHRA to assess the compliance of manufacturers; and
- investigate medical devices as a result of adverse incident reports or intelligence indicating a potential problem.

If the MHRA considers that a person or company has committed a serious offense by failing to comply with applicable regulations or the conditions of a notice issued then a person/company may be subject to prosecution.

UK Regulations Applicable to Organs Intended for Transplantation

The standards for the quality and safety of organs for transplantation has been enacted into UK law through The Quality and Safety of Organs Intended for Transplantation Regulations 2012, as amended. This Regulation provided for the establishment of a competent authority for the regulation of organ transplantation, the Human Tissue Authority, or the HTA. The HTA has published the "The Quality and Safety of Organs Intended for Transplantation: a documentary framework" which details mandatory requirements as well as guidance on how those requirements may be met. While we are not directly affected by this regulation and guideline, our UK customers are, and our products may either help or impede their compliance with this regulation.

Regulation in Other Countries

We are subject to regulations and product registration requirements in many foreign countries in which we may sell our products, including in the areas of:

- design, development, manufacturing and testing (including with respect to significant changes to the products);
- product standards;
- product safety;
- product safety reporting;
- marketing, sales and distribution;
- packaging and storage requirements;
- labeling requirements;
- content and language of instructions for use;
- clinical trials/investigations;
- record keeping procedures;
- advertising and promotion;
- recalls and field corrective actions;

- post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury;
- import and export restrictions;
- tariff regulations, duties and tax requirements;
- registration for reimbursement, agreement of prices with government; and
- necessity of testing performed in country by distributors for licensees.

The time required to obtain marketing authorization in foreign countries may be longer or shorter than that for FDA approval or clearance, and requirements for licensing a product in a foreign country may differ significantly from FDA requirements. 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.

Adverse events and potential adverse events are monitored closely by regulatory authorities. For example, if, as a result of manufacturing error, the efficacy of our products does not meet the standards claimed in the accompanying instructions for use, regulatory authorities could prevent our products from being placed on the market.

Internationally, the regulatory requirements relating to product defects may vary. A regulatory authority in a specific country may request or require a product recall while others may not.

Federal, State and Foreign Fraud and Abuse and Physician Payment Transparency Laws

In addition to FDA restrictions on marketing and promotion of drugs and devices, other federal, state, international laws, as well as laws with extra-territorial effect and market practices restrict our business practices. These laws include, without limitation, U.S. and foreign laws intended to prohibit or otherwise regulate activities that might result in fraud, abuse and bribery.

U.S. Laws

U.S. federal healthcare fraud and abuse laws generally apply to our activities because our products are covered under federal healthcare programs such as Medicare and Medicaid. The principal U.S. federal healthcare fraud and abuse laws applicable to us and our activities include: (1) the Anti-Kickback Statute, which prohibits the knowing and willful offer, solicitation, payment or receipt of anything of value in order to generate business reimbursable by a federal healthcare program; (2) the False Claims Act, which prohibits the submission of false or otherwise improper claims for payment to a federally-funded healthcare program, including claims resulting from a violation of the Anti-Kickback Statute; and (3) healthcare fraud statutes that prohibit false statements and improper claims to any third-party payor. There are also similar state anti-kickback and false claims laws that apply to activities involving state-funded Medicaid and other healthcare programs as well as to private third-party payers.

The Anti-Kickback Statute is particularly relevant because of its broad applicability. Specifically, the Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving, or providing remuneration, directly or indirectly, in exchange for, or to induce, either the referral of an individual, or the furnishing, arranging for or recommending a good or service for which payment may be made in whole or part under federal healthcare programs, such as the Medicare and Medicaid programs. Almost any financial interaction with a healthcare provider, patient or customer will implicate the Anti-Kickback Statute. Statutory exceptions and regulatory safe harbors protect certain interactions if specific requirements are met. Only those interactions that represent fair market value exchanges, however, are generally protected by an exception or safe harbor. The government can exercise enforcement discretion in taking action against unprotected activities. Many interactions in which we commonly engage, such as the provision of business courtesies to healthcare practitioners, could implicate the Anti-Kickback Statute and may not be protected by an exception or safe harbor. If the government determines that these activities are abusive, we could be subject to enforcement action. Penalties for Anti-Kickback Statute violations may include both criminal penalties such as imprisonment and civil sanctions such as fines and possible exclusion from Medicare, Medicaid, and other federal healthcare programs. Exclusion would mean that our products were no longer eligible for reimbursement under federal healthcare programs.

Laws and regulations have also been enacted by the federal government and various states to regulate the sales and marketing practices of medical device and pharmaceutical manufacturers. The laws and regulations generally limit financial interactions between manufacturers and healthcare providers; require pharmaceutical and medical device companies to comply with voluntary compliance standards issued by industry associations and the relevant compliance guidance promulgated by the U.S. federal government; and/or require disclosure to the government and/or public of financial interactions, so-called “sunshine laws”.

The healthcare laws and regulations applicable to us, including those described above, contain ambiguous requirements and are subject to evolving interpretations and enforcement discretion. Manufacturers must adopt reasonable interpretations of requirements if there is ambiguity and those interpretations could be challenged. If a governmental authority were to conclude that we are not in compliance with applicable laws and regulations, we and our officers and employees could be subject to severe criminal and civil financial penalties, including, for example, exclusion from participation as a supplier of product to beneficiaries covered by Medicare or Medicaid. Any failure to comply with laws and regulations relating to reimbursement and healthcare goods and services could adversely affect our reputation, business, financial condition and cash flows.

International Laws

Many foreign countries have similar laws relating to healthcare fraud and abuse. Foreign laws and regulations may vary greatly from country to country. For example, the advertising and promotion of our products is subject to EU Directives concerning misleading and comparative advertising and unfair commercial practices, as well as other EU member state legislation governing the advertising and promotion of medical devices. Sometimes the relevant rules are found in industry guidance rather than legislation—for example, relationships with healthcare professionals in the UK are governed by the code of Association of British HealthTech Industries, or ABHI, and rules may limit or restrict the advertising and promotion of our products to the general public and impose limitations on our promotional activities with healthcare professionals.

In the European Union the consequences for failing to comply with advertising and promotional laws might lead to reputational damage, fines, exclusions from public tenders and actions for damages from competitors for unfair competition.

Laws with Extra-territorial Effect

Many countries in which we operate have laws with extra-territorial effect—those laws apply to our operations outside the relevant country, to the extent they are breached. Examples of such laws include the Foreign Corrupt Practices Act, or the FCPA, the UK Bribery Act of 2010, or the Bribery Act, and the General Data Protection Regulation, or the GDPR.

The extra-territorial effect of those laws affects our sales and marketing strategy, since in many countries healthcare professionals are officers of the state. This is particularly important in the context of bribery offenses, which in the UK and in the United States include the offense of bribing a foreign public official.

Data Privacy and Security Laws

We are, and in the future may become, subject to various U.S. federal and state as well as foreign laws that protect the confidentiality of certain patient health information, including patient medical records, and restrict the use and disclosure of patient health information by healthcare providers.

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, governs the conduct of certain electronic healthcare transactions and requires certain entities, called covered entities, to handle and protect, among other things, the privacy and security of protected health information, or PHI, in certain ways. HIPAA also requires business associates to enter into business associate agreements with covered entities and to safeguard a covered entity's PHI against improper use and disclosure.

HIPAA privacy regulations cover the use and disclosure of PHI by covered entities as well as business associates, which are defined to include subcontractors that create, receive, maintain, or transmit PHI on behalf of a business associate. These regulations also set forth certain rights that an individual may have with respect to his or her PHI maintained by a covered entity, including the right to access or amend certain records containing PHI, or to request restrictions on the use or disclosure of PHI. HIPAA security regulations set forth requirements for safeguarding the confidentiality, integrity, and availability of protected health information that is electronically transmitted or electronically stored. The Health Information Technology for Economic and Clinical Health Act, among other things, provides certain health information security breach notification requirements. Under these laws, the covered entity must notify any individual whose PHI is breached as required under the breach notification rule. Although we believe that we currently are neither a "covered entity" nor a "business associate" directly under HIPAA, a business associate relationship may be imputed from facts and circumstances even in the absence of an actual business associate agreement. In addition, HIPAA may affect our interactions with customers who are covered entities or their business associates.

The HIPAA privacy and security regulations establish a uniform federal “floor” and do not supersede state laws that are more stringent or provide individuals with greater rights with respect to the privacy or security of, and access to, their health and other personal information. States are increasingly regulating the privacy and security of individually identifiable information, including financial information and health information. For example, the California Consumer Privacy Act, or CCPA, gives California residents certain rights, including the right to ask covered companies to disclose the types of personal information collected and delete a consumer’s personal information, and imposes several obligations on covered companies to provide notice to California consumers regarding their data processing activities and limitations on covered companies’ ability to sell personal information. These protections have been expanded by California Privacy Rights Act of 2020, or CPRA, along with new privacy laws in Virginia, Colorado and several other states. We expect additional federal and state legislative and regulatory efforts to regulate consumer privacy in the future. Some states have also passed further protections focused on data protection for health information, including the Washington My Health My Data Act.

In the EEA, as well as in the United Kingdom, or the UK, -post-Brexit, we may be subject to laws relating to our collection, control, processing and other use of personal data, such as data relating to an identified or identifiable living individual. Following Brexit, the UK has substantively retained the same privacy rules as it had when a member of the European Union. We process personal data in relation to our operations. We process data of both our employees and our customers, including health and medical information. The data privacy regime in the EEA includes the GDPR, regarding the processing of personal data and the free movement of such data, which became applicable on May 25, 2018, the E-Privacy Directive 2002/58/EC and national laws implementing or supplementing each of them. Each EU member state has transposed the requirements laid down by the E-Privacy Directive into its own national data privacy regime and therefore the laws may differ by jurisdiction, sometimes significantly. The GDPR was retained post-Brexit in the UK as the UK GDPR. In addition, many EEA member states have passed legislation addressing areas where the GDPR permits member states to derogate from the regulation’s requirements, thus leading to divergent requirements between member states in spite of the GDPR’s stated goal of creating a uniform privacy law for the entire EEA. The UK has done the same. We need to ensure compliance with the rules in each jurisdiction where we are established. Even if not established in the EEA (or the UK), we may otherwise be subject to local privacy laws in those regions. For example, we may be subject to the GDPR (or UK GDPR) even when processing personal data in connection with offering goods or services to persons located in the EEA (or UK) or monitoring the behavior of persons located in the EEA (or UK).

GDPR requirements include that personal data may only be collected for specified, explicit and legitimate purposes based on a certain legal bases set forth in GDPR, and may only be processed in a manner consistent with those purposes. Processing of personal data also needs to be adequate, relevant, not excessive in relation to the purposes for which it is collected and secure. Personal data must not be kept for longer than necessary for the purposes of collection. To the extent that we process, control or otherwise use sensitive data relating to living individuals (for example, patients’ health or medical information, or genetic data or biometric data used for identification purposes, and other types of "special category data" listed in GDPR), more stringent rules may apply, limiting the circumstances and the manner in which we are legally permitted to process that data and transfer that data outside of the EEA (UK). In particular, in order to process such data, explicit consent to the processing (including any cross-border transfer) may be required from the data subject (being the person to whom the personal data relates), though in certain cases, and depending on the jurisdiction in which the data originate or are processed, such data may be processed absent explicit consent for purposes of medical diagnosis, public interest in the area of public health (including the safety and efficacy of medical devices) or scientific research. The same rules apply to us in the UK under the UK GDPR.

The GDPR and UK GDPR also impose potentially onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and privacy policies/notices. They require data controllers to be transparent and disclose to data subjects in privacy notices (in a concise, intelligible and easily accessible form but at the same time at a sufficiently granular level) how their personal information is to be used, impose limitations on retention of information, encourage the use of pseudonymization techniques (i.e., key-coded) data, introduces mandatory data breach notification requirements and sets higher standards for data controllers to demonstrate that they have obtained valid consent for certain data processing activities. Fines for non-compliance with the GDPR and the UK GDPR may be significant. The GDPR provides that EEA member states may introduce further conditions, including limitations, to the processing of genetic, biometric or health data (and other special category data), which could limit our ability to collect, use and share personal data, or could cause our compliance costs to increase, ultimately having an adverse impact on our business.

EU GDPR (or UK GDPR) protected data must not be transferred outside of the EEA or UK, respectively, to a non-adequate country (i.e. a country that has not been recognized by the European Commission (in respect of the EU GDPR protected data) or the Secretary of State (in respect of the UK GDPR protected data) as providing an adequate level of protection for the transferred data), unless certain steps are taken to ensure an adequate level of protection. In practice, these extra steps would normally mean (i) entering into EU Standard Contractual Clauses (or, in case of the UK personal data, the UK Addendum to EU Standard Contractual Clauses or, alternatively, the IDTA i.e. the ICO's International Data Transfer Agreement) or putting in place another data transfer mechanism, (ii) carrying out a transfer impact assessment and where necessary to protect the data, implementing supplementary measures. There are exemptions to these data transfer restrictions but these are interpreted narrowly.

The July 2020 invalidation by the Court of Justice of the European Union of the EU-U.S. Privacy Shield framework, one of the mechanisms used to legitimize the transfer of personal data from the EEA (and, post-Brexit, the UK to the U.S., has led to increased scrutiny on data transfers from the EEA (and UK) to the U.S. generally and may increase our costs of compliance with data privacy legislation due to the requirement to enter into EU Standard Contractual Clauses (or, in case of the UK personal data, the UK Addendum to EU Standard Contractual Clauses or the IDTA) and further extra steps set out above. In July 2023, the European Commission announced that it had adopted its adequacy decision on the EU-US transfers of personal data - the new Data Privacy Framework, or EU-US DPF, which became effective in July 2023. Under the EU-US DPF, it is possible to transfer EEA personal data freely to the US recipient that has self-certified under the EU-US DPF regime, although this may be challenged in the European Union Court of Justice by EU based privacy advocates.

We are subject to the supervision of local data protection authorities in those jurisdictions where we are established or otherwise subject to applicable law.

We depend on third parties in relation to provision of our services, a number of which process personal data on our behalf. With such providers we are legally required to enter into contractual arrangements which contain the minimum terms set out in the GDPR (and the UK GDPR), including to ensure that they process personal data only according to our instructions, and that they have adequate technical and organizational security measures in place. Where personal data is being transferred outside the EEA (or the UK), it must be done in compliance with applicable data export requirements. Any failure by us or third parties to comply with applicable data laws, could lead to a security or privacy breach, regulatory enforcement, or regulatory, reputational or financial harm.

U.S. Healthcare Reform

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. Additional healthcare reform efforts have sought to address certain issues related to the COVID-19 pandemic. Current and future legislative proposals to further reform healthcare or reduce healthcare costs may limit coverage of or lower reimbursement for the procedures associated with the use of our products. The cost containment measures that payors and providers are instituting and the effect of any healthcare reform initiative implemented in the future could impact our revenue from the sale of our products.

We expect additional state and federal healthcare reform measures to be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure. We cannot, however, predict the ultimate content, timing or effect of any healthcare reform legislation or action, or its impact on us, and healthcare reform could increase compliance costs and may adversely affect our future business, operations and financial results.

Human Capital Management

Our human capital strategy is comprehensive and leverages our work practices and collaborative culture. As of December 31, 2025, we employed 898 people globally, most of whom were full-time and located in the United States.

Our Culture

We strive to foster a global, engaging, and safe work environment where employees want to grow their careers. Our workforce consists of individuals from countries all over the world, representing many different faiths, languages, backgrounds, and cultures. We want our employees to feel welcome and comfortable in our organization and feel that they are supported in growing their career. We promote understanding of our mission, vision, and values and create strong relationships with our employees through various engagement and career development initiatives. For example, we hold quarterly Town Hall meetings

with all employees to provide them with an open forum to ask questions, voice any concerns, and provide input on our corporate goals and vision for the future.

We have adopted policies to promote compliance with laws and regulations as well as to foster a respectful workplace for all employees. These policies include a code of business conduct and ethics, an insider trading policy, a Regulation FD policy, a sexual harassment policy, a regulated fraternization policy, and a whistleblower policy. Along with an overview of the company, our culture and expectations, training on these policies is a key component of our employee onboarding process.

Health and Safety: We are committed to maintaining compliance with laws and regulations surrounding the health and safety of our employees and strive to follow best practices in our operations. We require relevant employees to complete workplace safety training before performing any job duties that entail potential health hazards, such as trainings for employees who handle hazardous chemicals and biohazardous materials.

Talent Attraction, Retention, and Development

We seek exceptionally talented and dedicated people to join our team to help shape both our future and the future of transplant medicine. The focus of our recruitment efforts has been centered on finding talent for the NOP, our engineering, manufacturing, and supply chain operations, and in the field of logistics and aviation, including logistics coordinators, pilots and aviation mechanics. We aim to hire people with the right skill sets, growth mindset, and work ethic to drive business results and help us achieve our goals. We provide relocation benefits to eligible employees whom we request to move in connection with their employment with the objective of attracting and deploying top talent.

Compensation and Benefits: We offer competitive compensation and benefits in an exciting, demanding, and fast-paced work environment. We provide employee benefits to eligible employees to promote personal health and well-being and to provide certain financial security and protection upon retirement or in the event of death, disability or illness.

Career Development: We are proud to have a work environment that promotes continued development for our employees. Employees are provided with formal written feedback, at least annually, and together with their manager, develop individual goals that are derived from our overall corporate and financial goals. Moreover, we collaborate with our employees to provide customized career development plans as well as general and targeted training curricula based on their roles.

Corporate Information and Organizational Transactions

TransMedics Group, Inc., was incorporated in the Commonwealth of Massachusetts in October 2018 to facilitate our initial public offering, or IPO. TransMedics, Inc., an operating company and wholly-owned subsidiary of TransMedics Group, Inc., was incorporated in the State of Delaware in August 1998. Our principal executive offices are located at 200 Minuteman Road, Andover, Massachusetts 01810, and our telephone number at that address is (978) 552-0900.

Available Information

Our Internet address is www.transmedics.com. Our website and the information contained on, or that can be accessed through, the website will not be deemed to be incorporated by reference in, and are not considered part of, this Annual Report on Form 10-K. Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, including exhibits, proxy and information statements and amendments to those reports filed or furnished pursuant to Sections 13(a), 14, and 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, are available through the "Investors" portion of our website free of charge as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. In addition, our filings with the SEC may be accessed through the SEC's Electronic Data Gathering, Analysis and Retrieval system at *http://www.sec.gov*. All statements made in any of our securities filings, including all forward-looking statements or information, are made as of the date of the document in which the statement is included, and we do not assume or undertake any obligation to update any of those statements or documents unless we are required to do so by law.

Item 1A. Risk Factors.

An investment in our common stock involves risks. The following risks and all of the other information contained in this Annual Report on Form 10-K should be considered carefully before investing in our common stock. The risks described below are those that we believe are the material risks that we face. If any of the following risks actually occurs, our business, prospects, operating results and financial condition could suffer materially, the trading price of our common stock could decline and investors could lose all or part of their investment. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may also adversely affect our business. See "Forward-Looking Statements" in this Annual Report on Form 10-K.

Risks Related to Our Financial Position and Need for Additional Capital

Our financial results may fluctuate from quarter to quarter, which makes our results difficult to predict and may cause our results to fall short of expectations.

Our financial results may fluctuate from quarter to quarter due to a number of factors, including the availability of donor organs for transplantation and transplant center surgeons, which is unpredictable and could impact the volume of transplant procedures performed at transplant centers using the OCS and demand for our NOP. Our revenue from sales may fluctuate significantly from quarter to quarter, and our future quarterly and annual expenses as a percentage of our revenue may be significantly different from those we have recorded in the past. In addition, we intend to opportunistically evaluate acquisitions of additional aircraft for our aviation transportation services, for which the timing is uncertain and the amount we incur for such acquisitions is likely to differ from quarter to quarter. Our financial results in some quarters may fall below expectations. Comparing our financial results on a period-to-period basis may not be meaningful, and past results may not be an indication of our future performance.

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

As of December 31, 2025, our outstanding principal balance of long-term debt under our credit agreement with Canadian Imperial Bank of Commerce, or CIBC, was $60.0 million, which we refer to as the CIBC Credit Agreement. Our payment obligations under the CIBC Credit Agreement reduce cash available to fund working capital, capital expenditures, research and development and general corporate needs. In addition, indebtedness under the CIBC Credit Agreement bears interest at a variable rate, making us vulnerable to increases in market interest rates. If market rates increase substantially, we will have to pay additional interest on this indebtedness, which would further reduce cash available for our other business needs. We may not have sufficient funds, and may be unable to arrange for additional financing, to pay the amounts due under or refinance our indebtedness under the CIBC Credit Agreement, which is repayable in equal monthly installments starting in July 2026 and a final payment due at maturity in July 2027.

Our obligations under the CIBC Credit Agreement are secured by substantially all of our assets and the assets of our wholly-owned material subsidiaries, subject to certain exceptions. The security interest granted over our assets could limit our ability to obtain additional debt financing. In addition, the CIBC Credit Agreement contains covenants requiring certain financial performance metrics that restrict our activities, including (x) a requirement to maintain a minimum liquidity amount of the greater of either (i) the consolidated adjusted EBITDA loss (or gain) for the trailing four month period (only if EBITDA is negative) and (ii) $10.0 million, and (y) a requirement to maintain total net revenue of at least 75% of the level set forth in the total revenue plan presented to CIBC. Failure to comply with the covenants in the CIBC Credit Agreement, including the financial covenants, could result in the acceleration of our obligations under the CIBC Credit Agreement, which are also subject to acceleration upon the occurrence of specified events of default, including payment default, change in control, bankruptcy, insolvency, certain defaults under other material debt, certain events with respect to regulatory approvals and a material adverse change in our business, operations or other financial condition. If an event of default (other than certain events of bankruptcy or insolvency) occurs and is continuing, CIBC may declare all or any portion of the outstanding principal amount of the borrowings plus accrued and unpaid interest to be due and payable. Upon the occurrence of certain events of bankruptcy or insolvency, all of the outstanding principal amount of the borrowings plus accrued and unpaid interest will automatically become due and payable. If such acceleration were to occur, it would materially and adversely affect our business, financial condition, operating results, cash flows and prospects.

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

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

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

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

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

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

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

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

We may not be able to sustain profitability.

Prior to 2024, we had incurred significant operating losses and we have only recently achieved profitability. Our ability to generate revenue sufficient to achieve sustained profitability will depend on the continued customer utilization of our NOP. We generated net income of $190.3 million and $35.5 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $278.0 million.

Our efforts to grow our business may be costlier than we expect. If our operating and capital expenditures are greater than we expect and if our revenue growth is not sufficient to support these expenditures, we will not be able to sustain profitability. We expect our operating and capital expenditures will continue to increase for the foreseeable future as we focus on growing commercial sales of our products in both the U.S. and select non-U.S. markets, including expanding our commercial team, growing our NOP, scaling our manufacturing and sterilization operations, continuing research, development and clinical trial efforts, including expanding our research and development and manufacturing capabilities in Italy, seeking regulatory approval for the next generation OCS, new products and product enhancements, including new indications, both in the United States and in select non-U.S. markets, establishing and relocating to a new long-term global headquarters, and seeking greater control of air and

ground transport for our NOP. The timing and amount of our operating and capital expenditures will depend on many factors, including:

- revenue generated from our NOP services and sales of our OCS Consoles, OCS Perfusion Sets and OCS Solutions and other products that may be approved in the United States and select non-U.S. markets;
- the costs and expenses of expanding our U.S. and non-U.S. commercial 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 costs associated with maintaining and growing our transplant 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 and timing of research and development of the next generation of OCS products;
- the degree of success we experience in commercializing our OCS products for additional indications;
- the costs, timing and outcomes of pre- and post-approval studies and any future clinical studies and regulatory reviews, including to seek and obtain approvals for the next generation of OCS products or for new indications for our OCS products;
- the emergence of competing or complementary technologies;
- the number and types of future products we develop and commercialize;
- the cost of constructing research and development and manufacturing facilities in Italy;
- the costs related to establishing and relocating to a new long-term global headquarters to accommodate the growing scale and complexity of our business;
- 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.

Because of the numerous risks and uncertainties associated with product development and commercialization, we are unable to accurately predict the timing or amount of increased expenses or if we will be able to maintain profitability.

Our ability to use our net operating losses and research and development credit carryforwards to offset future taxable income may be subject to future limitations.

As of December 31, 2025, we had federal net operating loss, or NOL, carryforwards of $370.9 million, which may be available to offset future taxable income, of which $74.0 million expire at various dates beginning in 2030, while the remaining $296.9 million do not expire but are limited in their usage to an annual deduction equal to 80% of taxable income. As of December 31, 2025, we had state NOL carryforwards of $261.6 million, which may be available to offset future taxable income and expire at various dates beginning in 2030. As of December 31, 2025, we also had U.S. federal and state research and development tax credit carryforwards of $7.3 million and $4.0 million, respectively, available to offset future tax liabilities. Our U.S. federal research and development tax credit carry forwards expire at various dates beginning in 2026. A portion of our NOL and tax credit carryforwards could expire unused if we do not generate sufficient federal and state taxable income prior to their expiration. In addition, a corporation that undergoes an "ownership change," generally defined in Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, as a greater than 50% change by value in its equity ownership over a three-year period, is subject to limitations on its ability to utilize its pre-change NOLs and its research and development credit carryforwards to offset future taxable income. Our existing NOLs and research and development credit carryforwards may be subject to limitations arising from future ownership changes. Our NOLs and credits may also become impaired under state law. For these reasons, if an ownership change occurs, or in the event we experience a change of control, we may not be able to utilize a portion of the NOLs and research and development credit carryforwards.

We may need to raise additional funding, which might not be available on favorable terms or at all. Raising additional capital may cause dilution to our shareholders.

Until such time, if ever, that we can generate substantial revenue sufficient to achieve sustained profitability, we may need to finance our operations through a combination of equity offerings, debt financings and strategic alliances. We also may elect to raise additional funds because we believe market conditions are attractive or as a risk mitigation measure. Additional capital might not be available when we need it, and our actual cash requirements might be greater than anticipated. If we require additional capital at a time when investment in our industry or in the marketplace in general is limited, we might not be able to raise funding on favorable terms, if at all. If we are not able to obtain financing on terms favorable to us, we may need to significantly delay, scale back or discontinue our development or commercialization activities, sell or license to third parties some or all of our assets or merge with another entity or may be forced to reduce or terminate our operations.

If we raise additional funds through the issuance of equity or convertible securities, the issuance of these securities could dilute shareholders' percentage ownership in our company. Furthermore, newly issued securities may have rights, preferences or privileges senior to those of common shareholders. If we raise additional funds through additional debt financing, we may need to dedicate a substantial additional portion of any operating cash flows to the payment of principal and interest on such indebtedness. The terms of any debt financing also could impose significant restrictions on our operations.

Risks Related to Product Commercialization and Development

Our long-term growth depends on our ability to expand access to the OCS through our NOP.

We have developed the NOP, an innovative turnkey solution to provide outsourced organ procurement and OCS perfusion management, to provide transplant programs with a more efficient process to procure donor organs with the OCS. We believe the NOP will continue to expand access and use of the OCS. However, continued operations of our NOP depend on recruiting, training and retaining qualified surgeons, clinical specialists, pilots, and other personnel and establishing and maintaining effective coordination with transplant centers and regional Organ Procurement Organizations to locate donor organs and recipients. We may not be able to continue to recruit, train and retain qualified personnel, including due to demand for their capabilities and competitive compensation offered by other employers. In order to recruit, train and retain such highly qualified employees, we also may need to increase the level, or change the form or composition, of the compensation that we pay to them, which would increase our expenses.

In addition to our own surgical and clinical personnel, we utilize a network with a limited number of partners for organ procurement, organ preservation and transportation services offered through our NOP. If any of these relationships are interrupted or terminated, or if one or more partners are unable or unwilling to fulfill their obligations for any reason, NOP services to our customers may be interrupted. We also may not be able to identify or negotiate with additional partners on terms that are commercially reasonable to us. The interruption or failure to retain or replace partners for our NOP would negatively impact our operations and financial results. Furthermore, the expenses incurred by us to customers who participate in our NOP are dependent on many different market dynamics, including the cost of fuel and other transportation costs. Additional expenses incurred by our NOP could adversely affect our business, gross margin, financial condition, operating results, cash flows and prospects.

Our long-term growth depends on our ability to improve the OCS platform, including by developing the next generation of our products or expanding into new indications.

Our business plan contemplates that we will continue to improve the OCS platform, including by developing the next generation of our products or expanding into additional organs. Developing such new or modified products is expensive and time-consuming and diverts management’s attention away from current operations. The success of any new product offering or product enhancements to our OCS platform will depend on several factors, including our ability to:

- properly identify and anticipate surgeon and patient needs;
- develop and introduce new products and product modifications in a timely manner;
- avoid infringing upon, misappropriating or otherwise violating the intellectual property rights of third parties;
- demonstrate the safety and efficacy of new products and product modifications;
- obtain necessary regulatory clearances or approvals;
- comply with regulations regarding the marketing of new products or product modifications;
- provide adequate training to potential users of our products;

- receive adequate coverage and reimbursement for procedures performed with our products; and
- develop an effective commercialization effort.

If we are not successful in expanding our indications and developing the next generation of our products, our ability to increase our revenue may be impaired, which could materially and adversely affect our business, financial condition, operating results, cash flows and prospects.

We will need to increase our manufacturing and sterilization capacity in the future and may encounter problems at our manufacturing facility or otherwise.

In order to manufacture the OCS in quantities sufficient to meet our anticipated commercial opportunity, we will need to continue to increase our manufacturing capabilities and retain third parties to sterilize our products. We anticipate that our new headquarters, which we expect to move into on or before January 1, 2028, will meet these increased requirements but we may encounter technical challenges to increasing the scale at which we manufacture the OCS, including with respect to material procurement and quality control and assurance. An increase in production could make it more difficult for us to comply with quality system regulations or other applicable requirements that are currently enforced by the FDA and other regulatory authorities, or that may be introduced in the future, in both the United States and in other countries. Further, we may experience disruptions to our manufacturing as a result of the move to the new headquarters that could potentially limit our production capacity. Commercial scale production of the OCS on a continuing basis also will require us to continue to hire and retain additional management and technical personnel who have the necessary manufacturing experience and skills. We might not successfully identify, hire or retain qualified personnel on a timely basis or at all. To maintain quality of our OCS, we may not be able to scale production of our OCS products at a rate that meets customer demand for our products. Our inability to increase the scale of our manufacturing of the OCS could impair our ability to generate revenue and adversely affect market acceptance of our product.

In addition, all of our manufacturing operations are currently conducted at a single facility in Andover, Massachusetts and we may continue to conduct certain manufacturing activities at this facility while utilizing additional facilities over time. Any interruption in operations at this location could result in our inability to satisfy product demand. Despite our efforts to safeguard this facility, including acquiring insurance on commercially reasonable terms, adopting environmental health and safety protocols and utilizing off-site storage of computer data, a number of factors could damage or destroy our manufacturing equipment or our inventory of component supplies or finished goods, cause substantial delays in our operations, result in the loss of key information, and cause us to incur additional expenses, including:

- operating restrictions, partial suspension or total shutdown of production imposed by regulatory authorities;
- equipment malfunctions or failures;
- technology malfunctions;
- work stoppages;
- damage to or destruction of the facility due to natural disasters or other events; or
- regional or local power shortages.

Our insurance may not cover our losses in any particular case, or insurance may not be available on commercially reasonable terms to cover certain of these catastrophic events. In addition, regardless of the level of insurance coverage, damage to our facilities or any disruption that impedes our ability to manufacture the OCS in a timely manner could materially and adversely affect our business, financial condition, operating results, cash flows and prospects.

We rely on third-party vendors to sterilize our disposable sets prior to sale. If vendors are unable to sterilize our products, whether due to capacity, availability of materials for sterilization, regulatory or other constraints, including federal and state regulations on the use of ethylene oxide used in the sterilization process, we will not be able to sell products until we can retain an alternative vendor to sterilize the products. We may be unable to transition to alternative methods of sterilization in a timely or cost-effective manner or at all, which could harm our business and results of operations.

Our results of operations could be materially harmed if we are unable to accurately forecast customer demand for our products and manage our inventory.

We seek to maintain sufficient levels of inventory, including our OCS Perfusion Sets, in order to protect ourselves from supply interruptions and to support the demand from customers, but keep limited components, sub-assemblies, materials and finished products on hand. To ensure adequate inventory supply and manage our operations with our suppliers, we forecast anticipated materials requirements and demand for our products in order to predict inventory needs and then place orders with our suppliers based on these predictions. Our ability to accurately forecast demand for our products could be negatively affected by many factors, including the rate of transplantations, product recalls, failure to accurately manage our commercial strategy, product introductions by competitors, an increase or decrease in customer demand for our products, our failure to accurately forecast customer acceptance of new products, changes to hospital capacity, staffing, procedure and protocol changes, unanticipated changes in general market conditions or regulatory matters and weakening of economic conditions or consumer confidence in future economic conditions. We also maintain inventory reserves at regional locations for distribution through our NOP. If we are not able to maintain sufficient inventory at these locations, or if we are not able to accurately predict the regional demand for our OCS products, we will incur additional costs to transport inventory to our regional locations, including rebalancing inventory amongst regional locations, and we may not be able to grow our commercial sales as anticipated.

Inventory levels in excess of customer demand may result in a portion of our inventory becoming obsolete or expiring, as well as inventory write-downs or write-offs. Conversely, if we underestimate customer demand for our products or our own requirements for components, subassemblies and materials, our manufacturing partners and suppliers may not be able to deliver components, sub-assemblies and materials to meet our requirements and our manufacturing may be affected by the impact of inflation and labor shortages on our suppliers, which could result in inadequate inventory levels or interruptions, delays or cancellations of deliveries to our customers, any of which would damage our reputation, customer relationships and business. In addition, several components, sub-assemblies and materials incorporated into our products require lengthy order lead times, and additional supplies or materials may not be available when required on terms that are acceptable to us or our manufacturing partners, or at all, and our manufacturing partners and suppliers may not be able to allocate sufficient capacity in order to meet our increased requirements, any of which could have an adverse effect on our ability to meet customer demand for our products and our results of operations.

We aim to maintain strategic reserves of our OCS Perfusion Sets, but if we are not able to manufacture and assemble OCS Perfusion Sets at a rate that will allow us to maintain these reserves, then we will be required to rely on alternative strategies to deliver OCS Perfusion Sets in a timely manner, which may impact our expenses and results of operations.

We depend heavily on the success of the OCS and it gaining additional market acceptance as well as the success of the next generation OCS. If we are unable to continue to successfully commercialize the OCS or the next generation OCS, our business may fail.

We have invested substantial efforts and financial resources in the development of the OCS, educating surgeons, transplant centers, Organ Procurement Organizations and private and public payors of the benefits of the OCS, providing services related to the OCS and developing and operating our NOP. Although we have received PMA approvals from the FDA for each of our three OCS products, we might not be able to continue to successfully commercialize the OCS for these approved indications or obtain approvals for additional indications or in additional jurisdictions on our planned timing or at all. Our ability to generate product revenue and remain profitable depends primarily on sales of OCS Perfusion Sets and OCS Solutions, which we refer to collectively as disposable sets. Our assumptions regarding demographic trends, donor organ availability and the use of transplantation as a treatment for end-stage organ failure may prove to be incorrect.

We expect that we will need to continue to demonstrate to surgeons, transplant center program directors, Organ Procurement Organizations and private and public payors that the OCS potentially results in some or all of the following: improvements in post-transplant clinical outcomes, increases in the utilization of donor organs, expansion of the pool of potential donors and reduction in the total cost of care as compared to available alternatives.

Surgeons, transplant centers and private and public payors often are slow to adopt new products, technologies and treatment practices that require additional upfront costs and training. The cost of the OCS significantly exceeds the cost of cold storage preservation. In addition, our international customers and some U.S. customers use a direct acquisition model pursuant to which transplant centers train their own teams for organ procurement and OCS perfusion management using the OCS rather than utilizing our NOP. Surgeons may not be willing to undergo training to use the OCS, may decide the OCS is too complex to adopt without appropriate training and may choose not to use the OCS, which may limit the adoption of the OCS under the direct acquisition model. Further, the OCS replaces a decades-old standard of care and the NOP has significantly expanded service offerings available to transplant centers for the complicated organ procurement process that often requires resources and logistics beyond a transplant center's existing clinical capabilities and capacity. As a result, we may face opposition from industry participants reluctant to change. An activist short seller published a disparaging report about our business, which may impact our reputation in the market and deter surgeons and transplant centers from adopting the OCS or utilizing our NOP. In addition, this activist short seller has submitted a petition to the FDA, requesting that the FDA suspend the PMA approval for the OCS and take other adverse actions related to the OCS, and in particular the OCS Liver, due to alleged off-label use of the device. We have responded to this petition, stating both legal and factual bases for rejection. Even if the FDA rejects the petition, the petition may nonetheless impact how surgeons, patients and transplant centers perceive the safety and efficacy of our OCS products, which would have a material adverse effect on our business, financial condition, results of operations and prospects, as well as harm our reputation. Based on these or other factors, transplant center program directors, Organ Procurement Organizations and private and public payors may decide not to use OCS. In addition, adoption of the OCS may be constrained by the capacity of individual transplant centers to perform transplants due to factors such as the number of its surgeons trained on the use of the OCS. As a result, demand for the OCS could be materially lower than we expect it to be, which would materially and adversely affect our business, financial condition, operating results, cash flows and prospects.

We must continue to educate surgeons, transplant centers and private and public payors and demonstrate the merits of the OCS compared with cold storage or new competing technologies.

Directors of transplant programs are key decision-makers in the adoption of novel medical devices used in organ transplantation. An important part of our commercialization efforts is to educate transplant center program directors and other surgeons on the relative merits of the OCS. Our success depends, in large part, on effectively marketing and educating program directors and other surgeons about the benefits of the OCS and our NOP. Acceptance of the OCS also depends on educating program directors, other surgeons and private and public payors as to the distinctive characteristics, perceived medical and economic benefits, safety, ease of use and cost-effectiveness of the OCS and our NOP. If program directors, other surgeons and private and public payors do not find our body of published clinical evidence and data compelling or wish to wait for additional studies, they may choose not to use or provide coverage and reimbursement for our products and NOP Services. Currently, most universal national healthcare systems outside of the United States do not reimburse transplant centers for the use of the OCS, and reimbursement in international markets may require us to undertake additional clinical studies.

In addition, the long-term effects of our OCS following transplantation are not yet known. Certain surgeons, transplant centers and private and public payors may prefer to see longer-term safety and efficacy data than we have produced. We cannot provide assurance that any data that we or others may generate in the future will be consistent with that observed in our existing clinical studies. In addition, as the NOP expands access to the OCS, transplant surgeons may increasingly rely on clinical data regarding the organ provided to them by our clinical specialists and surgeons. We are responsible for the clinical data regarding the organ that is provided to transplant surgeons who participate in the NOP.

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

Since our acquisition of Summit, an aviation business, in 2023, we have separately acquired 22 fixed-wing aircraft, and intend to opportunistically evaluate acquisitions of additional fixed-wing aircraft that will be operated as part of our NOP. In addition, in August 2023, we acquired certain assets related to lung and heart perfusion technology from Bridge to Life Ltd. and its subsidiary Tevosol, Inc., or together Bridge to Life. Utilization of these acquired assets may be complex, costly and time consuming and we may face unanticipated issues, expenses and liabilities. We may not successfully or profitably utilize newly acquired assets or integrate, operate, maintain and manage any newly acquired operations or employees. We may decide that only certain of the acquired technology is useful for the next generation of the OCS, or that integration of the acquired technology is not feasible or is too costly.

We have a limited history of providing aviation transportation services and we continue to depend on certain members of the former management team of Summit for the successful operation and integration into our NOP services offering. Even if we are able to utilize the Bridge to Life Assets and fully realize the benefits of our acquisition of Summit, we may not realize the expected benefits of other future transactions. We may review additional acquisition, joint ventures and strategic investment opportunities to expand our current product offerings, increase the size and geographic scope of our operations or otherwise offer growth and operating efficiency opportunities. We may not be able to identify suitable candidates or consummate future transactions on favorable terms. If required, the financing for future transactions could result in an increase in our indebtedness, dilute the interests of our shareholders or both. The purchase price for some acquisitions or joint ventures interests may include additional amounts to be paid in cash in the future, a portion of which may be contingent on the achievement of certain future operating results of the acquired business. If the performance of any such acquired business or joint venture exceeds such operating results, then we may incur additional charges and be required to pay additional amounts. Our failure to successfully utilize any acquired assets, complete the integration of any acquired business, including retention of key employees, customers and strategic partners, achieve the long-term plan for such assets or businesses, as well as any other adverse consequences associated with our acquisition and investment activities, could have an adverse effect on our business. Any acquisition may also disrupt our ongoing business, divert resources, increase our expenses, and distract our management from our ongoing operations.

We depend on a limited number of customers for a significant portion of our revenue and the loss of, or a significant shortfall in demand from, these customers could have a material adverse effect on our financial condition and operating results.

We generate a significant amount of our revenue from a limited number of customers. However, our customers may not continue to utilize our products or services at current levels, pricing, or at all, and our revenue could fluctuate significantly due to changes in economic conditions, the use of other methods for organ preservation, such as cold storage or normothermic regional perfusion, or the loss of, reduction of business with, or less favorable terms with any of our largest customers. Our future success will depend upon the timing and volume of business from our largest customers and the financial and operational success of these customers. If we were to lose a key customer or have a key customer significantly reduce their volume of business with us, our revenue may be materially reduced, which would materially and adversely affect our business, financial condition, operating results, cash flows and prospects.

Substantially all of our U.S. customers now participate in our NOP and our success will depend on our ability to maintain the function and efficiency, while increasing capacity and capability, of the NOP. If we are unable to deliver OCS products to customers through their participation in the NOP, our revenue would be materially reduced, which would materially and adversely affect our business, financial condition, operating results, cash flows and prospects.

We depend on single-source suppliers and, in a few cases, sole-source suppliers for many of the components used in the OCS, and any supply interruption could harm our business.

We rely on single-source suppliers and, in a few cases, sole-source suppliers for many of the components used in the OCS. For example, each of Fresenius Kabi Austria GmbH and Fresenius Kabi AB, which we refer to collectively as Fresenius, is our single-source supplier of OCS Solutions for the OCS Lung and the OCS Heart, respectively. While we have manufacturing and supply agreements with certain of our suppliers, for most of our suppliers, we place purchase orders on an as-needed basis. Our suppliers could discontinue the manufacturing or supply of these components at any time. We do not carry a significant inventory of some of these components. Our suppliers may not be able to meet our demand for their products, either because of acts of nature, the nature of our agreements with those manufacturers or our relative importance to them as a customer, and our manufacturers may decide in the future to discontinue or reduce the level of business they conduct with us. If our single or sole-source suppliers are unable or unwilling to deliver components to us, whether due to a labor shortage, slow down or stoppage, or for any other reason, we may not be able to manufacture or have available one or more products during such period of unavailability and our business could suffer, possibly materially. In such a case, we would be required to seek alternative suppliers. We might not be able to identify and qualify additional or replacement suppliers for any of these components quickly or at all or without incurring significant additional costs. We cannot guarantee that we will be able to establish alternative relationships on similar terms, without delay or at all.

We also may choose to establish our own manufacturing process of certain components and we may not be successful in doing so. In addition, the components we design may not be successful or may not provide a functional or economic benefit compared to similar components manufactured by third parties. We would also need to seek FDA approval for any change in the design of our device, including different components, which may not be granted in a reasonable time, if at all. If we choose to establish our own manufacturing process of components of the OCS, we may be required to procure additional raw materials for such processes, which may not be available. In addition, many of the components used in the OCS are specifically designed for use in the OCS, which means that off-the-shelf components may not be available as substitutes. We could be adversely affected if we experience any delay or deficiency in the quality of products obtained from suppliers and/or if we have to replace our suppliers.

Establishing additional or replacement suppliers for any of these materials or components, if required, or any supply interruption from our suppliers, could limit our ability to manufacture our products, result in production delays and increased costs and adversely affect our ability to deliver products to our customers on a timely basis, which could harm our business. Our inability to obtain sufficient quantities of components for the OCS also could adversely affect development of the next generation of the OCS. If we are not able to identify alternate sources of supply for the components, we might have to modify our product to use substitute components, which could lead to additional regulatory obligations that could impact our marketing ability, cause delays in shipments, increase design and manufacturing costs and increase prices for our products. Any such modified product might not be as effective as the predecessor product or might not gain market acceptance. This could lead to customer dissatisfaction and damage to our reputation and could materially and adversely affect our business, financial condition, operating results, cash flows and prospects.

In addition to our aviation transportation services, we also depend on third parties to transport donor organs and medical personnel for our NOP, and limited availability of, or increases in the cost of, transportation could limit our ability to grow or operate the NOP.

In addition to our aviation transportation services, our NOP depends on the use of a third-party network of private aircraft to transport medical personnel to retrieve donor organs and deliver donor organs to patients for transplantation. Reliance on private aircraft is subject to various risks, including those associated with change in fuel prices, work stoppages and weather-related operating hazards. In particular, private aircraft are occasionally in high demand and/or subject to price fluctuations based on market conditions. Further, availability is constrained by a limited number of private aircraft available in the United States and a limited number of qualified pilots. As a result, third-party private aircraft providers may not be able to prioritize our use of their services.

If we are unable to obtain flight services for our NOP when needed, we may be unable to utilize our NOP to satisfy demand. We also may be required to seek alternative and, potentially more costly, flight services. Although the cost of flights is paid by our customers, a substantial increase in the cost of flight services, due to prolonged increases in fuel prices, lack of availability of aircraft or otherwise, may require us to incur additional costs to identify and obtain alternative flights or rebalance our inventory by shipping products to locations for which flight costs are less expensive or from which flights are more readily available, and customers may be unwilling or unable to incur higher costs of flights and therefore forgo use of our services and products for the procurement of donor organs despite availability. Further, the capacity of our NOP is limited by the number of aircraft and pilots available for our use and as we continue to grow our NOP, we will be required to obtain access to a greater number of available aircraft and pilots.

We may not be able to achieve or maintain satisfactory pricing and margins for our products or services.

Manufacturers of medical devices have a history of price competition, and we may not be able to achieve satisfactory prices for our products or maintain prices at the levels we have historically achieved. Any decline in the amount that payors reimburse our customers for OCS products or services could make it difficult for customers to continue using, or to adopt, our products and could create additional pricing pressure for us. If we are forced to lower the price we charge for our products or services, our gross margins will decrease, which will adversely affect our ability to invest in and grow our business. If we are unable to maintain our prices, or if our costs increase and we are unable to offset such increase with an increase in our prices, our margins could erode. We will continue to be subject to significant pricing pressure, which could harm our business and results of operations.

Price increases of the components used to manufacture our products and supply shortages could adversely affect our business and operating results.

The supply of raw materials to our component parts suppliers could be interrupted for a variety of reasons, including availability and pricing. We may experience supply chain disruptions due to general impacts of inflation and labor shortages and these disruptions to the supply chain could adversely affect our ability to meet commitments to customers. Significant price increases could adversely affect our results of operations and operating margins. In particular, inflation, changes in trade policies, the imposition of duties and tariffs and public health crises could adversely impact the price or availability of raw materials and the components of our products. The U.S. continues to implement certain trade actions, including imposing tariffs on certain goods imported from China and other countries. Significant tariffs have been proposed by the new administration, although it is not possible to predict the extent or focus of any such tariffs at this time. Additional tariffs, trade restrictions and export controls imposed by the U.S. on a broader range of imports, or further retaliatory trade measures taken by China or other countries in response, may impact our suppliers and the price of our components for our OCS products or our aircraft. We may not be able to pass along increased component part prices to customers in the form of price increases or our ability to do so could be delayed. Consequently, our results of operations and financial condition may be adversely affected.

Our failure to compete effectively will harm our business and operating results.

A broad range of medical device, pharmaceutical and biotechnology companies offer products, procedures and therapies that have the potential to limit the demand for organ transplantation. Companies within this group vary depending on the type of organ. New therapies for COPD, which includes emphysema and chronic bronchitis, could limit the demand for lung transplants. Alternative products, procedures and therapies including ventricular assist devices, cardiac rhythm management products, total artificial hearts, and drug therapies for the heart and surgical procedures could limit demand for heart transplants. Improved treatments for chronic diseases or conditions affecting the liver as well as efforts to develop artificial livers could limit the need for liver transplants. If demand for organ transplants decreases, sales of the OCS and its components will suffer.

Other companies may develop technologies and products that result in improved patient outcomes or are safer, easier to use, less expensive or more readily accepted than the OCS. These products or technologies could make the OCS obsolete or noncompetitive and reduce demand for our OCS products. Many of these providers of alternative products, procedures and therapies have greater name recognition, significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and clearances and marketing and selling products than we do. Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Third parties may also compete with us in recruiting and retaining qualified medical, engineering and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to or necessary for our products or development programs or otherwise advantageous to our business. Our failure to compete effectively will harm our business and operating results.

The clinical trial process that may be required to obtain future regulatory approvals is lengthy and expensive, with uncertain outcomes.

Clinical trials are necessary to support PMA applications and may be necessary to support future PMA supplements for modified versions of our marketed device products. Conducting clinical trials is a complex and expensive process, can take many years and outcomes are inherently uncertain. For the development of the next generation of OCS products or the development of OCS products for additional organs, we may incur substantial expense for, and devote significant time to, clinical trials but cannot be certain that the product tested will ever generate revenue sufficient to cover the costs of trials. We may experience significant setbacks in clinical trials, even after earlier clinical trials showed promising results, and failure can occur at any time during the clinical trial process. Any of our products may malfunction or may produce undesirable adverse effects that could cause us or regulatory authorities to interrupt, delay or halt clinical trials. We, the FDA or another regulatory authority may suspend or terminate clinical trials.

Successful results in early studies do not assure positive results in subsequent clinical trials. The data we collect from our preclinical studies and clinical trials may not be sufficient to support FDA or other regulatory clearance or approval. Additionally, the FDA may disagree with our interpretation of the data from our studies and trials. The FDA may conclude that the clinical trial design, conduct or results are inadequate to prove safety or effectiveness, and the FDA may require us to undertake expensive and lengthy additional trials, which may delay clearance or approval of products.

Clinical trials often require enrollment of large numbers of subjects, who may be difficult to identify, recruit and maintain as participants in the clinical trial. As a condition to our PMA approvals, we are required to conduct post-market studies. For example, we have post-approval registries ongoing or completed for all three of our organ products, including the OCS Lung Thoracic Organ Perfusion Registry, or TOP Registry, the OCS Heart Perfusion Registry, or OHP, and the OCS Liver Perfusion Registry, or OLP.

Adverse outcomes in post-approval studies can result in withdrawal of approval of a PMA or restrictions on the approval. We will need to conduct additional clinical studies to support use of the OCS in, and development of OCS products for, new organs, and potentially for commercialization of our products in additional foreign jurisdictions. Clinical trials in organ transplant are difficult to design and implement, take substantial time to conduct and are expensive. The results of clinical trials are inherently uncertain. The initiation and completion of any studies may be prevented, delayed or halted for numerous reasons. The following could adversely affect the costs, timing or successful completion of any clinical trial:

- we have been required and, prior to collecting clinical data in the future to support new PMA applications, may be required again to submit an IDE application to the FDA, which must become effective prior to commencing human clinical trials, and the FDA may reject our IDE application and notify us that we may not begin investigational trials;
- regulators and other comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical trials;
- regulators and/or IRBs, or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site;
- we may not reach agreement on acceptable terms with prospective clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different trial sites;
- clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of subjects or patients required for clinical trials may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, and the number of clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors, including those manufacturing or sterilizing our products, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner or at all;
- we might have to suspend or terminate clinical trials for various reasons, including a finding that the subjects are being exposed to unacceptable health risks;
- we may have to amend clinical trial protocols or conduct additional studies to reflect changes in regulatory requirements or guidance, which we may be required to submit to an IRB and/or regulatory authorities for re-examination;
- regulators, IRBs or other reviewing bodies may require or recommend that we or our investigators suspend or terminate clinical research for various reasons, including safety signals or noncompliance with regulatory requirements;
- the cost of clinical trials may be greater than we anticipate;
- we may be unable to recruit a sufficient number of clinical trial sites;
- regulators or other reviewing bodies may fail to accept as satisfactory, fail to approve, or subsequently find fault with our manufacturing processes or facilities of third-party manufacturers with which we enter into agreement for clinical and commercial supplies, the supply of devices or other materials necessary to conduct clinical trials may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply;
- approval policies or regulations of FDA or applicable foreign regulatory agencies may change in a manner rendering our clinical data insufficient for approval; and
- our current or future products may have undesirable side effects or other unexpected characteristics.

Failure can occur at any stage of clinical testing. For example, our clinical studies may produce negative or inconclusive results, and, in the case of our ENHANCE and DENOVO clinical trials, we may not be successful in demonstrating superiority when compared to static cold storage methods. Additionally, in the future, we may decide, or regulators may require us, to conduct clinical and non-clinical testing in addition to those we have planned. After submission of our PMA applications for OCS Lung and OCS Heart, the FDA requested certain additional clinical analyses, technical information and clarifications as part of the agency's normal review process. The FDA ultimately approved both PMAs. The FDA could ask us to conduct additional clinical trials or submit additional evidence to support PMA applications in the future. Our failure to adequately demonstrate the safety and effectiveness of any product we may develop in the future would prevent receipt of regulatory clearance or approval and, ultimately, the commercialization of that product or indication for use. Even if our future products are cleared or approved in the United States, commercialization of our products in foreign countries would require marketing authorization from regulatory authorities in those countries. Authorization approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials. Any of these occurrences could materially and adversely affect our business, financial condition, operating results, cash flows and prospects.

Risks Related to Our Transplant Logistics Operations

We have limited experience operating aircraft, and we may not be able to achieve the anticipated benefits of our aircraft operations.

We have limited experience operating aircraft, and we continue to depend on certain members of the former management team of Summit and additional employees we may hire for the successful operation of aviation transportation services and the integration into our NOP services offering. We must comply with applicable laws and regulations to manage our growing NOP transplant logistics network. The operation of aircraft is a highly regulated activity and one that involves unique risks, including those described above, which we have not needed to manage previously. We may not successfully manage these risks or profitably utilize, integrate, operate, maintain and manage our newly acquired aircraft, employees and other aircraft operations.

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

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

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

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

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

As part of our services offered under our NOP, we have acquired a fleet of fixed-wing aircraft. All of the aircraft we currently operate are standardized variants of a certificated model produced by a single manufacturer. Parts and services from this manufacturer are subject to their product and workmanship warranties and capacity to service aircraft. If this manufacturer fails to adequately fulfill its obligations towards us or experiences interruptions or disruptions in production or provision of services due to, for example, bankruptcy, natural disasters, labor strikes or disruption of its supply chain we may experience a significant delay in the delivery of or fail to receive previously ordered parts, which would adversely affect our revenue and results of operations and could jeopardize our ability to meet the demands of our customers. If there is a shortage of replacement parts that are compatible with the model of aircraft we operate, our entire fleet may be impacted and we would not be able to rely on other model aircraft during replacement part shortages or outages. Our operation of a single model of aircraft may therefore limit flexible use of our fleet. Although we could choose to operate aircraft of other manufacturers or increase our reliance on third-party operators, such a change would involve substantial expense to us and could disrupt our business activities.

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

The FAA could suspend or restrict the use of our aircraft in the event of actual or perceived mechanical problems or safety issues while it conducts its own investigation, whether involving our aircraft or another operator's aircraft. For example, in 2023, the FAA required the removal of certain Pratt & Whitney engines for inspection. If the FAA requires inspections of the types of Pratt & Whitney aircraft engines that we utilize, our ability to operate our NOP may be limited, which could adversely impact our business, operations, cash flow, financial condition and liquidity.

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

Our pilots are subject to stringent pilot qualification (including medical certification) and crew member flight training standards, or FAA qualification standards, which among other things require minimum flight hours for pilots, mandate strict rules to minimize pilot fatigue and require periodic recertification. These requirements limit the availability of qualified pilot candidates and increase pilot salaries and related labor costs, which increases our operating expenses. Such requirements also impact pilot scheduling, work hours and the number of pilots required to be employed for our operations. Further, in recent years, the airline industry has experienced significant volatility in pilot attrition, including volatility resulting from pilot wage and bonus increases at other industry participants, the growth of air cargo, additional charter operations and airlines, and more pilots reaching retirement age. If our attrition rates are higher than our ability to hire and retain replacement pilots, our operations and financial results would be adversely affected. We may not be able to balance the number of pilots we employ with the number of aircraft in our fleet and demand for our NOP, as well as accurately forecast pilot attrition and hiring needs. If our forecasts are inaccurate and we do not effectively balance the number of pilots we employ, or if the supply of pilots becomes constricted, such events could disrupt our business activities.

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

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

We are exposed to operational disruptions due to maintenance and third-party services.

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

We rely on third-party service providers to perform functions integral to our operations, including ground handling, landing fees, fueling, maintenance, and other services. Disruptions could occur and increase our operating costs or ability to meet customer demands.

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

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

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

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

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

Our aircraft operations are affected by factors beyond our control, including air traffic congestion at airports, air traffic control inefficiencies and staffing shortages, increased and changing security measures, changing regulatory and governmental requirements, and new or changing travel-related taxes. For example, in November 2024, the FAA announced that a shortage of air traffic controllers had significantly impacted flight traffic. Additionally, U.S. federal government shutdowns have negatively affected the FAA, including causing significant impacts on flight traffic, and any future shutdown could negatively impact our aviation transportation operations. Factors that cause flight delays could prevent us from effectively transporting organs in a timely manner, which could have a material adverse effect on our business, results of operations and financial condition.

In the United States, the federal government singularly controls all U.S. airspace, and aviation operators are completely dependent on the FAA to operate that airspace in a safe, efficient and affordable manner. The air traffic control system, which is operated by the FAA, in the U.S., faces challenges in managing the growing demand for U.S. air travel and attracting air traffic controllers. U.S. air-traffic controllers often rely on outdated technologies that routinely overwhelm the system and compel aviation operators to fly inefficient, indirect routes resulting in delays and increased operational cost. For example, in January 2023, the FAA experienced an unexpected technical system outage that resulted in all domestic commercial air traffic being

temporarily grounded for several hours, which adversely impacted airlines and private aviation industry operators during the duration of the outage. There have also been recent instances where understaffing of certain U.S. air traffic control systems have led to flight delays and cancellations, and resulted in significant costs to aviation operators. These instances are capable of repetition and may harm our business and results of operations in the future.

In addition, discussions regarding privatization of the U.S. air traffic control system are ongoing, which could adversely affect our business. Further, implementation of the Next Generation Air Transport System by the FAA could result in changes to aircraft routings and flight paths that could lead to increased noise complaints and lawsuits, resulting in increased costs. Future changes to air traffic control systems or protocols could lead to increased costs, legal issues or operational inefficiencies, in each case which adversely impact our business and results of operations.

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

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

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

Revocation of permits, approvals, authorizations and licenses.

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

Our aircraft maintenance costs will increase as our fleet ages.

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

We are subject to risks associated with climate change, including the potential increased impacts of severe weather events on our operations and infrastructure.

The potential physical effects of climate change, such as increased frequency and severity of storms, floods, fires, and other climate-related events, could affect our operations, infrastructure, and financial results. Operational impacts, such as the delay or cancellation of flights or physical damage to our aircraft, could result in loss of revenue from our NOP and reputational harm if we are unable to fulfil customer demand for our NOP. In particular, severe weather events in the Dallas area may have an adverse impact on our ability to utilize our Dallas facility for maintenance of our aircraft and we would be required to rely on third parties to complete required aircraft maintenance. In addition, certain airports that we frequently utilize and certain of our facilities are in locations susceptible to the impacts of storm-related flooding, fires and other climate-related events, which could result in increased costs and loss of revenue from NOP customers those regions.

Risks Related to Our Business

Failure to maintain an ethical and inclusive corporate culture, or damage to our reputation, could have a material adverse effect on our business.

We strive to create a culture in which our employees act with integrity, treat each other with respect and consider themselves empowered to report suspected misconduct. Our ability to attract and retain a high-quality workforce depends upon our commitment to an inclusive environment, along with our perceived trustworthiness and ethics. Issues can arise in any number of circumstances, including employment-related offenses such as workplace harassment and discrimination, regulatory noncompliance, failure to properly use and protect data and systems, and violations of our employee policies, as well as from actions taken by regulators or others in response to such conduct. Addressing allegations of misconduct detracts focus from business operations and is expensive. We have adopted policies to promote compliance with laws and regulations as well as to foster a respectful workplace for all employees. These policies, which include a code of business conduct and ethics, an insider trading policy, a Regulation FD policy, a sexual harassment policy, a regulated fraternization policy, and a whistleblower policy, are a component of our effort to minimize employee misconduct as well as activities that frequently result in allegations of misconduct. We continuously assess our policies and provide training to our employees, but our employees may fail to abide by these policies. In addition to damaging our reputation, actual or alleged misconduct could affect the confidence of our shareholders, regulators and other parties and could have a material adverse effect on our business, financial condition and operating results.

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

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

As the cyber-threat landscape evolves, attacks are growing in frequency, sophistication and intensity, are becoming increasingly difficult to detect, and are being perpetrated by a broadening array of threat actors, including criminal hackers, hacktivists, nation-states and state-sponsored actors, perpetrators of industrial espionage and sabotage, and inside threats. New and expanding threats to our information systems, including computer viruses, ransomware and phishing attacks, insider attacks, and more sophisticated and targeted cyber-related attacks, as well as cybersecurity failures resulting from human error and technological errors, pose a risk to the security of our systems and the systems of our customers, business partners and suppliers, as well the confidentiality, availability and integrity of the data we process. For example, during the second quarter of 2023, we became aware of an infiltration of portions of our information technology network. As part of our investigation into this incident, we engaged outside security experts and identified unauthorized theft of data although no sensitive data were involved. While the impact from this incident was not material to the operations of the Company, future impacts from such threats may be material. While we maintain insurance coverage for these types of incidents, such policies, may not provide coverage for, or offset the costs of responding to and remediating such incidents or any other liability that may arise from such incident.

We have access to sensitive, confidential or personal data or information that is subject to privacy and security laws, regulations or customer-imposed controls. Despite our implementation of controls designed to protect our systems and sensitive, confidential or personal data or information, the infiltration of our information technology systems, including security breaches, theft, misplaced, lost or corrupted data, employee errors and/or malfeasance (including misappropriation by departing employees) could lead to the compromise of sensitive, confidential or personal data or information.

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

Economic, political and other risks associated with foreign operations could adversely affect our international sales and our results of operations.

Because we market the OCS in countries in Europe, Asia-Pacific, Central Asia and Canada and plan to market it in other international markets, we are subject to risks associated with doing business internationally. During the years ended December 31, 2025, 2024 and 2023, 3%, 3% and 6%, respectively, of our revenue was generated from customers located outside of the United States. We anticipate that international sales will continue to represent a portion of our total sales. In addition, some of our employees and suppliers are located outside of the United States. Accordingly, our results of operations could be harmed by a variety of factors, including:

- changes in a country's or region's political or economic conditions;
- longer payment cycles of foreign customers and difficulty of collecting receivables in foreign jurisdictions;
- different or changing regulatory or insurance practices regarding reimbursement for transplant procedures;
- difficulties in developing effective marketing campaigns in unfamiliar foreign countries;
- trade protection measures, import or export licensing requirements or customs clearance and shipping delays;
- fluctuations in foreign currency exchange rates;
- differing tax laws and changes in those laws in the countries in which we are subject to tax, or potentially adverse tax consequences, including the complexities of foreign value-added tax systems, tax inefficiencies related to our corporate structure, and restrictions on the repatriation of earnings;
- changes in international legislation or regulations governing the approval or clearance process for the OCS or ongoing compliance requirements;
- differing business practices associated with foreign operations;
- difficulties in staffing and managing our international operations;
- political, social, and economic instability abroad, terrorist attacks, and security concerns in general;
- the burdens of complying with a wide variety of foreign laws and different legal standards, such as anti-bribery laws, including the FCPA, and the Bribery Act, data privacy requirements, labor laws and anti-competition regulations;
- differing protection of intellectual property; and
- increased financial accounting and reporting burdens and complexities.

We rely on shipping providers to deliver products to our customers globally. Labor, tariff or World Trade Organization-related disputes, piracy, physical damage to shipping facilities or equipment caused by severe weather or terrorist incidents, congestion at shipping facilities, inadequate equipment to load, dock and offload our products, energy-related tie-ups or other factors could disrupt or delay shipping or off-loading of our products domestically and internationally. Such disruptions or delays could materially and adversely affect our business, financial condition, operating results, cash flows and prospects.

If one or more of these risks are realized, our business, financial condition, operating results, cash flows and prospects could be materially and adversely affected.

Our success depends on our ability to retain our founder and President and Chief Executive Officer and other members of our management team and to attract, retain and motivate qualified personnel.

Our success depends on our continued ability to attract, retain and motivate highly qualified clinicians, surgeons, scientists, engineers, managers and sales personnel. Dr. Waleed H. Hassanein, our founder and President and Chief Executive Officer, and other members of our management team are important to the success of our operations. All of these key employees, including Dr. Hassanein, are at-will employees and can terminate their employment with us at any time. The loss of any of these key members of our management team and, in particular, Dr. Hassanein, could impede our achievement of our research, development and commercialization objectives. We maintain a "key person" insurance policy on the life of Dr. Hassanein, but we do not maintain such insurance on any of our other employees.

In addition, our expected growth will require us to hire a significant number of qualified personnel, including clinical development, regulatory, sales, marketing, engineering, scientific, clinical, logistics and aviation support and administrative personnel. There is intense competition from other companies and research and academic institutions for qualified personnel in the areas of our activities. If we cannot continue to attract and retain, on acceptable terms, the qualified personnel necessary for the continued development of our business, we might not be able to sustain our operations or become profitable.

The failure to manage our growth effectively could harm our business.

To manage our anticipated future growth effectively, we must enhance our manufacturing and sterilization capabilities, information technology infrastructure and financial and accounting systems and controls. Our growth will require significant capital expenditures and may divert financial resources from other projects, such as the development of the OCS for transplants involving additional indications or other organs. Operating our NOP requires significant capital expenditures, including the acquisition and maintenance of our fleet of aircraft. If we are unable to effectively manage our growth, our expenses may increase more than expected, our revenue could grow more slowly than expected and we might not be able to achieve our research and development and commercialization goals, which in turn could materially and adversely affect our business, financial condition, operating results, cash flows and prospects.

We may experience disruptions to our business as a result of the relocation of our headquarters and general expansion of our operations.

We may experience disruptions as we continue to expand our operations and facilities and execute on our growth strategy. In January 2026, we entered into a lease agreement with the intent to move our headquarters to a larger space in Somerville, Massachusetts. We intend to renovate the facility before moving our operations, including manufacturing, to this facility. The process of moving our business, opening new facilities and bringing operations online at this new site is inherently complex and is not part of our day-to-day operations. The relocation and expansion of our headquarters and the opening of any additional new facilities, including our planned expansion in Italy, may cause significant disruption to our operations, divert management attention and resources and involve significant costs, all of which could have a material adverse effect on our business, financial condition and results of operations. The relocation of our headquarters and any additional facilities that we seek to open may take longer than anticipated or may not proceed as planned, and the expected benefits may be less than anticipated.

Our international expansion may expose us to operational, compliance and financial risks that could adversely affect our business and results of operations.

We are expanding our operations outside the United States, which increases operational complexity and may require significant management attention and resources. Our international operations involve increased logistics and supply chain complexity, foreign customs and trade requirements, and reliance on third-party service providers, which may result in delays or increased costs. Operating internationally also exposes us to legal and compliance risks, as well as differing healthcare systems and reimbursement frameworks that may limit adoption of our OCS technologies, NOP services or related offerings or reduce expected revenues and margins, If we are unable to effectively manage these risks, our business, financial conditions and results of operations could be materially and adversely affected.

Our use of artificial intelligence, or AI, and other emerging technologies could adversely impact our business and financial results.

We currently make limited use of AI technologies in our operations, and we may continue to explore further use cases. The rapid advancement of these technologies presents opportunities for us in research, manufacturing, commercialization, and other business endeavors, but also entails risks, including that AI-generated content, analyses, or recommendations we utilize could be deficient, that our competitors may more quickly or effectively adopt AI capabilities, or that our use of AI or other emerging technologies increases regulatory, privacy, cybersecurity and other significant risks. In addition, any disruption or failure in the AI functionality we incorporate into our business activities, products or services could adversely impact our business or result in delays or errors in our product offerings. The legal and regulatory landscape surrounding AI technologies is rapidly evolving and uncertain, including in the areas of intellectual property, cybersecurity and privacy and data protection. Compliance with new or changing laws, regulations or industry standards relating to AI may impose significant costs on us and limit our ability to effectively develop, deploy or use AI technologies. Furthermore, if we are unable to effectively manage the use of AI technologies by our employees and service providers, our confidential information, intellectual property and reputation could be put at risk. Failure to appropriately respond to this evolving landscape may result in reputational, competitive and business harm as well as litigation and regulatory action and fines, penalties and expenses related thereto.

Risks Related to Our Intellectual Property

If we infringe or are alleged to infringe the intellectual property rights of third parties or are otherwise subject to litigation or other proceedings regarding our intellectual property rights, our business or competitive position could be adversely affected.

Our commercial success will depend in part on not infringing, misappropriating or otherwise violating the patents or other intellectual property or proprietary rights of others. Significant litigation regarding patent and other intellectual property rights occurs in the medical device industry. Third parties may claim that the OCS or aspects or uses of the OCS infringe intellectual property rights for which we do not hold licenses or other rights in the United States and abroad. Third parties in both the United States and abroad may have applied for or obtained, or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our products.

Given the vast number of patents in our field of technology, we cannot be certain that we do not infringe existing patents or that we will not infringe patents that may be granted in the future. For example, patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived, so there may be applications of others now pending or recently revived patents of which we are unaware. These applications may later result in issued patents, or the revival of previously abandoned patents, that will prevent, limit or otherwise interfere with our ability to make, use or sell our products. Third parties may, in the future, assert claims that we are employing their proprietary technology without authorization, including claims from competitors or from non-practicing entities that have no relevant product revenue and against whom our own patent portfolio may have no deterrent effect. As we continue to commercialize our products in their current or updated forms, launch new products and enter new markets, competitors may claim that one or more of our products infringe their intellectual property rights as part of business strategies designed to impede our successful commercialization and entry into new markets. The large number of patents, the rapid rate of new patent applications and issuances, the complexities of the technology involved, and the uncertainty of litigation may increase the risk of business resources and management's attention being diverted to patent litigation.

If any third-party patents were asserted against us, even if we believe such claims are without merit, a court may not find in our favor on questions of infringement, validity, enforceability, or priority. A court of competent jurisdiction could hold that the asserted third-party patents are valid, enforceable, and infringed, which could materially and adversely affect our ability to commercialize our products. In order to successfully challenge the validity of any U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, a court of competent jurisdiction may not invalidate the claims of any such U.S. patent. We may choose or, if we are found to infringe a third party's patent rights and we are unsuccessful in demonstrating that such patents are invalid or unenforceable, we could be required to obtain a license from such third party to continue developing, manufacturing, and marketing any of our products. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We also could be forced, including by court order, to cease developing, manufacturing, and commercializing the infringing technology or products. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent or other intellectual property right. There could also be public announcements of the results of hearing, motions, or other interim developments. If securities analysts or investors

perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar material adverse effect on our business, financial condition, results of operations and prospects.

Our industry has experienced substantial litigation and other proceedings regarding patent and other intellectual property rights and lawsuits to protect or enforce our patents and other intellectual property rights could be expensive, time-consuming and unsuccessful.

In addition to infringement claims against us, we may become a party to other types of patent litigation and other proceedings, including post-grant proceedings declared by the United States Patent and Trademark Office, or USPTO, and opposition proceedings in the European Patent Office, regarding intellectual property rights with respect to the OCS. For example, we may be subject to a third-party preissuance submission of prior art to the USPTO, or become involved in post-grant review procedures, oppositions, derivations, reexaminations, *inter partes* review or interference proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete. Patent litigation and other proceedings may also absorb significant management time.

In addition, competitors and other third parties may infringe, misappropriate or otherwise violate our patents and other intellectual property rights. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming and divert the time and attention of our management. In addition, many of our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can.

A court may disagree with our allegations and may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the third-party technology in question. Furthermore, the other party could counterclaim that we infringe their intellectual property or counterclaim that a patent we have asserted against them is invalid or unenforceable, or both. In patent litigation in the United States, counterclaims challenging the validity, enforceability or scope of asserted patents are commonplace. Similarly, third parties may initiate legal proceedings against us seeking a declaration that certain of our intellectual property rights are non-infringed, invalid, or unenforceable. The outcome of any such proceeding is generally unpredictable.

An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. If a defendant were to prevail on a legal assertion of invalidity or unenforceability of our patents covering one of our products, we would lose at least part, and perhaps all, of the patent protection covering such product. Competing products may also be sold in other countries in which our patent coverage might not exist or be as strong. Any of these outcomes would have a material adverse effect on our business.

Because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearing, motions, or other interim developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Even if we ultimately prevail, a court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may not be an adequate remedy. Furthermore, the monetary cost of such litigation and the diversion of the attention of our management could outweigh any benefit we receive as a result of the proceedings. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our business.

If we are unable to establish, maintain or adequately protect our intellectual property rights relating to the OCS, the commercial value of the OCS will be adversely affected and our competitive position could be harmed.

Our success and ability to compete depend in part upon our ability to establish and maintain intellectual property rights covering the OCS in the United States and other countries. We own several patents and patent applications in the United States and corresponding patents and patent applications in a number of foreign jurisdictions. With respect to the patents and patent applications that we own, any patents that have or may issue from our currently issued or pending patent applications would be expected to expire between 2026 and 2043, assuming all required fees are paid.

However, our patents or pending patent applications that mature into issued patents may not include claims with a scope sufficient to protect our OCS technology, any additional features we develop for our OCS technology or any new products. Other parties may have developed technologies that may be related to or competitive with our system, may have filed or may file patent applications and may have received or may receive patents that overlap or conflict with our patent applications, either by claiming the same methods or devices or by claiming subject matter that could dominate our patent position. The patent positions of medical device companies, including our patent position, may involve complex legal and factual questions, and, therefore, the scope, validity and enforceability of any patent claims that we may obtain cannot be predicted with certainty. Our pending and future patent applications may not issue as patents or, if issued, may not issue in a form that will be advantageous to us. Even if issued, our patents may be challenged, narrowed, held unenforceable, invalidated or circumvented, or others could challenge the inventorship, ownership or enforceability of our patents and patent applications, any of which could limit our ability to stop competitors from marketing similar products or limit the term of patent protection we may have for our products, or cause us to lose our right to manufacture, market and sell the OCS products or components of the OCS products. Additionally, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. In addition, the Leahy-Smith Act has transformed the U.S. patent system into a first-to-file system. The first-to-file provisions became effective on March 16, 2013. It is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. For example, the Leahy-Smith Act provides that an administrative tribunal known as the Patent Trial and Appeals Board, or PTAB, provides a venue for challenging the validity of patents at a cost that is much lower than district court litigation and on timelines that are much faster. Proceedings challenging our patents could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. Furthermore, an adverse decision in an interference proceeding can result in a third party receiving the patent right sought by us, which in turn could affect our ability to commercialize our products.

Changes in either patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection, which in turn could diminish the commercial value of the OCS. The laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the United States, and we may encounter significant problems in protecting our proprietary rights in these countries.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- any of our patents, or any of our pending patent applications, if issued, will include claims having a scope sufficient to protect the OCS;
- any of our pending patent applications will issue as patents;
- we will be able to successfully commercialize our products on a substantial scale, if approved, before any relevant patents we may have expire;
- we were the first to make the inventions covered by each of our patents and pending patent applications;
- we were the first to file patent applications for these inventions;
- others will not develop similar or alternative technologies that do not infringe our patents;
- any of our patents will be found to ultimately be valid and enforceable;
- any patents issued to us will provide a basis for an exclusive market for our commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties;
- we will develop additional proprietary technologies or products that are separately patentable; or
- our commercial activities or products will not infringe upon the patents of others.

If we are unable to obtain patent term extension under the Hatch-Waxman Act, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of our products, one or more of the U.S. patents we own or license may be eligible for patent term restoration (also referred to as patent term extension) under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years for a patent covering an approved product as compensation for effective patent term lost as a result of product development and the FDA regulatory review process. However, even if, at the relevant time, we have an issued patent covering our product, we may not be granted an extension if we were, for example, to fail to apply within applicable deadlines or prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the time period of the extension could be less than we request, for example, if we are found to have failed to exercise due diligence during the testing phase or regulatory review process. Only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years after approval and only patents claiming the approved product, a method for using it or a method for manufacturing it may be extended. If we are unable to obtain patent term extension, the term of any such extension is less than we request, or the scope of patent protection is less than we would expect it to be during extension period, the period during which we could enforce our patent rights for the applicable product may be shortened and our competitors may obtain approval of competing products sooner. As a result, our ability to generate revenue could be materially adversely affected. Further, our competitors may launch their product earlier than might otherwise be the case. If we do not have adequate patent protection or other exclusivity for our products, our business, financial condition or results of operations could be materially adversely affected.

We may be unable to enforce our intellectual property rights throughout the world.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. This could make it difficult for us to stop infringement of our foreign patents, if obtained, or the misappropriation of our other intellectual property rights. For example, some foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, some countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries.

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of our intellectual property.

If we are unable to protect the confidentiality of our trade secrets, the value of the OCS and our business and competitive position could be harmed.

In addition to patent protection, we also rely upon trade secret protection, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants and third parties, to protect our confidential and proprietary information. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using commonly accepted physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. Even though we use commonly accepted security measures, trade secret violations are often a matter of state law, and the criteria for protection of trade secrets can vary among different jurisdictions. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. We also have agreements with our employees, consultants and third parties that obligate them to assign inventions made in the course of their work for us to us, however these agreements may not be self-executing, not all employees or consultants may enter into such agreements, or employees or consultants may breach or violate the terms of these agreements, and we may not have adequate remedies for any such breach or violation. If any of our intellectual property or confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, the value of the OCS and our business and competitive position could be harmed.

We may be subject to claims that we or our employees have misappropriated the intellectual property of a third party, including trade secrets or know-how, or are in breach of non-competition or non-solicitation agreements with our competitors and third parties may claim an ownership interest in intellectual property we regard as our own.

Many of our employees and consultants were previously employed at or engaged by other medical device, biotechnology or pharmaceutical companies, including our competitors or potential competitors, hospitals or other third parties. Some of these employees, consultants and contractors may have executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may be subject to claims that we or these individuals have, inadvertently or otherwise, misappropriated the intellectual property or disclosed the alleged trade secrets or other proprietary information, of these former employers, competitors or other third parties. Additionally, we may be subject to claims from third parties challenging our ownership interest in or inventorship of intellectual property we regard as our own, based on claims that our agreements with employees or consultants obligating them to assign intellectual property to us are ineffective or in conflict with prior or competing contractual obligations to assign inventions to another employer, to a former employer, or to another person or entity. Litigation may be necessary to defend against claims, and it may be necessary or we may desire to enter into a license to settle any such claim; however, we may not be able to obtain a license on commercially reasonable terms, if at all. If our defense to those claims fails, in addition to paying monetary damages or a settlement payment, a court could prohibit us from using technologies, features or other intellectual property that are essential to our products, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. An inability to incorporate technologies, features or other intellectual property that are important or essential to our products could have a material adverse effect on our business and competitive position, and may prevent us from selling our products. In addition, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. Any litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our products, which could materially and adversely affect our business, financial condition, operating results, cash flows and prospects.

Risks Related to Government Regulation

Even after approval for the OCS, we are subject to continuing regulation by regulatory authorities and entities in the United States and other countries, and if we fail to comply with any of these regulations, our business could suffer.

Even after approval of the OCS for a specific indication, we are subject to extensive continuing regulation by the FDA and other regulatory authorities and entities. We are subject to Medical Device Reporting regulations, which require us to report to the FDA if we become aware of information that reasonably suggests our product may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device we market would likely cause or contribute to a death or serious injury if the malfunction were to recur. We must report corrections and removals to the FDA where the correction or removal was initiated to reduce a risk to health posed by the device or to remedy a violation of the FDCA caused by the device that may present a risk to health, and maintain records of other corrections or removals. The FDA closely regulates promotion and advertising and all claims that we make for the OCS. If the FDA determines that our promotional materials, training or advertising activities constitute promotion of an unapproved use of the OCS, it could request that we cease or modify our training or promotional materials or subject us to regulatory enforcement actions.

The FDA and state authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement actions by the FDA or state agencies, which may include any of the following sanctions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- recall, suspension or termination of distribution, administrative detention, injunction or seizure of organ-specific OCS Consoles or disposable sets;
- customer notifications or repair, replacement or refunds;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for PMA of new products or for modifications to existing products, and refusing or delaying our requests for PMAs for new intended uses of the OCS;
- withdrawing or suspending PMA approvals that have already been granted, resulting in prohibitions on sales of our products;
- FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries; and

- criminal prosecution.

Any corrective action, whether voluntary or involuntary, as well as potentially defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

For our currently marketed OCS Lung, OCS Heart and OCS Liver, as part of the conditions of approval, we must complete PMA post-approval studies. For example, the OCS Lung TOP Registry must be completed, which is a prospective, single-arm, multi-center, observational study designed to evaluate short- and long-term safety and effectiveness of the OCS Lung for both donor lungs currently utilized and unutilized for transplantation. Our TOP Registry entails submission of regular reports to the FDA. Failure to comply with the conditions of approval can result in material adverse action, including withdrawal of the approval.

We also are required to comply with strict post-marketing obligations that accompany the affixing of the CE mark to medical devices in the European Union. These include the obligation to report incidents which meet the criteria for reporting, and to provide periodic safety update reports and trend reports. Additionally, national competent authorities in the European Union also closely monitor the marketing programs implemented by device companies. The obligations that companies must fulfill concerning premarketing approval of promotional material vary among member states of the European Union. A failure to comply with our obligations in marketing and promoting the OCS in the European Union could harm our business and results of operations.

In addition, certain changes and other events with respect to regulatory approvals may cause an event of default under our CIBC Credit Agreement. See "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—Long-term Debt" in this Annual Report on Form 10-K.

Our products have been and may in the future be subject to product recalls that could harm our reputation and could materially and adversely affect our business, financial condition, operating results, cash flows and prospects.

The OCS must be manufactured in accordance with federal and state regulations, and we or any of our suppliers or third-party manufacturers could be forced to recall our installed systems or suspend or terminate production if we fail to comply with these regulations. The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design, manufacture or labeling. In the case of the FDA, the recall order must be based on an FDA finding that there is a reasonable probability that the device would cause serious adverse health consequences or death. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us could occur as a result of component failures, security failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. The FDA requires that recalls initiated to reduce a risk to health posed by the device or to remedy a violation of the FDCA caused by the device that may present a risk to health be reported to the FDA within 10 working days after the recall is initiated. Companies are required to maintain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, we could be required to report those recalls. A recall announcement could harm our reputation with customers and negatively affect our sales. Additionally, any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results. In addition, the FDA could take enforcement action for failing to initiate a recall or to report recalls when they were conducted, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, seizure of our products or delay in clearance or approval of future products.

We have voluntarily recalled certain OCS products from clinical sites in the past and may need to take similar actions in the future, which may result in notices to regulatory agencies in other jurisdictions. As we continue to expand commercialization of our products and sell OCS products to new customers, the impact of any future product recall increases, and any future product recalls would require greater administrative and response efforts than historical product recalls.

Internationally, the regulatory requirements relating to product defects may vary. A regulatory authority in a specific country may request or require a product recall while others may not. Within the European Union, competent authorities are required without delay to take corrective action against a device (including withdrawal/recall of a device) and notify other national competent authorities, the European Commission and notified bodies (as applicable) of any devices that present an unacceptable risk to the health or safety of patients, users or other persons, or other aspects of the protection of public health. Other non-compliance with the MDR may also lead to corrective action being taken and notifications being sent if the non-compliance is not rectified within a given time period (as determined by the competent authority). Therefore, a recall in one EU member state may lead to recalls in the rest of the European Union.

If we fail to maintain necessary FDA approvals for the OCS, or obtain necessary FDA approval for future uses of the OCS, we will not be able to commercially sell and market the OCS.

The OCS products are medical devices subject to extensive regulation in the United States by the FDA and other federal, state and local authorities. The FDA regulates the design, development, testing, manufacturing, labeling, selling, promoting, distributing, importing, exporting and shipping of the OCS. We have obtained a PMA for each of the OCS Lung, OCS Liver and OCS Heart for both DBD and DCD indications. We received 510(k) clearances for the OCS Lung Solution for cold flush, storage and transportation of donor lungs in July 2021, for the OCS Lung Donor Flush Set in November 2022, and for the OCS Heart Leukocyte Reducing Filter in October 2023.

PMA approval could be withdrawn or other restrictions imposed if post- market data demonstrate safety issues or inadequate performance. The FDA can also require removal of 510(k) cleared devices from the market in case of safety issues.

If we are not able to maintain the necessary regulatory approvals for the OCS, or obtain the necessary regulatory approvals or clearances for future products on a timely basis or at all, our financial condition and results of operations would suffer, possibly materially, and our business might fail.

If we fail to maintain the CE mark in the European Union, Northern Ireland and the UKCA mark (as applicable) in Great Britain, we will not be able to commercially sell and market the OCS in the EU or UK.

In the European Union, we have the right to affix a CE mark for the sale of the OCS Lung, OCS Heart and OCS Liver for lung, heart and liver transplants, respectively. Our notified body, BSI, is based in the Netherlands and issues the certificates that allow CE marking of the OCS products. Our sales in the EU are dependent on obtaining and maintaining the CE mark certifications for each of our OCS products. As required by the 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 order to be able to continue to use the CE mark we will have to meet the conditions set out in the MDR.

Post-Brexit the MDR applies in Northern Ireland in accordance with the Northern Ireland Protocol but does not apply in Great Britain (England, Wales and Scotland). The UK Medical Devices Regulations 2002 (UK MDR 2002) provided a transitional period under which the UK will recognize EU CE marks and the MHRA has confirmed that this will apply potentially until June 30, 2030 (although a consultation is expected that may further extend this period). To be placed on the market in Great Britain after this date, medical devices must have undergone a conformity assessment in accordance with the UK MDR 2002 (as amended or replaced) and have the UKCA mark affixed. However, even devices that benefit from the transition period must still comply with the other requirements of the UK MDR 2002; for example, there are broader registration requirements with the Medicines and Healthcare products Regulatory Agency, or the MHRA, and if the manufacturer is located outside the UK, a UK Responsible Person must be appointed.

To continue to place products on the market in the European Union and United Kingdom, we will need to meet the conditions set out in the EU MDR or UK MDR 2002, as applicable. We might not be able to continue to place the devices on the market in the European Union and/or United Kingdom for any current use of the OCS if we are not able to maintain certifications of our products for their current use under the MDR and/or obtain certification under the UK MDR 2002 when required. If any variation in the uses for which the CE/UKCA mark has been affixed to the OCS requires us to perform further research or to modify the technical documentation required to affix the CE/UKCA mark, our revenue and operating results could be adversely affected and our reputation could be harmed.

If we fail to obtain and maintain regulatory approval in foreign jurisdictions, our market opportunities will be limited.

FDA clearance or approval or a CE mark does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries. However, the failure to obtain clearance or approval in one jurisdiction may have a negative impact on our ability to obtain clearance or approval elsewhere. If we do not obtain or maintain necessary market authorizations to commercialize our products in markets outside the United States, it would negatively affect our overall market penetration. For example, if, as a result of manufacturing error, the efficacy of our products does not meet the standards claimed in the accompanying instructions for use, regulatory authorities could prevent our products from being placed on the market in the European Union, Northern Ireland, Great Britain and elsewhere.

If transplant centers and hospitals cannot obtain adequate reimbursement or funding from governments or third-party payors for purchases of the OCS and additional disposable sets and for costs associated with procedures that use the OCS and the NOP, our prospects for generating revenue and maintaining profitability will suffer materially.

Our prospects for generating revenue and maintaining profitability depend heavily upon the availability of adequate reimbursement or funding in both the United States and other markets for purchases of the OCS and for organ transplant procedures that use the OCS and the NOP.

In the United States, Medicare generally reimburses the facilities in which transplant procedures are performed based upon prospectively determined amounts. For hospital inpatient treatment, the Medicare prospective payment generally is determined by the patient's condition and other patient data and procedures performed during the patient's hospital stay, using a classification system known as MS-DRGs. Prospective rates are adjusted for, among other things, regional differences and whether the hospital is a teaching hospital. Because prospective payments are based on predetermined rates and may be less than a hospital's actual costs in furnishing care, hospitals have incentives to lower their inpatient operating costs by utilizing products, devices and supplies that will reduce the length of patients' hospital stays, decrease labor or otherwise lower their costs.

In addition to these MS-DRG-based payments, Medicare reimburses transplant centers for "reasonable and necessary" organ acquisition costs, which are considered "pass-through" costs distinct from the prospective payment system, and are not based on the payments for the applicable MS-DRG. Pass-through organ acquisition costs include services required for the acquisition of an organ, such as tissue typing, organ preservation, transport of organs, donor evaluation and other acquisition costs. The separate payments for these costs are determined on a reasonable cost basis established through the transplant center's Medicare cost report. The costs incurred by transplant centers for the organ-specific OCS Console, OCS Perfusion Sets and OCS Solutions are classified as organ acquisition costs for which Medicare provides additional reimbursement. However, Medicare does not reimburse for items determined not to be reasonable and necessary for diagnosis or treatment of an illness or injury. The CMS and Medicare contractors who administer Medicare around the country have substantial discretion in determining whether the OCS is reasonable and necessary in this context. Either CMS or a Medicare contractor might determine that Medicare will not cover and reimburse for the cost of the OCS in the absence of reliable clinical data evidencing the benefits to patients of the use of the OCS. The data we collect from our prior, ongoing and planned clinical studies and patient registry may not be deemed sufficient to support a finding by CMS or a Medicare contractor that use of the OCS is reasonable and necessary such that coverage is warranted. Accordingly, Medicare might not reimburse transplant centers for all or a portion of the cost of the OCS. We believe that private insurers and other public insurers in the United States generally will follow the coverage and payment policies of Medicare.

Outside of the United States, reimbursement and funding systems vary significantly by country, and within some countries, by region. Many foreign markets have government managed healthcare systems that govern reimbursement and funding for medical devices and procedures. In the European Union member states, the costs associated with organ transplant procedures may be paid for by national insurance and in some cases private insurers or by both national insurance and private insurers, depending on the priorities established by individual programs. These reimbursement arrangements are subject to complex rules and regulations at the national and regional levels that can vary between member states of the European Union and may require that we perform additional clinical studies to demonstrate that the OCS is superior to existing preservation methods. We have no studies currently planned to collect such clinical data, and any studies of this kind likely would be expensive and lengthy and may not ultimately produce results adequate to secure reimbursement. In some cases, we might not be able to secure adequate reimbursement for the OCS at all or until we have collected additional clinical data supporting the benefits associated with the use of the OCS in transplant procedures. Hospitals or surgeons in countries or regions where separate additional reimbursement or funding for the OCS is not available may determine that the benefits of the OCS do not or will not outweigh the cost of the OCS. Alternatively, we may be required to enter into risk sharing arrangements with payers.

Adoption of our products in the European Union may be hindered if the adoption impedes or otherwise compromises our customer's compliance with the requirements of Directive 2010/53/EU (formerly Directive 2010/45/EU), and the Quality and Safety of Organs Intended for Transplantation Regulations 2012 (Statutory Instrument (SI) 2012 No. 1501) (the Regulations) in the United Kingdom which imposes certain standards on procurement, preservation and transport of organs intended for transplantation. Even where reimbursement or funding is available, in some foreign countries, particularly in the European Union, the pricing of medical devices is subject to governmental control and a determination of affordability for medical devices to be accessed. In these countries, reimbursement and pricing negotiations with governmental authorities can take considerable time after the CE marking of a product. For example, some foreign reimbursement systems provide for limited payments in a given period and, therefore, result in extended payment periods, which could hinder adoption of the OCS for use in transplantation, limiting sales. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, it may not be profitable to sell our products in certain foreign countries, which could negatively affect the long-term growth of our business.

Even if existing reimbursement and funding arrangements of governmental programs and other third-party payors provide for sufficient payments to make purchases of the OCS cost-effective for hospitals, the laws and regulations governing these arrangements are subject to change. The continuing efforts of governments, insurance companies and other payors of healthcare costs to contain or reduce these costs could lead to legislative or regulatory reform of the United States or foreign reimbursement and funding systems in a manner that significantly reduces or eliminates reimbursement for the OCS or for transplant procedures.

If hospitals in the United States or the European Union are not able to obtain reimbursement or funding for the cost of the OCS and additional disposable sets or for transplant procedures generally, they may not have sufficient economic incentives to purchase the OCS. If hospitals or surgeons determine that the benefits of the OCS do not or will not outweigh the initial cost and ongoing expense of the OCS, we might fail to achieve significant sales and may fail to maintain profitability on a sustained basis.

Reimbursement in international markets is likely to require us to undertake country-specific reimbursement activities, including additional clinical studies, which could be time-consuming and expensive and may not yield acceptable reimbursement rates.

In international markets, market acceptance of our products will likely depend in large part on the availability of reimbursement within prevailing healthcare payment systems. Reimbursement and healthcare payment systems in international markets vary significantly by country, and by region in some countries, and include both government-sponsored healthcare and private insurance. We may not obtain international reimbursement approvals in a timely manner, if at all. In addition, even if we do obtain international reimbursement approvals, the level of reimbursement may not be enough to commercially justify expansion of our business into the approving jurisdiction. To the extent we or our customers are unable to obtain reimbursement for products in major international markets in which we seek to market and sell our products, our international revenue growth would be harmed, and our business and results of operations would be adversely affected.

If we modify our products, we may be required to obtain approval of new PMAs or PMA supplements, vary existing CE marking, and may be required to cease marketing or recall any modified products until the required approvals are obtained.

Certain modifications to a PMA-approved device or to its manufacturing processes require approval of a new PMA or a PMA supplement, while other modifications can be reported in an annual report or through a 30-day Notice. The FDA may not agree with our decisions regarding whether a new PMA or PMA supplement is necessary. We may make modifications to our approved devices and manufacturing processes in the future that we believe do not require approval of a new PMA application or PMA supplement, or submission of a 30-day Notice. If the FDA disagrees with our determination and requires us to submit a new PMA, PMA supplement or 30-day Notice for modifications to our previously approved products or manufacturing processes, we may be required to cease marketing or to recall the modified product until we obtain approval or submit the 30-day Notice, and we may be subject to significant regulatory fines or penalties. In addition, the FDA may not approve our products for any future indications that are desirable for commercialization or could require clinical trials to support any modification to the device or any modified indications or claims. Any delay or failure in obtaining required approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

Additionally, any significant change to the quality system or the product range in relation to a CE marked device will require notification to the notified body which certified the product. The notified body will assess the proposed change. We might not be able to have the CE mark varied without taking additional steps, or at all. For example, we might need to conduct additional clinical trials and provide additional technical information to the appropriate notified body before the CE mark can be affixed to the changed product.

If we fail to comply with the FDA's QSMR, or FDA or EU requirements that pertain to clinical trials or investigations, the FDA or the relevant EU competent authority could take various enforcement actions, including halting our manufacturing operations, and our business would suffer.

In the United States, as a manufacturer of a medical device, we are required to demonstrate and maintain compliance with the FDA's QMSR. The QMSR is a complex regulatory scheme that covers the methods and documentation of the design, testing, control, manufacturing, labeling, quality assurance, packaging, storage and shipping of medical devices. The FDA enforces the QMSR through periodic inspections and unannounced "for cause" inspections. The QMSR recently replaced the QSR and incorporates by reference ISO 13485:2016. The QSMR became effective on February 2, 2026, at which time we transitioned to the QMSR. Unlike the QSR, the QMSR gives FDA the authority to inspect management review, quality audits, and supplier audit reports.

We are subject to periodic FDA inspections to determine compliance with the QSMR and pursuant to the Bioresearch Monitoring Program, which have in the past and may in the future result in the FDA issuing Form 483s, including during the conduct of clinical trials. Outside the United States, our products and operations are also often required to comply with standards set by international standards bodies, such as the International Organization for Standardization. For example, in the European Union the MDR includes detailed requirements for clinical investigations, which are in line with the international standard ISO 14155:2020 on good clinical practical, or GCP. Foreign regulatory bodies may evaluate our products or the testing that our products undergo against these standards. The specific standards, types of evaluation and scope of review differ among foreign regulatory bodies. Our failure to comply with FDA or local requirements that pertain to clinical trials/investigations, including GCP requirements, and the QMSR (in the United States), or failure to take satisfactory and prompt corrective action in response to an adverse inspection, could result in enforcement actions, including a warning letter, adverse publicity, a shutdown of or restrictions on our manufacturing operations, delays in approving or clearing our products, refusal to permit the import or export of our product, prohibition on sales of our product, a recall or seizure of our products, fines, injunctions, civil or criminal penalties, or other sanctions, any of which could cause our business and operating results to suffer.

We may not be able to obtain or maintain regulatory qualifications outside the United States, which could harm our business.

Sales of the OCS outside the United States are subject to foreign regulatory requirements that vary widely from country to country. The foreign regulatory approval process generally includes all of the risks associated with obtaining FDA clearance or approval in addition to other risks. Complying with international regulatory requirements can be an expensive and time-consuming process, and approval is not certain. The time required to obtain foreign clearances or approvals may exceed the time required for FDA clearance or approval, and requirements for such clearances or approvals may differ significantly from FDA requirements. Foreign regulatory authorities may not clear or approve our product for the same uses cleared or approved by the FDA. In addition, we may not be able to affix the CE mark to new or modified products and we may fail to obtain any additional regulatory qualifications, clearances or approvals or to comply with additional legal obligations required by the individual member states of the European Union or other countries in which we seek to market the OCS. The FDA also regulates the export of medical devices from the United States. If we are not successful in obtaining and maintaining foreign regulatory approvals or complying with U.S. export regulations, our business will be harmed.

Foreign regulatory agencies periodically inspect manufacturing facilities both in the United States and abroad. While we implement corrective and preventive action related to any inspection observations, we may fail to pass future inspections of our facility by applicable regulatory authorities or entities both in the United States and in other countries. Delays in receiving necessary qualifications, clearances or approvals to market our product outside the United States, or the failure to receive those qualifications, clearances or approvals, or to comply with other foreign regulatory requirements, could limit or prevent us from marketing our products or enhancements in international markets. Additionally, the imposition of new requirements could significantly affect our business and our product, and we might not be able to adjust to such new requirements. If we fail to comply with applicable foreign regulations, we could face substantial penalties and our business, financial condition, operating results, cash flows and prospects could be adversely affected.

We could face product liability suits or regulatory delays due to defects in the OCS, which could be expensive and time-consuming and result in substantial damages payable by us and increases in our insurance rates.

If our products are deemed to be defectively designed, manufactured or labeled, contain defective components, suffer security failures or are hacked, or are counterfeited, we could face substantial and costly litigation by transplant centers that purchase or use the OCS or by their patients or others claiming damages on their behalf. Moreover, transplantations are complex and inherently risky medical procedures. Many of the patients currently on a waiting list for a lung, heart or liver transplant already are very sick, with some of them receiving intensive care. All of these patients have a significant risk of death if they do not receive a transplant. Thus, we may incur substantial liability if the OCS fails to perform as expected and, as a result of this failure, patients do not receive the intended transplants or receive transplants that are not successful. Although death is an anticipated adverse event of the organ transplant population, if the rate of deaths or other serious adverse events using the OCS is greater than expected using conventional transplant procedures, transplant surgeons may cease using the OCS as often or at all, which could materially and adversely affect our business, financial condition, operating results, cash flows and prospects.

Because the OCS represents a novel approach to organ transplantation, a patient or transplant center may choose to name us as a party to a lawsuit relating to the use of the OCS in connection with a planned or completed transplant procedure regardless of whether the OCS caused or contributed to a serious adverse event or death of a patient. Any claim, whether or not we are ultimately successful, could divert management's attention from our core business, be expensive to defend and result in sizable damage awards against us.

Currently, we maintain global product liability insurance covering damages of up to $10 million per occurrence for both the human clinical and commercial use of our product. We also maintain local insurance policies as required. Our current insurance coverage might not be sufficient to cover future claims and is subject to deductibles. Moreover, in the future, we may not be able to obtain insurance in amount or scope sufficient to provide us with adequate coverage against potential liabilities. Any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, could harm our reputation in the industry, impair our current or future preclinical studies or clinical trials, hinder acceptance of our products in the market and reduce product sales. Furthermore, we would need to pay any product liability losses in excess of our insurance coverage or within the deductibles provided under our insurance policies applicable to the claim out of cash reserves, which could materially and adversely affect our business, financial condition, operating results, cash flows and prospects.

The FDA has recognized the threat of cyberattacks on medical devices, and imposes requirements on medical device manufacturers to ensure the cybersecurity of devices. Hackers and other third parties may try to circumvent security controls on an OCS to gain access to information on the OCS, alter the way an OCS operates, to act as a trojan horse or other entry point to other systems that could lead to those systems suffering cybersecurity breaches or attacks, or to cause harms to transplanted organs or individuals. If our security controls fail to fully protect the OCS and the information on it, we could suffer reputational harm, could undergo regulatory investigations and enforcement, or could have claims brought against us.

Third parties may attempt to produce counterfeit versions of our products, which may harm our ability to sell the OCS and its components, negatively affect our reputation or harm patients and subject us to product liability.

Counterfeit medical devices are an increasing presence on the market. Third parties may seek to develop, manufacture, distribute and sell systems that we believe infringe our proprietary rights, which would compete against the OCS and impair our ability to sell the OCS in jurisdictions in which our proprietary rights are not upheld. In addition, counterfeit products may be promoted in a way that misleads consumers into believing they are affiliated with us. If a counterfeit version of the OCS were to appear on the market, we would expect to be obliged to verify all OCS products currently on the market, and possibly to withdraw all OCS products from the market while verifications are made. We also might be named in a lawsuit relating to any side effects or fatalities allegedly related to the use of a counterfeit OCS irrespective of whether the counterfeit device in fact contributed to such an adverse event or whether we were aware of the existence of the counterfeit device.

Improper marketing or promotion of our products or misuse or off-label use of the OCS may harm our reputation in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business.

Our OCS products have been approved for marketing in the United States, European Union and other jurisdictions for specific indications, and our promotional materials and training methods must comply with regulatory requirements in the countries where they are sold. We train our commercial team to not promote the OCS for uses outside of the approved indications for use/intended purpose, known as "off-label uses." We cannot, however, prevent a surgeon from using the OCS off-label, when in the surgeon's independent professional medical judgment he or she deems it appropriate. There may be increased risk of injury to patients if surgeons attempt to use the OCS off-label. Furthermore, the use of the OCS for indications other than those approved by the FDA or by any foreign regulatory body or for which they are CE marked may not effectively treat such conditions, which could harm our reputation in the marketplace among surgeons and patients.

If the FDA or any foreign regulatory body determines that our promotional materials or training constitute promotion of an off-label use, or that the materials or training are false or misleading, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance or imposition of a warning letter, an untitled letter (which is used for violations that do not necessitate a warning letter), injunction, seizure, civil fine or criminal penalties. In the EU the MDR expressly prohibits misleading claims in the form of off-label promotion and the MDR grants enforcement powers to national competent authorities. It is also possible that other federal, state or foreign enforcement authorities might take action under other regulatory authority, such as false claims laws or consumer protection laws, if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment of our operations.

In addition, surgeons may misuse the OCS or use improper techniques if they are not adequately trained, potentially leading to unsatisfactory patient outcomes, patient injuries, negative publicity and an increased risk of product liability. If the OCS is misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. Similarly, in an effort to decrease costs, surgeons may also reuse the component and accessories of the OCS that are intended for a single use or may purchase reprocessed OCS components from third-party reprocessors in lieu of purchasing new components from us, which could result in product failure and liability. As described above, product liability claims could divert management's attention from our core business, be expensive to defend and result in sizeable damage awards against us that may not be covered by insurance.

Legislative or regulatory reforms in the United States or other jurisdictions may make it more difficult and costly for us to obtain regulatory clearances or approvals for our products or to manufacture, market or distribute our products after clearance or approval is obtained.

From time to time, legislation is drafted and introduced in the U.S. Congress that could significantly change the statutory provisions governing the regulation of medical devices. In addition, FDA regulations and guidance may be revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new statutes, regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of any future products or make it more difficult to obtain approval for, manufacture, market or distribute our products. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require additional testing prior to obtaining clearance or approval; changes to manufacturing methods; recall, replacement or discontinuance of our products; or additional record keeping.

In the EU, the MDR repealed and replaced the Medical Devices Directive (93/42/EEC) with effect from May 26, 2021. Although the MDR now applies so all new devices placed on the market must be CE marked under it, the transition periods provided by the MDR may extend the validity of the certificates issued by notified bodies for medical devices under the Medical Devices Directive before May 26, 2021 provided that certain conditions are satisfied. As such, devices CE marked under the Medical Devices Directive may continue to be placed on the EU market until the end of December 2027 or 2028 (depending on the class of device) and provided the manufacturer satisfies certain requirements, including that there are no significant changes in the design and intended purpose of these devices. Post-Brexit the MDR applies in Northern Ireland in accordance with the Northern Ireland Protocol but does not apply in Great Britain (England, Wales and Scotland). The UK Medicines and Healthcare products Regulatory Agency (MHRA) has provided a transitional period under which the UK will recognize EU CE marks under the EU MDR potentially until June 30, 2030 depending on the class of device and subject to certain conditions and depending on the type of device. To be placed on the market in Great Britain after this date, medical devices must have undergone a conformity

assessment in accordance with UK legislation and have the UKCA mark affixed (although the UK Government has announced its intent to consult on the indefinite recognition of the CE mark, which may change the time frame for UKCA mark requirements).

All of our products that were previously certified under the Medical Devices Directive, including OCS Heart, OCS Liver and OCS Lung systems, which includes the OCS Console, the OCS disposables, and the OCS solution additives, have now been recertified under the MDR. 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.

We also recognize that our products may need to be certified and have a UKCA mark affixed to be placed on the market in Great Britain in the future. However, although neither the EU MDR nor EU IVDR apply in Great Britain, the national UK medical devices rules currently allow manufacturers to place devices CE marked under the EU MDR or EU IVDR (including their relevant transition periods) on the market in Great Britain, potentially up until June 30, 2030, depending on the class of device and provided certain conditions are met. The UK Government has recently adopted post-market surveillance legislation and plans to adopt further changes to pre-market medical device regulation in 2026. This might lead to substantial changes in the regulatory framework/requirements imposed on medical devices for the Great Britain market. We will need to continue to monitor the developments in the UK to assess how they impact our devices sold in Great Britain.

We are subject to certain federal, state and foreign fraud and abuse laws, health information privacy and security laws and transparency laws, which, if violated, could subject us to substantial penalties. Additionally, any challenge to or investigation into our practices under these laws could cause adverse publicity and be costly.

There are numerous U.S. federal and state, as well as foreign, laws pertaining to healthcare fraud and abuse, including anti-kickback, false claims and physician transparency laws. Our business practices and relationships with providers are subject to scrutiny under these laws. We may also be subject to privacy and security regulation related to patient, customer, employee and other third-party information by both the federal government and the states and foreign jurisdictions in which we conduct our business. The healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual or furnishing or arranging for a good or service, for which payment may be made, in whole or in part, under federal healthcare programs, such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. The U.S. government has interpreted this law broadly to apply to the marketing and sales activities of manufacturers. Moreover, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Violations of the federal Anti-Kickback Statute may result in substantial civil monetary and criminal penalties. Similarly, violations can result in exclusion from participation in government healthcare programs, including Medicare and Medicaid;

- the federal civil and criminal false claims laws and civil monetary penalties laws, including the federal civil False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other federal healthcare programs that are false or fraudulent. These laws can apply to manufacturers who provide information on coverage, coding, and reimbursement of their products to persons who bill private payors. Private individuals can bring False Claims Act “qui tam” actions, on behalf of the government and such individuals, commonly known as “whistleblowers,” may share in amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the federal civil False Claims Act, the government may impose substantial civil fines and penalties, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;

- the federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary’s decision to order or receive items or services reimbursable by the government from a particular provider or supplier;

- HIPAA, which created additional federal criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;

- the federal Physician Payments Sunshine Act, which require certain applicable manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program to report annually to CMS information related to payments and other transfers of value to physicians and other prescribers and teaching hospitals. Applicable manufacturers are required to submit annual reports to CMS. Failure to submit required information may result in substantial civil monetary penalties;

- many countries in which we operate have laws with extra-territorial effect; those laws apply to our operations outside the relevant country, to the extent they are breached. Examples of such laws include: the FCPA, the Bribery Act and the GDPR. The extra-territorial effect of those laws affects our sales and marketing strategy, since in many countries healthcare professionals are officers of the state. This is particularly important in the context of bribery offences, which in the UK and in the United States include the offence of bribing a foreign public official. Failure by our sales staff to comply with those laws may result in criminal and civil penalties and damage our reputation; and
- analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any private payor, including commercial insurers or patients; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm customers; foreign and state laws, including the GDPR, governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; and state laws related to insurance fraud in the case of claims involving private insurers.

These laws and regulations, among other things, constrain our business, marketing and other promotional activities by limiting the kinds of financial arrangements, including sales programs, we may have with customers, physicians or other potential purchasers of our products. In particular, these laws will influence, among other things, how we structure our sales offerings, including discount and rebate practices, customer support, education and training programs, and physician consulting and other service arrangements. Due to the breadth of these laws, the narrowness of statutory exceptions and regulatory safe harbors available, and the range of interpretations to which they are subject, it is possible that some of our current or future practices might be challenged under one or more of these laws.

To enforce compliance with the healthcare regulatory laws, certain enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. For example, the member states of the European Union closely monitor perceived unlawful marketing activity by companies, including inducement to prescribe and the encouragement of off-label use of devices. Responding to investigations can be time-and resource-consuming and can divert management's attention from the business. Additionally, as a result of these investigations, healthcare companies and healthcare providers may have to agree to additional compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity and be costly to respond to. If our operations are found to be in violation of any of the healthcare laws or regulations described above or any other healthcare regulations that apply to us, we may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, imprisonment, contractual damages, reputational harm, disgorgement and the curtailment or restructuring of our operations. Moreover, industry associations closely monitor the activities of their member companies. If these organizations or national authorities were to name us as having breached our obligations under their laws, regulations, rules or standards, our reputation would suffer and our business, financial condition, operating results, cash flows and prospects could be adversely affected.

Failure to comply with anti-bribery, anti-corruption, and anti-money laundering laws, including the FCPA, as well as export control laws, customs laws, sanctions laws and other laws governing our operations could result in civil or criminal penalties, other remedial measures and legal expenses.

As we grow our international presence, we are increasingly subject to anti-corruption laws, anti-money laundering laws, export control laws, customs laws, sanctions laws and other laws and regulations imposed by the United States, the European Union and other governments and organizations in countries where we operate. The U.S. Departments of Justice, Commerce, and State, and the U.S. Treasury and other federal agencies and authorities, may seek to impose a broad range of civil and criminal penalties against corporations and individuals for violations of sanctions laws, export control laws, the FCPA, and other federal statutes and regulations, including those established by the Office of Foreign Assets Control, or OFAC. In addition, the Bribery Act prohibits both domestic and international bribery across both private and public sectors. We have implemented policies and procedures designed to ensure compliance by us and our directors, officers, employees, representatives, consultants, and agents with the FCPA, OFAC restrictions, the Bribery Act and other export control, anti-corruption, anti-money-laundering and anti-terrorism laws and regulations. However, given that we sell our products to government or government-affiliated entities, we may be exposed to heightened risk of potential violations of the FCPA, the Bribery Act, or other anti-bribery or anti-corruption laws. In addition, various government agencies may require export licenses, or may seek to impose modifications to business practices,

including cessation of business activities in sanctioned countries or with sanctioned persons or entities, and modifications to compliance programs, which may increase costs. Violations of the FCPA, OFAC restrictions, the Bribery Act or other export control, anti-corruption, anti-money laundering and anti-terrorism laws or regulations may result in severe criminal or civil sanctions, and other potential liabilities, which could have a material adverse effect on our business, financial condition, and results of operations.

We are subject to, and may in the future become subject to additional, U.S., state and foreign laws and regulations imposing obligations on how we collect, store, process or share information concerning individuals. Our actual or perceived failure to comply with such obligations could harm our business. Complying with such laws could also impair our efforts to maintain and expand our customer base, and thereby decrease our revenue.

In the conduct of our business, we may at times collect, process or share data concerning individuals, including health-related personal data. The U.S. federal government and various states have adopted or proposed laws, regulations, guidelines and rules for the collection, distribution, use and storage of personal information of individuals. We may also be subject to U.S. federal rules, regulations and guidance concerning cybersecurity for medical devices, including guidance from the FDA. State privacy and cybersecurity laws vary and, in some cases, can impose more restrictive requirements than U.S. federal law. For example, the CCPA affords California residents expanded privacy rights and protections, including civil penalties for violations and statutory damages under a private right of action for data security breaches. These protections were expanded by CPRA, and more than a dozen states now have similar laws. Where state laws are more protective, we must comply with the stricter provisions. In addition to fines and penalties that may be imposed for failure to comply with state law, some states also provide for private rights of action to individuals for misuse of personal information. Our ongoing efforts to comply with evolving laws and regulations may be costly and require ongoing modifications to our policies, procedures and systems. Failure to comply with laws regarding data protection would expose us to risk of enforcement actions and penalties under such laws. Even if we are not determined to have violated applicable data laws, government investigations into these issues can be expensive and lengthy and generate adverse publicity, which could harm our business, financial condition, results of operations or prospects.

The EEA and the UK, as well as other international jurisdictions, also have laws and regulations dealing with the collection, use and processing of personal data concerning individuals. Those laws are often more restrictive than analogous privacy laws in the United States. For example, we are subject to the requirements of the GDPR, which imposes more stringent administrative requirements for controllers and processors of personal data, including, for example, demanding timelines for notifying personal data breaches, limitations on retention of personal information, stringent requirements pertaining to the processing of health data, rules regulating pseudonymized (i.e., key-coded) data, additional obligations when we contract with service provider processors, and robust rights for individuals with respect to their personal data. The GDPR also provides that EU member states may impose further conditions on the processing of personal data, including genetic, biometric and health data, which could limit our ability to use and share personal data or cause our costs to increase, and harm our business and financial condition. If we do not comply with our obligations under the GDPR, we could be exposed to enforcement activity from EU regulators, who may impose substantial fines, and civil litigation. In addition, EU law restricts transfers of personal data to the United States unless certain requirements are met. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. For example, in July 2020, the Court of Justice of the European Union invalidated the U.S.-EU Privacy Shield Framework, which has since been replaced by the EU-U.S. Data Privacy Framework. There continues to be heightened scrutiny of data transfers from the EEA and the UK to the United States generally, as well as other jurisdictions, and this may increase our costs of compliance with data privacy legislation. We rely on a mixture of mechanisms to transfer personal data from our European business to the United States. We are also subject to the laws of each EU member state implementing any EU directive applicable to our processing activities, including Directing 2002/58/EC.

As a result of the UK's decision to leave the EU (i.e., Brexit), we are subject to the requirements of the UK Data Protection Law as amended and superseded from time to time. UK Data Protection Law means: (i) the GDPR as it forms part of UK law by virtue of section 3 of the European Union (Withdrawal) Act 2018; (ii) the UK Data Protection Act 2018; (iii) the UK Privacy and Electronic Communications (EC Directive) Regulations 2003 as they continue to have effect by virtue of section 2 of the European Union (Withdrawal) Act 2018; and (iv) any other laws pertaining to data protection in force in the UK from time to time applicable (in whole or in part) to us.

Any actual or perceived failure by us or the third parties with whom we work to comply with data privacy or security laws, policies, legal obligations or industry standards, or any security incident that results in the unauthorized release or transfer of information concerning individuals, may result in governmental enforcement actions and investigations, including by European data protection authorities and U.S. federal and state regulatory authorities, fines and penalties, litigation and/or adverse publicity, including by consumer advocacy groups, and could cause our customers, their patients and other healthcare professionals to lose

trust in us, which could harm our reputation and have a material adverse effect on our business, financial condition and results of operations.

Healthcare policy changes, including recently enacted or potential future legislation reforming the U.S. healthcare system, could harm our business, financial condition and results of operations.

We operate in a highly regulated industry. The U.S. and state governments continue to propose and pass legislation or take administrative action that may affect the availability and cost of healthcare. Healthcare reform initiatives could harm our business, financial condition and results of operations. There is substantial uncertainty as to how, if at all, the current administration will seek to revise the policies of the FDA and other government agencies. While many of the current administration's proposed policies appear to be focused on deregulation, the administration and federal government could adopt legislation, regulation, or policy that adversely affects our business or creates a more challenging and costly environment to pursue future clinical trials for, or expand commercialization of, our OCS products. Additionally, because one objective of the current administration appears to be to decrease spending in the federal government, the FDA could face staff reductions, which could impact the FDA's ability to engage in routine regulatory and oversight activities and result in delays or limitations on our ability to proceed with clinical development programs and obtain regulatory approvals. It is difficult to predict how executive actions that may be taken under the current administration may affect the FDA's ability to exercise its regulatory authority. Inadequate funding for the FDA or other government agencies could impact the timeliness of responses or action and may slow the time necessary for agency reviews, which in turn would have a material adverse effect on our business, financial condition and results of operations

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs and improve access to transplantation. There have been and will likely continue to be ongoing healthcare reform efforts. These reform efforts have and may continue to focus on coverage and payment for organ procurement and transplant. For example, the Centers for Medicare & Medicaid Services issued regulations in 2020 and 2021 that revised Medicare conditions of participation for organ procurement organizations as well as organ acquisition payment policies for organ procurement organizations, transplant centers and donor hospitals. In addition, in 2023, the Securing the U.S. Organ Procurement and Transplantation Network Act was signed into law, which allows HRSA to award multiple grants, contracts or cooperative agreements to support the operation of the OPTN. It also specifies that the awards to operate the OPTN shall be distinct from awards to support the networks' board of directors. In September 2024, HRSA began awarding contracts aimed at supporting the multi-vendor model.

HRSA continues to implement efforts to improve and modernize the OPTN, including enhancements to patient data on organ procurement, expanded transparency through a publicly accessible data dashboard for allocation out of sequence (AOOS) events, expanded outreach and financial support for living organ donors, and a new OPTN fee collection process whereby HRSA directly collects and distributes patient registration fees under authorities originally granted by the 2025 Full-Year Continuing Appropriations and Extensions Act and extended by the 2026 Continuing Appropriations, Agriculture, Legislative Branch, Military Construction and Veterans Affairs, and Extensions Act. The impact that HRSA's initiatives and the Securing the U.S. Organ Procurement and Transplantation Network Act may have on our business, including on our NOP, is uncertain at this time.

We expect additional state and federal healthcare policies and reform measures to be adopted in the future, any of which could limit coverage or reimbursement for healthcare products and services or otherwise result in reduced demand for the OCS or additional pricing pressure and have a material adverse effect on our industry generally and on our customers. Any changes of, or uncertainty with respect to, coverage or reimbursement of services provided by organ procurement organizations, transplant centers or hospitals could affect demand for the OCS, which in turn could have a material adverse effect on our business, financial condition and results of operations.

In addition, other broader legislative changes have been adopted that could have an adverse effect upon, and could prevent, our products' commercial success. The Budget Control Act of 2011, as amended, or the Budget Control Act, includes provisions intended to reduce the federal deficit, including reductions in Medicare payments to providers through fiscal year 2032 (except May 1, 2020 to March 31, 2022). Any significant spending reductions affecting Medicare, Medicaid, or other publicly funded or subsidized health programs, or any significant taxes or fees imposed as part of any broader deficit reduction effort or legislative replacement to the Budget Control Act, or otherwise, could have an adverse impact on our anticipated product revenue.

Our business activities involve the use of hazardous materials, which require compliance with environmental and occupational safety laws regulating the use of such materials. If we violate these laws, we could be subject to significant fines, liabilities or other adverse consequences.

Our research and development programs involve the controlled use of hazardous materials. Accordingly, we are subject to international, federal, state and local laws governing the use, handling and disposal of these materials. Although we believe that our safety procedures for handling and disposing of these materials comply in all material respects with applicable regulations, we

cannot eliminate the risk of accidental contamination or injury from these materials. In the event of an accident or failure to comply with environmental laws, we could be held liable for damages that result, and any such liability could exceed our assets and resources. Our general liability and umbrella insurance policies provide for coverage up to annual aggregate limits of $2 million per occurrence but exclude coverage for liabilities relating to the release of pollutants. The insurance that we currently hold may not be adequate to cover all liabilities relating to accidental contamination or injury due to pollution conditions or other extraordinary or unanticipated events. Furthermore, an accident could damage or force us to shut down our operations.

U.S. federal government shutdowns could adversely affect our business, financial condition, operating results, cash flows and prospects.

Congressional disagreement over the federal budget and the maximum amount of debt the federal government is permitted to have outstanding (commonly referred to as the "debt ceiling") caused the U.S. federal government to recently shut down. Prolonged government shutdowns impact us and our customers, vendors and others we do business with. During a U.S. government shutdown, certain regulatory agencies, such as the FDA, FAA and the SEC, have had to furlough critical FDA, FAA, SEC, and other government employees and stop critical activities. In addition, the current administration has stated that it could eliminate jobs at federal agencies. Furthermore, although air traffic controllers are deemed to be essential employees who are required to continue to work during a government shutdown, in past shutdowns, including the most recent shutdown, air traffic controllers have more frequently called out of work, creating staffing shortages that affect flights and which could impact our aviation services.

Product development and regulatory activities depend on the continuity and capacity of the FDA and other health authorities. Disruptions at the FDA and other agencies may slow the time necessary for new products to be reviewed and/or approved by necessary government agencies, which could adversely affect our business. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in the past as a result. In addition, government funding of the FDA and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. If there are future shutdowns, our business, financial condition, operating results, cash flows or prospects could be adversely affected.

Risks Related to Our Common Stock and General Risks

The market price of our common stock has been and may continue to be volatile and could subject us to securities class action litigation.

During the year ended December 31, 2025, the price per share of our common stock has ranged from as low as $55.00 to as high as $156.00. Some of the factors that may cause the market price of our common stock to fluctuate include:

- price and volume fluctuations in the overall stock market;
- volatility in the market price and trading volume of comparable companies;
- actual or anticipated changes in our earnings or fluctuations in our operating results or in the expectations of securities analysts;
- results of post-approval studies or clinical trials relating to next generation products for the OCS or competing products;
- failure or discontinuation of any of our product development and research programs;
- regulatory or legal developments in the United States and other countries, including changes in the healthcare payment systems;
- results or changes in the status of, or developments relating to, applications for regulatory approvals or clearances for the OCS or competing products;
- our announcements or our competitors' announcements of new products, procedures or therapies;
- departure of key personnel;
- litigation involving us or that may be perceived as having an adverse effect on our business;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- market conditions in the medical device and biotechnology sectors;

- changes in general economic, industry and market conditions and trends;
- investors' general perception of us; and
- sales of large blocks of our stock.

The market for medical device and biotechnology companies, in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Because of the potential volatility of our stock price, we may become the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management's attention and resources from our business.

If securities or industry analysts issue an adverse or misleading opinion regarding our business or do not publish research or publish unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that industry or securities analysts or activist investors or other third parties publish about us or our business. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. Moreover, if any of the analysts who cover us issue an adverse or misleading opinion regarding us, or if activist investors continue to, our business model or our stock performance, or if our operating results fail to meet the expectations of the investor community, one or more of the analysts who cover our company may change their recommendations regarding our company, and our stock price could decline.

We have adopted anti-takeover provisions in our restated articles of organization and amended and restated bylaws and are subject to provisions of Massachusetts law that may frustrate any attempt to remove or replace our current board of directors or to effect a change of control or other business combination involving our company.

Our restated articles or organization and amended and restated bylaws and certain provisions of Massachusetts law may discourage certain types of transactions involving an actual or potential change of control of our company that might be beneficial to us or our security holders. For example, our amended and restated bylaws grant the chairperson presiding over any meetings of shareholders the right to adjourn such meeting. Our board of directors also may issue shares of any class or series of preferred stock in the future without shareholder approval and upon such terms as our board of directors may determine. The rights of the holders of our common stock will be subject to, and may be harmed by, the rights of the holders of any class or series of preferred stock that may be issued in the future. Massachusetts state law also prohibits us from engaging in specified business combinations unless the combination is approved or consummated in a prescribed manner. These provisions, alone or together, could delay hostile takeovers and changes in control of our company or changes in our management.

Our restated articles of organization designate the Business Litigation Session of the Superior Court of Suffolk County, Massachusetts (or, if and only if the Business Litigation Session of the Superior Court of Suffolk County, Massachusetts lacks jurisdiction, another state or federal court located within the Commonwealth of Massachusetts) as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our shareholders, which could discourage lawsuits against us and our directors and officers.

Our restated articles of organization designate the Business Litigation Session of the Superior Court of Suffolk County, Massachusetts (or, if and only if the Business Litigation Session of the Superior Court of Suffolk County, Massachusetts lacks jurisdiction, another state or federal court located within the Commonwealth of Massachusetts) as the sole and exclusive forum for any action under Massachusetts statutory or common law: brought derivatively on our behalf, asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our shareholders, asserting a claim arising pursuant to any provision of the Massachusetts Business Corporation Act or asserting a claim governed by the internal affairs doctrine, in all cases subject to the court's having personal jurisdiction over the indispensable parties named as defendants. In addition, our restated articles of organization provide that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the foregoing provisions. This provision will not apply to actions arising under the Exchange Act, or the Securities Act of 1933, as amended, or the Securities Act. Additionally, this exclusive forum provision may limit the ability of our shareholders to bring a claim in a judicial forum that such shareholders find favorable for disputes with us or our directors or officers, which may discourage such lawsuits against us and our directors and officers. Alternatively, if the Business Litigation Session of the Superior Court of Suffolk County, Massachusetts or a court outside of Massachusetts were to find this exclusive forum provision inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings described above, we may incur additional costs associated with resolving such matters in other venues or jurisdictions, which could materially and adversely affect our business, financial condition, operating results, cash flows and prospects.

We have identified a material weakness in our internal control over financial reporting, and we may identify additional material weaknesses in the future. If we fail to maintain effective internal control over financial reporting and effective disclosure controls and procedures, we may not be able to accurately report our financial results in a timely manner or prevent fraud, and current and potential shareholders may lose confidence in our financial and other public reporting, which would harm our business and have a negative effect on the trading price of our common stock.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, as amended, our management is required to report on, and our independent registered public accounting firm is required to attest to, the effectiveness of our internal control over financial reporting. This assessment includes disclosure of any material weakness identified by our management in our internal control over financial reporting. In addition, we are required to comply with the SEC's rules implementing Section 302 of the Sarbanes-Oxley Act, which requires management to certify financial and other information in our quarterly and annual reports, and we are required to disclose significant changes made in our internal controls and procedures on a quarterly basis.

As described in Item 9A – Controls and Procedures elsewhere in this Annual Report on Form 10-K, in connection with the audit of our financial statements for the year ended December 31, 2024, we identified a material weakness in our internal control over financial reporting with regard to a deficiency in our control over inventory movement within our manufacturing network. Management, with the oversight of the audit committee of our board of directors, is actively implementing a remediation plan to address the material weakness in internal control over financial reporting. The remediation plan includes the design and implementation of new control activities, including system-based controls, to ensure that inventory movements are recorded in a timely and accurate manner throughout the reporting period, as well as strengthening review and approval procedures. However, our remediation efforts with respect to our identified material weakness may be inadequate. The elements of our remediation plan can only be accomplished over time and our remediation plan may not ultimately have its intended effects.

In addition, if we identify any additional material weaknesses or significant deficiencies in our internal control over financial reporting, we may not be able to remediate such material weaknesses or significant deficiencies identified in a timely manner or maintain all of the controls necessary to remain in compliance with our reporting obligations or to prevent fraud. If we identify any additional material weaknesses in our internal controls over financial reporting or if we are unable to comply with the requirements of Section 404 in a timely manner or assert that our internal controls over financial reporting are effective, or if our independent registered public accounting firm is unable to express an unqualified opinion as to the effectiveness of our internal control over financial reporting in future periods, investors may not have a complete understanding of our operations or may lose confidence in our financial and other public reporting. Our future access to capital markets could be restricted and we may face other consequences imposed by the SEC or Nasdaq. Such events would harm our business and have a negative effect on the trading price of our common stock.

Changes in accounting standards and subjective assumptions, estimates and judgments by management related to complex accounting matters could significantly affect our financial condition and results of operations.

Accounting principles and related pronouncements, implementation guidelines and interpretations we apply to a wide range of matters that are relevant to our business, including, but not limited to, revenue recognition, leases and stock-based compensation, are complex and involve subjective assumptions, estimates and judgments by our management. Changes in accounting pronouncements or their interpretation or changes in underlying assumptions, estimates or judgments by our management could significantly change our reported or expected financial performance.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

We have adopted processes designed to identify, assess and manage material risks from cybersecurity threats to our information systems. Those processes include response to and an assessment of internal and external threats to the security, confidentiality, integrity and availability of our data and systems along with other material risks to our operations, at least annually or whenever there are material changes to our systems or operations. These processes include plans to be used in the event of a cybersecurity incident, including incident reporting and business continuity. As part of our risk management process, we engage outside providers to conduct periodic internal and external penetration testing. We store our data in cloud environments with security appropriate to the data involved and have adopted controls around, among other things, vendor risk assessment, access and acceptable use and backup and recovery. Although we have experienced cybersecurity incidents in the past, cybersecurity threats, including as a result of previous cybersecurity incidents, have not materially affected the Company, including its business strategy, results of operations or financial condition.

Our executive team, along with our Audit Committee, assess and manage cybersecurity risk as part of our overall business strategy, financial planning and capital allocation. Our Audit Committee and Board of Directors engage with members of the executive team and are briefed on cybersecurity risks at least once each calendar year and with respect to any potentially material cybersecurity incidents. Our Chief Information Officer reports regularly, and at least annually, to our Audit Committee and such report may address overall assessment of our compliance with our cybersecurity policies, and include topics such as risk assessment, risk management and control decisions, service provider arrangements, test results, security incidents and responses, and recommendations for changes and updates to policies and procedures. Our Chief Information Officer has served in various senior information technology roles, responsible for information security for over 20 years.

Item 2. Properties.

Our corporate headquarters and manufacturing and clinical training facilities are located in Andover, Massachusetts, where we lease 135,199 square feet of space, including a 10,500 square foot laboratory and training facility and a 7,900 square foot ISO Class 7 cleanroom facility. The leases for these facilities expire on December 31, 2027 with an option to extend the term beyond the expiration date for one additional period of five years. On January 8, 2026, we entered into a lease agreement with BioMed Realty for the lease of approximately 498,286 square feet of space located at 188 Assembly Park Drive, Somerville, Massachusetts for our principal executive offices and for research and development, laboratory, manufacturing and assembly, vivarium, office and related uses. The premises is expected to serve as our new headquarters and we expect to transition certain of our operations on or before January 1, 2028, ultimately replacing our existing headquarters in Andover, Massachusetts. Base rent begins to accrue in the first quarter of 2028. The lease will expire one hundred ninety-two (192) months from the date base rent begins to accrue, unless earlier terminated. In connection with our acquisition of Summit, we acquired a 20-year operating lease with one 10-year renewal option, for space at the Bozeman Yellowstone International Airport in Bozeman, Montana where we constructed a commercial aircraft hangar that we use for our flight school aircraft and office space for personnel located in Bozeman. We have a designated maintenance hub for our aircraft in Dallas, Texas under a lease that expires in 2027, subject to certain early termination provisions. We also lease office space at various locations in the United States for our NOP and hangar space for our aircraft under both short-term and long-term leases. We have additional distribution, commercial and research and development operations in Europe.

We believe that these facilities are adequate to meet our current needs, although we may seek to negotiate new leases or evaluate additional or alternate space for our operations. We believe appropriate alternative space would be readily available on commercially reasonable terms.

Item 3. Legal Proceedings.

On February 14, 2025, a class action captioned Jewik v. TransMedics Group, Inc., et al., Case No. 1:25-cv-10385, was filed against the Company and certain of its current and former officers in the U.S. District Court for the District of Massachusetts. The complaint purported to assert claims pursuant to Sections 10(b) and 20(a) of the Exchange Act and SEC Rule 10b-5 promulgated thereunder, seeking unspecified damages on behalf of a putative class of investors who purchased or otherwise acquired the Company's shares between the Class Period, February 28, 2023 and January 10, 2025.

On April 2, 2025, another purported stockholder filed a putative class action lawsuit against the Company and certain of its current and former officers, also in the U.S. District Court for the District of Massachusetts (Collins v. TransMedics Group, Inc., et al., Case No. 1:25-cv-10778). The Collins complaint alleged claims substantially similar to those alleged in the Jewik action and also sought unspecified damages. On May 22, 2025, the court consolidated the Jewik and Collins actions and appointed the Peace Officers' Annuity and Benefit Fund of Georgia and Oguzhan Altun as lead plaintiffs, or the Lead Plaintiffs.

On August 8, 2025, Lead Plaintiffs filed a consolidated amended complaint. Like the earlier-filed complaints, the amended complaint purports to assert claims pursuant to Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5, on behalf of a putative class of investors who purchased or otherwise acquired the Company's shares during the Class Period. Lead Plaintiffs seek unspecified damages allegedly caused by purported misstatements and omissions contained in our 2022 Annual Report, certain earnings calls, and other public statements. The amended complaint claims these alleged statements and omissions operated to artificially inflate the price paid for our common stock during the Class Period. On October 7, 2025, defendants filed a motion to dismiss the amended complaint for failure to state a claim. Lead Plaintiffs' filed their response to the motion on November 21, 2025, and defendants' filed a reply in further support of their motion on December 22, 2025. We cannot anticipate when the court will rule on that motion.

From time to time, we may be involved in other legal proceedings or investigations, which could have an adverse impact on our reputation, business and financial condition and divert the attention of our management from the operation of our business.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

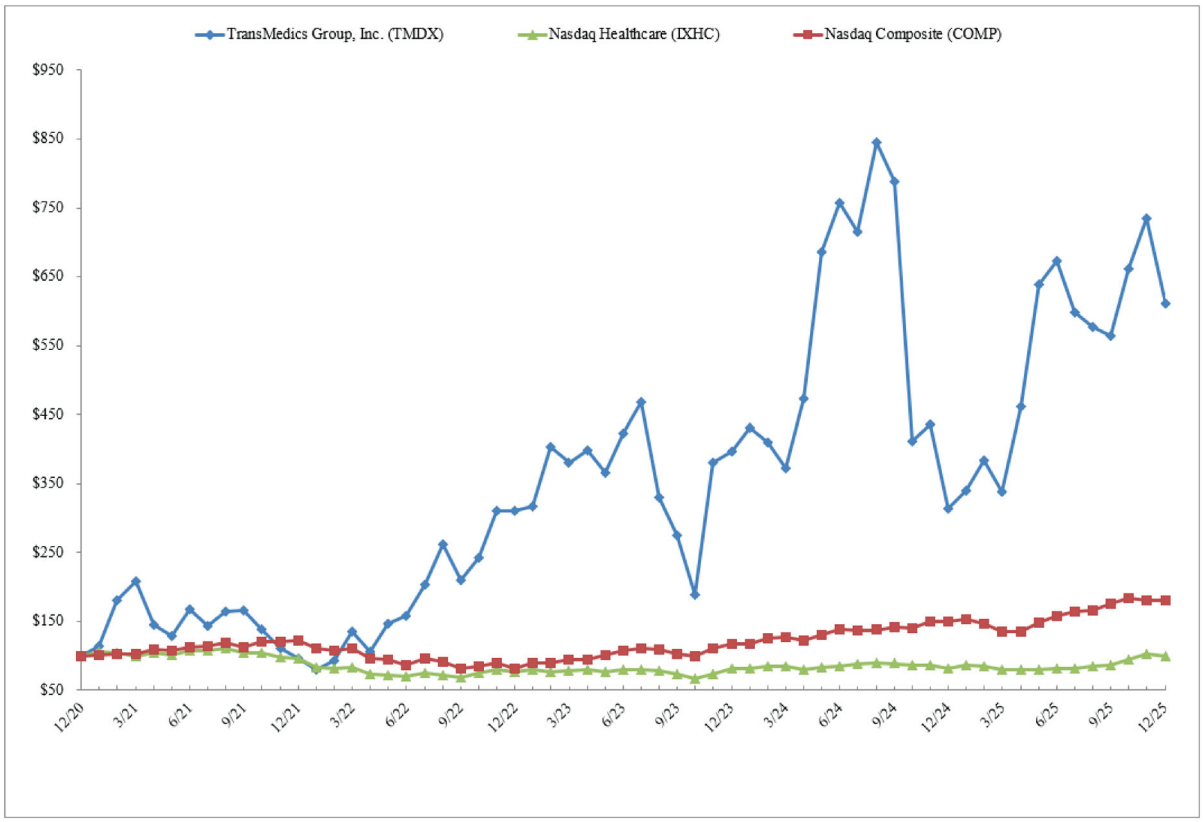
Certain Information Regarding the Trading of Our Common Stock

Our common stock trades under the symbol "TMDX" on the Nasdaq Global Market and has been publicly traded since May 2, 2019. Prior to this time, there was no public market for our common stock.

Stock Performance Graph[1]

The following graph shows a comparison from December 31, 2020 through December 31, 2025 of cumulative total return on assumed investments of $100.00 in cash in each of our common stock, the NASDAQ Composite Index and the NASDAQ Healthcare Index. Such returns are based on historical results and are not intended to suggest future performance. Data for the NASDAQ Composite Index and the NASDAQ Healthcare Index assumed reinvestment of dividends.

COMPARISON OF 60 MONTH CUMULATIVE TOTAL RETURN
Among TransMedics Group, Inc., the NASDAQ Composite Index and the NASDAQ Healthcare Index



[1] This performance graph shall not be deemed to be "soliciting material" or to be "filed" with the SEC for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended, or otherwise subject to the liabilities under that Section, and shall not be deemed incorporated by reference into any filings of TransMedics Group, Inc. under the Securities Act of 1933, as amended.

Holders of Our Common Stock

As of January 30, 2026, there were approximately 20 holders of record of shares of our common stock. These amounts do not include stockholders for whom shares are held in "nominee" or "street" name.

Securities authorized for issuance under equity compensation plans

Information about our equity compensation plans will be included in our definitive proxy statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders and is incorporated herein by reference.

Recent Sales of Unregistered Equity Securities

None.

Issuer Purchases of Equity Securities

We did not purchase any of our registered equity securities during the period from September 30, 2025 to December 31, 2025.

Dividends

We have never declared or paid any dividends on our capital stock. We do not anticipate declaring or paying any cash dividends on our capital stock in the foreseeable future. Any future determination to declare and pay cash dividends, if any, will be made at the discretion of our board of directors and will depend on a variety of factors, including applicable laws, our financial condition, results of operations, contractual restrictions, capital requirements, business prospects, general business or financial market conditions and other factors our board of directors may deem relevant. In addition, our CIBC Credit Agreement contains covenants that restrict our ability to pay cash dividends.

Item 6.

Reserved

Item 7. 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 Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, 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 Annual Report on 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 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 procurement, OCS perfusion management and transplant logistics services, to provide transplant programs in the United States with a more efficient process to procure donor organs with the OCS. Our transplant 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 PMA from the FDA, for both DBD organs and 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 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 from sales of our OCS products for use in clinical trials.

Prior to 2024, we had incurred significant annual operating losses since inception and we have only recently achieved profitability. Our ability to generate revenue sufficient to achieve sustained profitability will depend on the continued commercial sales of our products and services. We generated total revenue of $605.5 million and had net income of $190.3 million for the year ended December 31, 2025. We generated total revenue of $441.5 million and had net income of $35.5 million for the year ended December 31, 2024. As of December 31, 2025, we had an accumulated deficit of $278.0 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. 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 if we will be able to maintain profitability. 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.

The United Network for Organ Sharing, or UNOS, operated the OPTN under a sole-vendor federal contract from 1986 until 2024. 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 OPTN, including its intent to solicit contract proposals to manage the OPTN under a multi-vendor model following the expiration of the sole-vendor contract between UNOS and HRSA on March 29, 2024. Additionally, in September 2023, the Securing the U.S. Organ Procurement and Transplantation Network Act was signed into law. This legislation expressly authorizes HRSA to award multiple grants, contracts or cooperative agreements to support the operation

of the OPTN. It also specifies that the awards to operate the OPTN shall be distinct from awards to support the networks' board of directors. In September 2024, HRSA began awarding contracts aimed at supporting the multi-vendor model.

HRSA has consistently exercised options to extend the contract for UNOS to operate OPTN, albeit in a more limited capacity, since March 2024. Most recently, in December 2025, HRSA and UNOS reached a new agreement that took effect on December 30, 2025. This contract allows HRSA to extend UNOS' work for up to 12 months, until December 29, 2026, structured as four optional three-month periods. The new agreement reflects a shift of several former UNOS functions, including patient safety, reporting and tracking of donor-derived transmission events, and committee support, to HRSA or other contractors.

HRSA continues to implement efforts to improve and modernize the OPTN, including enhancements to patient data on organ procurement, expanded transparency through a publicly accessible data dashboard for allocation out of sequence (AOOS) events, expanded outreach and financial support for living organ donors, and a new OPTN fee collection process whereby HRSA directly collects and distributes patient registration fees under authorities originally granted by the 2025 Full-Year Continuing Appropriations and Extensions Act and extended by the 2026 Continuing Appropriations, Agriculture, Legislative Branch, Military Construction and Veterans Affairs, and Extensions Act. The impact that HRSA's 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 or changes in the amount 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, tariffs related to a small portion of components that we import moderately increased our cost of revenue in 2025. 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.

Key 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, these customers purchase an additional OCS disposable set for use on their existing organ-specific OCS Console. We also generate service revenue by providing outsourced organ procurement, OCS perfusion management and transplant logistics services under our NOP in the United States. With the acquisition of Summit in August 2023, the purchase of fixed-wing transplant aircraft and the addition of a logistics team, we have increased service revenue from our transplant logistics services.

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 procurement, OCS perfusion management or transplant logistics services under our NOP, and OCS Console, whether sold or loaned to the customer.

Through December 31, 2025, our sales outside of the United States have been commercial sales (unrelated to any clinical trials). Sales in the EU are dependent on obtaining and maintaining the CE mark certifications for each of our OCS products. As required by 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. While we expect our revenue to increase over the long term, revenue from sales may fluctuate from quarter to quarter as the timing of organ transplant procedures is generally unpredictable, and we have observed periodic fluctuations in the availability of donor organs and transplant center surgeons, which impacts the volume of transplants.

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 procurement and OCS perfusion management services and transportation and transplant 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.

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 is impacted by the relative mix of product and service revenue, as product and service revenue have different margin profiles. 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 of costs incurred for research activities, product development, hardware and software engineering and clinical trial activities, including salaries and related costs, including stock-based compensation, facilities costs, laboratory supplies, depreciation, testing, regulatory, data management and consulting costs.

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

Acquired In-Process Research and Development Expenses

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

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of salaries and related costs, including stock-based compensation, for personnel in our commercial team and personnel in executive, marketing, finance and administrative functions, and recruiting and temporary service fees for such personnel. 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. We expect that our selling, general and administrative expenses will increase over the long term as we increase our headcount and infrastructure to support the expected continued sales growth of our OCS products and our NOP.

Other Income (Expense)

Interest Expense

Interest expense consists of interest expense associated with outstanding borrowings under our loan 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), Net

Interest income and other income (expense), net includes interest income, realized and unrealized foreign currency transaction gains and losses and other non-operating income and expense items unrelated to our core operations. Interest income consists of interest earned on our 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.

Income Taxes

Our (provision) benefit for income taxes is based on taxable income (loss), applicable income tax rates, net research and development tax credits, net operating loss carryforwards, changes in valuation allowance estimates and deferred income taxes. During the fourth quarter of 2025, we concluded that it was more likely than not that we will realize substantially all of our net U.S. federal and state deferred tax assets and accordingly, recognized a benefit to income tax expense of $103.3 million related to the release of our valuation allowance. We relied primarily on cumulative income over the preceding twelve quarters, recent operating profits and, to a lesser extent, expected future profits in our assessment to release the valuation allowance. We maintained a valuation allowance of $0.9 million on certain state tax attributes as we considered it more-likely-than-not that these tax attributes would expire before realization.

As a result of the release of our valuation allowance we expect our income tax rate will increase in the future. To the extent allowed, we intend to use our available net operating loss carryforwards and tax credits to reduce cash tax payment obligations.

Results of Operations

Comparison of the Years Ended December 31, 2025, 2024 and 2023

The following table summarizes our results of operations for the years ended December 31, 2025, 2024 and 2023:

	Year Ended December 31,		
	2025	2024	2023
		(in thousands)	
Revenue:			
Net product revenue	$ 372,401	$ 273,866	$ 176,069
Service revenue	233,093	167,674	65,554
Total revenue	605,494	441,540	241,623
Cost of revenue:			
Cost of net product revenue	77,822	58,345	41,015
Cost of service revenue	164,866	121,114	46,515
Total cost of revenue	242,688	179,459	87,530
Gross profit	362,806	262,081	154,093
Operating expenses:			
Research, development and clinical trials	69,055	55,968	36,055
Acquired in-process research and development expenses	—	—	27,212
Selling, general and administrative	185,168	168,617	119,553
Total operating expenses	254,223	224,585	182,820
Income (loss) from operations	108,583	37,496	(28,727)
Other income (expense):			
Interest expense	(13,782)	(14,409)	(10,791)
Interest income and other income (expense), net	12,721	12,693	12,847
Total other income (expense), net	(1,061)	(1,716)	2,056
Income (loss) before income taxes	107,522	35,780	(26,671)
(Provision) benefit for income taxes	82,769	(316)	1,643
Net income (loss)	$ 190,291	$ 35,464	$ (25,028)

Revenue

OCS transplant-related revenue consists of:

	Year Ended December 31,		
	2025	2024	2023
		(in thousands)	
OCS transplant revenue by country by organ:			
United States			
Lung total revenue	$ 13,443	$ 15,755	$ 10,548
Heart total revenue	111,839	96,663	59,080
Liver total revenue	459,415	309,462	151,719
Total United States OCS transplant revenue	584,697	421,880	221,347
All other countries			
Lung total revenue	1,418	1,926	1,272
Heart total revenue	14,169	13,198	14,012
Liver total revenue	1,113	158	104
Total all other countries OCS transplant revenue	16,700	15,282	15,388
Total OCS transplant revenue	$ 601,397	$ 437,162	$ 236,735

We also had service revenue unrelated to OCS transplant of $4.1 million, $4.4 million and $4.9 million for the years ended December 31, 2025, 2024 and 2023, respectively.

Revenue from customers in the United States related to OCS transplant was $584.7 million in the year ended December 31, 2025 and increased by $162.8 million compared to the year ended December 31, 2024, primarily due to higher sales volumes of our OCS Liver and OCS Heart disposable sets. Revenue for each organ in the table above includes net product revenue from sales of disposable sets as well as service revenue for organ procurement, OCS perfusion management and transplant logistics services under the NOP in the United States. Revenue from customers outside the United States was $16.7 million and $15.3 million in the years ended December 31, 2025 and 2024, respectively.

Cost of Revenue, Gross Profit and Gross Margin

Cost of net product revenue increased by $19.5 million in the year ended December 31, 2025 compared to the year ended December 31, 2024. Cost of service revenue increased by $43.8 million in the year ended December 31, 2025 compared to the year ended December 31, 2024 as we increased utilization of the NOP. Gross profit increased by $100.7 million in the year ended December 31, 2025 compared to the year ended December 31, 2024. Cost of service revenue included approximately $2.9 million and $3.1 million for the years ended December 31, 2025 and 2024, respectively, of costs from Summit's legacy operations, unrelated to the NOP and organ transplant.

Overall gross margin was 60% and 59% for the years ended December 31, 2025 and 2024, respectively. Gross margin from net product revenue was 79% for each of the years ended December 31, 2025 and 2024. Gross margin from service revenue was 29% and 28% for the years ended December 31, 2025 and 2024, respectively, and consisted primarily of organ procurement, OCS perfusion management and transplant logistics services under our NOP.

Operating Expenses

Research, Development and Clinical Trials Expenses

	Year Ended December 31,		
	2025	2024	Change
		(in thousands)	
Personnel related (including stock-based compensation expense)	$ 25,720	$ 21,927	$ 3,793
Laboratory supplies and research materials	17,550	13,990	3,560
Consulting and third-party services	15,492	12,920	2,572
Clinical trials costs	1,459	478	981
Facility related and other	8,834	6,653	2,181
Total research, development and clinical trials expenses	$ 69,055	$ 55,968	$ 13,087

Total research, development and clinical trials expenses increased by $13.1 million from $56.0 million in the year ended December 31, 2024 to $69.1 million in the year ended December 31, 2025. Personnel related costs increased by $3.8 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 $4.7 million and $4.2 million for the years ended December 31, 2025 and 2024, respectively. Laboratory supplies and research materials costs increased by $3.6 million from the year ended December 31, 2024 to the year ended December 31, 2025 primarily due to our increased need for supplies and materials used for development of our next generation OCS. Consulting and third-party services costs increased by $2.6 million due to development efforts by our external development consultants for our next generation OCS program and other product development, including our kidney transport system. Clinical trial costs increased by $1.0 million due primarily to the initiation of clinical trial-related activities for our ENHANCE and DENOVO clinical trials. Facility related and other costs increased by $2.2 million from the year ended December 31, 2024 to the year ended December 31, 2025 due primarily to increased cost of supporting a larger group of research and development personnel.

Selling, General and Administrative Expenses

	Year Ended December 31,		
	2025	2024	Change
	(in thousands)		
Personnel related (including stock-based compensation expense)	$ 114,506	$ 109,475	$ 5,031
Professional and consultant fees	25,936	18,313	7,623
NOP support	6,826	12,289	(5,463)
Tradeshows and conferences	4,316	4,328	(12)
Facility related and other	33,584	24,212	9,372
Total selling, general and administrative expenses	$ 185,168	$ 168,617	$ 16,551

Total selling, general and administrative expenses increased by $16.6 million from $168.6 million in the year ended December 31, 2024 to $185.2 million in the year ended December 31, 2025. Personnel related costs increased by $5.0 million primarily due to an increase in stock-based compensation expense of $3.2 million and increases in contractor and recruiting costs to support the growth of our organization, partially offset by a decrease in personnel costs due to less time spent supporting marketing, finance and administrative activities. Personnel related costs included stock-based compensation expense of $30.8 million and $27.6 million for the years ending December 31, 2025 and 2024, respectively. Professional and consultant fees increased by $7.6 million due primarily to increased audit and tax-related fees and legal costs related to patents as well as increased professional and legal fees related to an independent review of business practices following allegations raised in a short seller report released in January 2025. We also incurred higher consulting services related to general business initiatives to support our growth. Facility related and other costs increased by $9.4 million due primarily to increased depreciation and amortization and information technology infrastructure costs as well as increases in non-income based state taxes. These increases were partially offset by a decrease in NOP support costs of $5.5 million due primarily to less activity supporting selling, general and administrative functions.

Other Income (Expense)

Interest Expense

Interest expense was $13.8 million and $14.4 million for the years ending December 31, 2025 and 2024, respectively, 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 5.7% as of December 31, 2025.

Interest Income and Other Income (Expense), Net

Interest income and other income (expense), net for the years ended December 31, 2025 and 2024 included interest income of $11.4 million and $13.4 million, respectively, from interest earned on cash balances. The decrease in interest income was primarily due to lower yields on our cash balances. Interest income and other income (expense), net also included $1.0 million of realized and unrealized foreign currency transactions gains for the year ended December 31, 2025, and $0.7 million of realized and unrealized foreign currency transactions losses during the year ended December 31, 2024.

(Provision) Benefit for Income Taxes

We had an income tax benefit of $82.8 million for 2025, as compared to a provision for income tax of $0.3 million in 2024. Our effective tax rate was (77.0%) and 0.9% for 2025 and 2024, respectively. Our effective tax rate for 2025 differs from the U.S. federal statutory income tax rate of 21.0% primarily due to the release of a U.S. valuation allowance. In the fourth quarter of 2025, we concluded that it is more likely than not that substantially all of our U.S. deferred tax assets are realizable, resulting in a valuation allowance release of $103.3 million. Our effective tax rate for 2024 differs from the U.S. federal statutory income tax rate of 21.0% primarily due to excess stock compensation deductions, partially offset by state and federal income taxes for the portion of our taxable income that was not offset by operating loss and tax credit carryforwards, and the impact from the change in valuation allowance.

Comparison of the Years Ended December 31, 2024 and 2023

For a discussion of our results of operations for the year ended December 31, 2024 as compared to the year ended December 31, 2023, see Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations—Components of Our Results of Operations—Comparison of the Years Ended December 31, 2024, 2023 and 2022 included in our Annual Report on Form 10-K for the year ended December 31, 2024.

Liquidity and Capital Resources

Prior to 2024, we had incurred significant annual operating losses since inception and we may incur losses in the future. 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 from sales of our OCS products for use in clinical trials. At December 31, 2025, our principal source of liquidity was cash of $488.4 million

Cash Flows

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

	Year Ended December 31,		
	2025	2024	2023
	(in thousands)		
Net cash provided by (used in) operating activities	$ 192,840	$ 48,803	$ (13,028)
Net cash used in investing activities	(59,251)	(129,303)	(193,953)
Net cash provided by financing activities	16,857	22,874	400,418
Effect of exchange rate changes on cash and restricted cash	1,270	(536)	193
Net increase (decrease) in cash and restricted cash	$ 151,716	$ (58,162)	$ 193,630

Operating Activities

During the year ended December 31, 2025, operating activities provided $192.8 million of cash, primarily resulting from our net income of $190.3 million and net cash provided by changes in our operating assets and liabilities of $18.4 million, partially offset by net non-cash income of $15.8 million. Net non-cash income included the change in deferred taxes of $83.5 million related primarily to the release of the deferred tax asset valuation allowance, partially offset by net non-cash charges. Net cash provided by changes in our operating assets and liabilities for the year ended December 31, 2025 consisted primarily of a decrease in accounts receivable of $14.0 million and a net increase in accounts payable and accrued expenses and other current liabilities of $17.7 million, partially offset by an increase in inventory of $7.7 million and an increase in prepaid expenses and other current assets of $3.8 million.

During the year ended December 31, 2024, operating activities provided $48.8 million of cash, primarily resulting from our net income of $35.5 million and net non-cash charges of $58.3 million, partially offset by net cash used by changes in our operating assets and liabilities of $45.0 million. Net cash used by changes in our operating assets and liabilities for the year ended December 31, 2024 consisted primarily of an increase in accounts receivable of $34.3 million, an increase in inventory of $8.4 million and an increase in prepaid expenses and other current assets of $6.3 million, partially offset by an increase in accounts payable and accrued expenses and other current liabilities of $6.5 million.

Investing Activities

During the year ended December 31, 2025, net cash used in investing activities of $59.3 million consisted of purchases of property, plant and equipment, primarily related to the purchase of transplant aircraft.

During the year ended December 31, 2024, net cash used in investing activities of $129.3 million consisted of purchases of property, plant and equipment of $129.7 million, primarily related to the purchase of transplant aircraft.

Financing Activities

During the year ended December 31, 2025, net cash provided by financing activities of $16.9 million consisted of proceeds from the issuance of common stock upon exercise of stock options of $13.7 million and proceeds from the issuance of common stock in connection with the 2019 Employee Stock Purchase Plan of $3.2 million.

During the year ended December 31, 2024, net cash provided by financing activities of $22.9 million consisted of proceeds from the issuance of common stock upon exercise of stock options of $20.8 million and proceeds from the issuance of common stock in connection with the 2019 Employee Stock Purchase Plan of $2.1 million.

For a discussion of our cash flows for the year ended December 31, 2023, see Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—Cash Flows included in our Annual Report on Form 10-K for the year ended December 31, 2024.

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 December 31, 2025, 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 December 31, 2025, and the Notes therefore became convertible at the noteholders' election in the calendar quarter ending March 31, 2026 (and only during this calendar quarter). 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%. We are obligated to repay the outstanding principal amount in equal monthly installments commencing in July 2026 with the remaining balance due on the maturity date in July 2027. At our option, we may prepay the outstanding principal amount under the CIBC Credit Agreement, without a prepayment fee. 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 December 31, 2025, 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 the outstanding principal amount, 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, including expanding our research and development and manufacturing capabilities in Italy, seek regulatory approval for the next generation OCS, new products and product enhancements, including new indications, both in the United States and in select non-U.S. markets, establish and relocate to a new long-term global headquarters, and seek greater control of air and ground transport for our NOP. 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, marketing and logistics 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 pre- and 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 constructing research and development and manufacturing facilities in Italy;
- the cost and timing of development of the next generation OCS;
- the costs associated with maintaining, improving and expanding our commercial operations, including the NOP globally;
- the costs associated with maintaining and growing our transplant 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;
- the level of our selling, general and administrative expenses; and
- the costs related to establishing and relocating to a new long-term global headquarters to accommodate the growing scale and complexity of our business.

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 our annual report on Form 10-K. 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 this Annual Report on Form 10-K.

Material Contractual Obligations

Our contractual obligations include amounts payable as principal and interest payments under the CIBC Credit Agreement. As of December 31, 2025, our outstanding principal balance was $60.0 million, which is repayable in equal monthly installments starting in July 2026 with the remaining balance due on the maturity date in July 2027. We estimate we will pay $10.0 million in principal payments and $3.4 million in interest payments during 2026. Our estimate of interest payments is based on an assumed rate of 5.7%, which was the interest rate in effect at December 31, 2025.

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

We lease facilities under long-term non-cancelable operating leases that have a weighted average remaining lease term of 2.8 years as of December 31, 2025. As of December 31, 2025, we had fixed lease payment obligations of $7.8 million, of which $3.7 million is payable during 2026.

On January 8, 2026, we entered into a lease agreement for space in Somerville, Massachusetts to eventually replace our existing headquarters in Andover, Massachusetts. Base rent begins to accrue in the first quarter of 2028 and the initial lease term expires 192 months from the date base rent begins to accrue, unless earlier terminated. The annual base rent under this lease will initially be $23.9 million and will be subject to a 2% annual increase during the first three years of the initial lease term and a 3% annual increase for each year thereafter during the remainder of the initial lease term. On January 8, 2026, we acquired two parcels adjacent to the leased premises in Somerville, Massachusetts for a purchase price of $15.0 million for each property.

In July 2025, we purchased two parcels of land in Mirandola, Italy. We plan to construct research and development and manufacturing facilities but have not yet entered into constructions contracts.

We may acquire additional fixed-wing aircraft to enhance our logistics capabilities and support international expansion. During the year ended December 31, 2025, we acquired 3 transplant-related fixed-wing aircraft with an aggregate purchase price of $42.9 million.

In January 2021, we 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. As of December 31, 2025, our remaining purchase commitment is $4.0 million.

We also enter into other contracts in the normal course of business with consulting firms, material suppliers and other third parties for clinical trials and testing and manufacturing services. These contracts do not contain material minimum purchase commitments and are cancelable by us upon prior written notice. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including noncancelable obligations of our service providers, up to the date of cancellation. These payments are not included in the discussion above as the amount and timing of such payments are not known.

Critical Accounting Policies and Significant 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.

While our significant accounting policies are described in more detail in Note 2 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Revenue Recognition

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 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, these customers purchase an additional OCS disposable set for use on their existing organ-specific OCS Console. We also generate service revenue by providing outsourced organ procurement, OCS perfusion management and transplant logistics services under our NOP in the United States.

We recognize revenue from sales to customers applying the following five steps: (1) identification of the contract, or contracts, with a customer, (2) identification of the performance obligations in the contract, (3) determination of the transaction price, (4) allocation of the transaction price to the performance obligations in the contract, and (5) recognition of revenue when, or as, performance obligations are satisfied.

Substantially all of our customer contracts have multiple-performance obligations that contain deliverables consisting of OCS Perfusion Sets and OCS Solutions. Customer contract deliverables may also include organ procurement, OCS perfusion management and transplant logistics services under our NOP or OCS Console, whether sold or loaned to the customer. We evaluate each promise within a multiple-performance obligation arrangement to determine whether it represents a distinct performance obligation. The primary performance obligations in our customer arrangements from which we derive revenue are the OCS Perfusion Sets, the OCS Solutions, the OCS Console, organ procurement, OCS perfusion management and transplant logistics services.

When a customer order includes an OCS Console, we have determined that customer training and the equipment set-up of the OCS Console, each performed by us, are not distinct because they are not sold on a standalone basis and can only be performed by us in conjunction with a sale or loan of our OCS Console. In addition, we have determined that the OCS Console itself is not distinct because the customer cannot benefit from the OCS Console without the training and equipment set-up having been completed. As a result, when the order includes an OCS Console, we have concluded that training, OCS Console equipment set-up, and the OCS Console itself are highly interdependent and represent a single, combined performance obligation. We recognize revenue from the single, combined performance obligation only once the OCS Console has arrived at the customer site and the training and equipment set-up have been completed by us.

Customer orders may include the loan of an OCS Console as well as OCS disposable sets used in each transplant procedure. When we loan the OCS Console to the customer, we retain title to the console at all times and do not require minimum purchase commitments from the customer related to any OCS products. In such cases, we invoice the customer for OCS disposable sets based on customer orders received for each new transplant procedure and the prices set forth in the customer agreement. Over time, we typically recover the cost of the loaned OCS Console through the customer's continued purchasing and use of additional OCS disposable sets. For these reasons, we have determined that part of the arrangement consideration for the disposable set is an implied rental payment for use of the OCS Console. Therefore, we allocate the arrangement consideration between the lease deliverables (i.e., the OCS Console) and non-lease deliverables (i.e., the OCS disposable sets) based on the relative estimated standalone selling price of each distinct performance obligation. To date, the amounts allocated to lease deliverables have been insignificant.

Revenue from sales to customers of OCS Perfusion Sets, OCS Solutions and OCS Consoles is classified as net product revenue in the our consolidated statements of operations. Revenue from sales to customers of organ procurement, OCS perfusion management and transplant logistics services is classified as service revenue in our consolidated statements of operations.

Revenue is recognized when control is transferred to the customer in an amount that reflects the consideration we expect to be entitled to in exchange for the product or services. When a customer order includes disposable sets and organ procurement, OCS perfusion management or transplant logistics services, we have determined that the disposable sets and services constitute separate performance obligations and we recognize revenue as the disposable sets and services are each delivered to the customer.

Payments Made to Customers

Under some of our customer clinical trial agreements, we made payments to our customers for reimbursements of clinical trial materials and for specified clinical documentation related to their use of our OCS products. We also make payments to customers involved in post-approval studies for information related to the transplant procedures performed. We determine the appropriate accounting treatments for these payments depending on the nature of the payment and whether they are for distinct goods or services.

Other Revenue Considerations

We only include estimated variable amounts in the transaction price to the extent it is probable that a significant reversal of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is resolved. We do not assess whether promised goods or services are performance obligations if they are deemed immaterial in the context of the contract with the customer. Additionally, we do not assess whether a contract has a significant financing component if the expectation at contract inception is that the period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less. Revenue is reported net of taxes.

Valuation of Inventory

We value inventory at the lower of cost or net realizable value, with cost computed using the first-in, first-out method. We regularly review inventory quantities on-hand for excess and obsolete inventory and, when circumstances indicate, record charges to write down inventories to their estimated net realizable value, after evaluating historical sales, future demand, market conditions and expected product life cycles. Such charges are classified as cost of revenue in our consolidated statements of operations. Any write-down of inventory to net realizable value creates a new cost basis. The reserve for excess and obsolete inventory was $3.0 million and $2.5 million as of December 31, 2025 and 2024, respectively.

At the end of each reporting period, we assess whether losses should be accrued on long-term manufacturing purchase commitments in accordance with ASC Topic 330, *Inventory*, which requires that losses that are expected to arise from firm, noncancelable and unhedged commitments for the future purchase of inventory, measured in the same way as inventory losses, should be recognized in the current period in the consolidated statements of operations unless they are deemed recoverable through firm sales contracts or when there are other circumstances that reasonably assure continuing sales without price decline. As of the end of each reporting period presented in our consolidated financial statements included elsewhere in this Annual Report on Form 10-K, we did not identify any potential losses arising from remaining future purchase commitments as compared to estimated future customer sales through the remainder of the term of the manufacturing purchase commitment and, as a result, did not recognize in a current period any loss provision for future-period remaining purchase commitments.

Business Combinations and Fair Value Estimates

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

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

determination of asset and liability fair values, whichever comes first. Adjustments to fair values of assets and liabilities made after the end of the measurement period are recorded within operating results.

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 Annual Report on Form 10-K.

Item 7A. 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 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.

Foreign Currency Exchange Risk

Our foreign currency transaction exposure results primarily from intercompany transactions and transactions with customers or vendors denominated in currencies other than the functional currency of the legal entity in which the transaction is recorded by us. Assets and liabilities arising from such transactions are translated into the legal entity's functional currency using the period-end exchange rates. Foreign currency transaction gains (losses) are included in the consolidated statements of operations as a component of other income (expense). We recognized foreign currency transaction gains of $1.0 million during the year ended December 31, 2025.

Foreign currency translation exposure results from the translation of the financial statements of our subsidiaries whose functional currency is not the U.S. dollar into U.S. dollars for consolidated reporting purposes. Assets and liabilities of these 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 on our consolidated balance sheets. We recorded a foreign currency translation gain of $0.5 million during the year ended December 31, 2025.

For the year ended December 31, 2025, 2% of our revenue and 3% of our operating costs and expenses were generated by subsidiaries whose functional currency is not the U.S. dollar and therefore are subject to foreign currency exposure.

Currently, our largest foreign currency exposure is that with respect to the Euro. We believe that a 10% change in the exchange rate between the U.S. dollar and Euro would not materially impact our operating results or financial position. We have experienced and we will continue to experience fluctuations in our net income (loss) as a result of revaluing our assets and liabilities that are not denominated in the functional currency of the entity that recorded the asset or liability. At this time, we do not hedge our foreign currency risk.

Interest Rate Sensitivity

As of December 31, 2025, we had cash of $488.4 million, including cash held in savings accounts. Interest income is sensitive to changes in the general level of interest rates; however, due to the nature of our savings accounts, an immediate 10% change in interest rates would not have a material effect on the fair market value of our cash balance.

In July 2022, we entered into our CIBC Credit Agreement with CIBC. Borrowings under the CIBC Credit Agreement bear interest at an annual rate equal to either, at our option, (i) the secured overnight financing rate for an interest period selected by us, subject to a minimum of 1.5%, plus 2.0% or (ii) 1.0% plus the higher of a) the prime rate, subject to a minimum of 4.0% or b) the Federal Funds Effective Rate, plus 0.5%. As of December 31, 2025 the outstanding principal under the CIBC Credit Agreement totaled $60.0 million and the interest rate applicable to such borrowings was 5.7%. An immediate 10% change in the Federal Funds Effective Rate would not have a material impact on our debt-related obligations, financial position or results of operations.

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

Item 8. Financial Statements and Supplementary Data.

TRANSMEDICS GROUP, INC.
Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of TransMedics Group, Inc.

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of TransMedics Group, Inc. and its subsidiaries (the "Company") as of December 31, 2025 and 2024, and the related consolidated statements of operations, of comprehensive income (loss), of stockholders' equity and of cash flows for each of the three years in the period ended December 31, 2025, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2025, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2025 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company did not maintain, in all material respects, effective internal control over financial reporting as of December 31, 2025, based on criteria established in Internal Control - Integrated Framework (2013) issued by the COSO because a material weakness in internal control over financial reporting existed as of that date as the Company did not design and maintain effective controls over inventory movement within its manufacturing network.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. The material weakness referred to above is described in Management's Annual Report on Internal Control over Financial Reporting appearing under Item 9A. We considered this material weakness in determining the nature, timing, and extent of audit tests applied in our audit of the 2025 consolidated financial statements, and our opinion regarding the effectiveness of the Company's internal control over financial reporting does not affect our opinion on those consolidated financial statements.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in management's report referred to above. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of

the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Revenue Recognition

As described in Note 2 to the consolidated financial statements, the Company recorded $605.5 million in total revenues for the year ended December 31, 2025. The Company generates product revenue from sales of its single-use, organ-specific disposable sets (i.e., its organ-specific OCS Perfusion Sets sold together with its organ-specific OCS Solutions) used on its organ-specific OCS Consoles, each being a component of the Company's Organ Care System (OCS) products, and service revenue, by providing outsourced organ retrieval, OCS organ management and logistics services under the Company's National OCS Program. Substantially all of the Company's customer contracts have multiple-performance obligations. Deliverables consist of OCS Perfusion Sets and OCS Solutions. In some of those customer contracts, the deliverables also include an OCS Console, whether sold or loaned to the customer. Management evaluates each promise within a multiple-performance obligation arrangement to determine whether it represents a distinct performance obligation. Management has concluded that training, OCS Console equipment set-up, and the OCS Console itself are highly interdependent and represent a single, combined performance obligation. Revenue is recognized when control of the OCS product or products is transferred to the customer in an amount that reflects the consideration the Company expects to be entitled to in exchange for the product or products. Control is transferred for the OCS products typically only after the product has arrived at the customer site and, in addition for OCS Consoles, the training and equipment set-up have been completed by the Company. Additionally, under the National OCS program, service deliverables available to customers include organ retrieval, OCS organ management, and transportation logistics which are distinct performance obligations and are recognized as service revenue when the services occur.

The principal considerations for our determination that performing procedures relating to revenue recognition is a critical audit matter are a high degree of auditor effort in performing procedures and in evaluating audit evidence related to management's determination of the point in time when control of the OCS product or products is transferred to the customer or services are performed and revenue is recognized.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to the revenue recognition process, including controls over the existence and point in time when control is transferred to the customer. These procedures also included, among others, evaluating, for a sample of transactions, the existence of transactions recognized as revenue, as well as evaluating the appropriate timing of revenue recognition by obtaining and inspecting customer purchase orders and, where applicable, invoices, customer agreements, shipping documents, completion of services documents and cash receipts from customers.

/s/ PricewaterhouseCoopers LLP
Boston, Massachusetts
February 24, 2026

We have served as the Company's auditor since 2001.

TRANSMEDICS GROUP, INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except share amounts)

	December 31,	
	2025	2024
Assets		
Current assets:		
Cash	$ 488,366	$ 336,650
Accounts receivable	84,282	97,722
Inventory	48,881	46,554
Prepaid expenses and other current assets	16,254	16,290
Total current assets	637,783	497,216
Property, plant and equipment, net	327,656	285,970
Operating lease right-of-use assets	5,155	6,481
Deferred tax assets	83,543	—
Restricted cash	500	500
Goodwill	11,549	11,549
Acquired intangible assets, net	1,948	2,152
Other non-current assets	239	208
Total assets	$ 1,068,373	$ 804,076
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 10,350	$ 10,292
Accrued expenses and other current liabilities	62,740	45,152
Current portion of long-term debt	10,000	—
Deferred revenue	2,905	1,742
Operating lease liabilities	3,310	2,727
Total current liabilities	89,305	59,913
Convertible senior notes, net	452,804	449,939
Long-term debt, net	49,587	59,372
Operating lease liabilities, net of current portion	3,577	6,249
Total liabilities	595,273	575,473
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, no par value; 25,000,000 shares authorized; no shares issued or outstanding	—	—
Common stock, no par value; 150,000,000 shares authorized; 34,267,802 shares and 33,617,972 shares issued and outstanding as of December 31, 2025 and 2024, respectively	750,926	697,208
Accumulated other comprehensive income (loss)	124	(364)
Accumulated deficit	(277,950)	(468,241)
Total stockholders' equity	473,100	228,603
Total liabilities and stockholders' equity	$ 1,068,373	$ 804,076

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

TRANSMEDICS GROUP, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except share and per share amounts)

	Year Ended December 31,		
	2025	2024	2023
Revenue:			
Net product revenue	$ 372,401	$ 273,866	$ 176,069
Service revenue	233,093	167,674	65,554
Total revenue	605,494	441,540	241,623
Cost of revenue:			
Cost of net product revenue	77,822	58,345	41,015
Cost of service revenue	164,866	121,114	46,515
Total cost of revenue	242,688	179,459	87,530
Gross profit	362,806	262,081	154,093
Operating expenses:			
Research, development and clinical trials	69,055	55,968	36,055
Acquired in-process research and development expenses	—	—	27,212
Selling, general and administrative	185,168	168,617	119,553
Total operating expenses	254,223	224,585	182,820
Income (loss) from operations	108,583	37,496	(28,727)
Other income (expense):			
Interest expense	(13,782)	(14,409)	(10,791)
Interest income and other income (expense), net	12,721	12,693	12,847
Total other income (expense), net	(1,061)	(1,716)	2,056
Income (loss) before income taxes	107,522	35,780	(26,671)
(Provision) benefit for income taxes	82,769	(316)	1,643
Net income (loss)	$ 190,291	$ 35,464	$ (25,028)
Net income (loss) per share:			
Basic	$ 5.60	$ 1.07	$ (0.77)
Diluted	$ 4.87	$ 1.01	$ (0.77)
Weighted average common shares outstanding:			
Basic	33,993,468	33,229,953	32,517,372
Diluted	40,540,694	35,216,837	32,517,372

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

TRANSMEDICS GROUP, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(In thousands)

	Year Ended December 31,		
	2025	2024	2023
Net income (loss)	$ 190,291	$ 35,464	$ (25,028)
Other comprehensive income (loss):			
Foreign currency translation adjustment	488	(165)	26
Total other comprehensive income (loss)	488	(165)	26
Comprehensive income (loss)	$ 190,779	$ 35,299	$ (25,002)

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

TRANSMEDICS GROUP, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(In thousands, except share amounts)

	Common Stock		Accumulated Other Comprehen-sive Income (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	493,935	6,155	—	—	6,155
Issuance of common stock in connection with employee stock purchase plan	25,894	955	—	—	955
Stock-based compensation expense	—	19,791	—	—	19,791
Purchases of capped calls related to convertible senior notes	—	(52,072)	—	—	(52,072)
Issuance of restricted common stock	10,304	—	—	—	—
Restricted common stock forfeitures	(698)	—	—	—	—
Foreign currency translation adjustment	—	—	26	—	26
Net loss	—	—	—	(25,028)	(25,028)
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	796,764	20,813	—	—	20,813
Issuance of common stock in connection with employee stock purchase plan	31,303	2,061	—	—	2,061
Issuance of common stock in connection with exercise of warrants	11,735	—	—	—	—
Issuance of restricted common stock	4,160	—	—	—	—
Net issuance of common stock upon vesting of restricted stock units	103,166	—	—	—	—
Conversion of convertible senior notes into common stock	41	4	—	—	4
Stock-based compensation expense	—	33,224	—	—	33,224
Foreign currency translation adjustment	—	—	(165)	—	(165)
Net income	—	—	—	35,464	35,464
Balances at December 31, 2024	33,617,972	697,208	(364)	(468,241)	228,603
Issuance of common stock upon the exercise of common stock options	431,771	13,746	—	—	13,746
Issuance of common stock in connection with employee stock purchase plan	58,996	3,249	—	—	3,249
Issuance of restricted common stock	1,737				
Restricted common stock forfeitures	(2,880)	—	—	—	—
Net issuance of common stock upon vesting of restricted stock units	160,206	(138)	—	—	(138)
Stock-based compensation expense	—	36,861	—	—	36,861
Foreign currency translation adjustment	—	—	488	—	488
Net income	—	—	—	190,291	190,291
Balances at December 31, 2025	34,267,802	$ 750,926	$ 124	$ (277,950)	$ 473,100

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

TRANSMEDICS GROUP, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Year Ended December 31,		
	2025	2024	2023
Cash flows from operating activities:			
Net income (loss)	$ 190,291	$ 35,464	$ (25,028)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation and amortization expense	27,185	19,758	8,177
Stock-based compensation expense	36,861	33,224	19,791
Acquired in-process research and development expenses	—	—	27,212
Deferred taxes	(83,543)	—	(1,660)
Non-cash interest expense and end of term accretion expense	3,080	3,111	2,128
Non-cash lease expense	2,132	1,564	1,041
Unrealized foreign currency transaction (gains) losses	(1,622)	665	(342)
Loss on disposal of fixed assets	80	17	—
Changes in operating assets and liabilities, net of acquired assets and liabilities:			
Accounts receivable	13,950	(34,310)	(33,816)
Inventory	(7,716)	(8,353)	(28,092)
Prepaid expenses and other current assets	(3,759)	(6,262)	(2,101)
Other non-current assets	(23)	(149)	(54)
Accounts payable	(19)	(1,396)	6,957
Accrued expenses and other current liabilities	17,694	7,938	14,250
Deferred revenue	1,144	(203)	83
Operating lease liabilities	(2,895)	(2,265)	(1,574)
Net cash provided by (used in) operating activities	192,840	48,803	(13,028)
Cash flows from investing activities:			
Purchases of property, plant and equipment	(59,251)	(129,744)	(151,847)
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	(59,251)	(129,303)	(193,953)
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	13,746	20,813	6,155
Proceeds from issuance of common stock in connection with employee stock purchase plan	3,249	2,061	955
Tax withholding payments related to net settlement of restricted stock units	(138)	—	—
Net cash provided by financing activities	16,857	22,874	400,418
Effect of exchange rate changes on cash and restricted cash	1,270	(536)	193
Net increase (decrease) in cash and restricted cash	151,716	(58,162)	193,630
Cash and restricted cash, beginning of period	337,150	395,312	201,682
Cash and restricted cash, end of period	$ 488,866	$ 337,150	$ 395,312
Supplemental disclosure of cash flow information:			
Cash paid for interest	$ 10,702	$ 11,297	$ 8,089
Supplemental disclosure of non-cash activities:			
Transfers of inventory to property, plant and equipment	$ 5,679	$ 5,803	$ 4,574
Purchases of property, plant and equipment included in accounts payable and accrued expenses	$ 1,753	$ 2,062	$ 2,454
Operating lease liabilities arising from obtaining right-of-use assets	$ 795	$ 1,499	$ 2,171
Conversion of convertible senior notes into common stock	$ —	$ 4	$ —
Reconciliation of cash and restricted cash:			
Cash	$ 488,366	$ 336,650	$ 394,812
Restricted cash	500	500	500
Total cash and restricted cash shown in the statement of cash flows	$ 488,866	$ 337,150	$ 395,312

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

TRANSMEDICS GROUP, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of the Business and Basis of Presentation

TransMedics Group, Inc. ("TransMedics Group" and, together with its consolidated subsidiaries, the "Company") was incorporated in the Commonwealth of Massachusetts in October 2018. TransMedics, Inc. ("TransMedics"), an operating company and wholly owned subsidiary of TransMedics Group, was incorporated in the State of Delaware in August 1998. The Company is a 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 procurement, OCS perfusion management and transplant 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 transplant logistics services include aviation transportation, ground transportation and other coordination activity.

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. Prior to 2024, the Company had incurred recurring annual losses since inception. During the years ended December 31, 2025 and 2024, the Company generated net income of $190.3 million and $35.5 million, respectively. As of December 31, 2025, the Company had an accumulated deficit of $278.0 million. The Company believes that its existing cash of $488.4 million as of December 31, 2025 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 Annual Report on Form 10-K. If the Company needs 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. 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. 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.

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

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenue and expenses during the reporting periods. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, revenue recognition, the valuation of inventory, the valuation of assets acquired and liabilities assumed in business combinations, including acquired intangible assets and the resulting goodwill, the valuation of stock-based awards, and income taxes. 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 consolidated financial statements, the Company is not aware of any specific event or circumstance that would require the Company to update estimates, judgments or revise the carrying value of any assets or liabilities. Actual results may differ from those estimates or assumptions.

Risk of Concentrations of Credit, Significant Customers and Significant Suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and accounts receivable. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships. Significant customers are those that accounted for 10% or more of the Company's revenue or accounts receivable. For the years ended December 31, 2025, 2024 and 2023 no customer accounted for more than 10% of revenue. As of December 31, 2025 and 2024, no customer accounted for more than 10% of accounts receivable.

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

Deferred Financing Costs

Deferred financing costs related to a recognized debt liability are recorded as a reduction of the carrying amount of the debt liability and amortized to interest expense using the effective interest method over the repayment term of the debt.

Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less at the date of purchase to be cash equivalents.

Restricted Cash

As of December 31, 2025 and 2024, the Company maintained two letters of credit totaling $0.5 million for the benefit of the landlord of its leased property. The Company was required to maintain a separate cash balance of $0.5 million to secure the letters of credit. Related to this separate cash balance, the Company classified $0.5 million as restricted cash (non-current) on its consolidated balance sheets as of December 31, 2025 and 2024.

Accounts Receivable

Accounts receivable are presented net of an allowance for credit losses, which is an estimate of amounts that may not be collectible. The Company performs ongoing credit evaluations of its customers and monitors economic conditions to identify facts and circumstances that may indicate its receivables are at risk of collection. The Company provides reserves against accounts receivable for estimated credit losses, if any, that may result from a customer's inability to pay based on the composition of its accounts receivable, current economic conditions and historical credit loss activity. Amounts deemed uncollectible are charged or written-off against the reserve. As of December 31, 2025 and 2024, the Company had no allowance for credit losses. During the years ended December 31, 2025, 2024 and 2023, the Company did not record any provisions for credit losses and has written off only insignificant balances.

Inventory

Inventory is valued at the lower of cost or net realizable value. Cost is computed using the first-in, first-out method. The Company regularly reviews inventory quantities on-hand for excess and obsolete inventory and, when circumstances indicate, records charges to write down inventories to their estimated net realizable value, after evaluating historical sales, future demand, market conditions and expected product life cycles. Such charges are classified as cost of revenue in the consolidated statements of operations. Any write-down of inventory to net realizable value creates a new cost basis.

At the end of each reporting period, the Company assesses whether losses should be accrued on long-term manufacturing purchase commitments in accordance with ASC Topic 330, *Inventory*, which requires that losses that are expected to arise from firm, noncancelable and unhedged commitments for the future purchase of inventory, measured in the same way as inventory losses, should be recognized in the current period in the consolidated statements of operations unless they are deemed recoverable through firm sales contracts or when there are other circumstances that reasonably assure continuing sales without price decline. As of the end of each reporting period presented in the accompanying consolidated financial statements, the Company did not identify any potential losses arising from remaining future purchase commitments as compared to estimated future customer sales through the remainder of the term of the manufacturing purchase commitment and, as a result, did not recognize any loss provision for future-period remaining purchase commitments for the year ended December 31, 2025.

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 December 31, 2025 and 2024, spare parts inventory of $4.7 million and $4.0 million, respectively, is included within prepaid expenses and other current assets on the accompanying consolidated balance sheets. 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 December 31, 2025 and 2024, the Company had no allowance for spare parts excess and obsolescence.

Business Combinations

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

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

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

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

Asset Acquisitions

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

On August 2, 2023, the Company acquired certain assets related to lung and heart perfusion technology from Bridge to Life Ltd. and its subsidiary Tevosol, Inc., together ("BTL") to further develop these technologies to expand its product offerings and indications for organ transplantation. The Company accounted for the purchase of BTL as an asset acquisition as substantially all of the fair value of gross assets acquired were concentrated on a single set of identifiable activities consisting of lung and heart perfusion technology, referred to as the IPR&D asset. Due to the stage of development of the IPR&D asset at the date of acquisition, it was not yet probable that there was future economic benefit from this asset. Absent successful clinical results and regulatory approval for the asset applications, there was no alternative future use associated with the asset. Accordingly, the value of the IPR&D asset of $27.2 million was expensed as research and development expense during the year ended December 31, 2023 in the consolidated statements of operations.

Goodwill and Acquired Intangible Assets

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

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

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

Property, Plant and Equipment

Property, plant and equipment are stated at cost less accumulated depreciation and amortization. Depreciation and amortization expense is recognized using the straight-line method over the estimated useful life of each asset as follows:

	Estimated Useful Life
Transplant aircraft	10 years
Transplant aircraft equipment	10 years
Flight school aircraft	5 years
OCS Consoles	5 years
Manufacturing equipment	5 years
Internal-use software	5 years
Computer equipment and software	3 years
Laboratory equipment	3 years
Office, trade show and training equipment	5 years
Leasehold improvements	Shorter of term of lease or the useful life of the improvement

Depreciation and amortization expense of aircraft is recognized over the estimated useful lives of each asset to their salvage value. Salvage values estimated for transplant and flight school aircraft are approximately 50% of the original purchase price.

Costs incurred for OCS Consoles are recorded as inventory unless and until the Company determines that an OCS Console will either be used for the NOP or loaned to a customer for its use, at which time the Company reclassifies the cost of the OCS Console from inventory to property, plant and equipment and begins to depreciate the OCS Console over its estimated useful life. Such depreciation expense is classified as a cost of revenue. The Company retains title to all OCS Consoles loaned to customers.

Costs for capital assets not yet placed into service are capitalized as construction-in-progress and depreciated once placed into service. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation and amortization are removed from the accounts and any resulting gain or loss is included in income (loss) from operations. Expenditures for repairs and maintenance are charged to expense as incurred.

Impairment of Long-Lived Assets

Long-lived assets consist of property, plant and equipment, right-of-use assets and intangible assets with finite lives. Long-lived assets to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset group for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset group to its carrying value. An impairment loss would be recognized in income (loss) from operations when estimated undiscounted future cash flows expected to result from the use of an asset group are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset group over its fair value, determined based on discounted cash flows. The Company did not record any impairment losses on long-lived assets during the years ended December 31, 2025, 2024 and 2023.

Software Development Costs

The Company incurs costs to develop computer software that is embedded in the hardware components of the Company's OCS Console and OCS Perfusion Sets. Research and development costs related to this software are expensed as incurred, except for costs of internally developed or externally purchased software that qualify for capitalization. Software development costs incurred subsequent to the establishment of technological feasibility, but prior to the general release of the product, are capitalized and amortized over their estimated useful life. Due to the short time period between achieving technological feasibility and product release and the insignificant amount of costs incurred during such periods, the Company did not capitalize any software development costs during the years ended December 31, 2025, 2024 and 2023.

The Company also capitalizes development costs related to internal-use software when it is probable that the expenditures will result in additional functionality. Costs incurred in the preliminary and post-implementation stages of development are expensed as incurred. Once an application has reached the development stage, internal and external costs, if direct and incremental, are capitalized until the software is substantially complete and ready for its intended use and depreciated over their estimated useful life. Capitalization ceases upon completion of all substantial testing performed to ensure the product is ready for its intended use. The Company capitalized costs associated with the development of internal-use software during the years ended December 31, 2025 and 2024 (see Note 4).

Leases

The Company accounts for leases under ASC Topic 842, *Leases* ("ASC 842"). In accordance with ASC 842, the Company accounts for a contract as a lease when it has the right to control the asset for a period of time while obtaining substantially all of the asset's economic benefits. The Company determines if an arrangement is a lease or contains an embedded lease at inception. For arrangements that meet the definition of a lease, the Company determines the initial classification and measurement of its right-of-use asset and lease liability at the lease commencement date and thereafter if modified. The lease term includes any renewal options that the Company is reasonably assured to exercise. The present value of lease payments is determined by using the interest rate implicit in the lease, if that rate is readily determinable; otherwise, the Company uses its estimated secured incremental borrowing rate for that lease term. The Company's policy is to not record leases with an original term of twelve months or less on its consolidated balance sheets and recognize those lease payments in the income statement on a straight-line basis over the lease term.

In addition to rent, the leases may require the Company to pay additional costs, such as utilities, maintenance and other operating costs, which are generally referred to as non-lease components. The Company has elected to not separate lease and non-lease components. Only the fixed costs for lease components and their associated non-lease components are accounted for as a single lease component and recognized as part of a right-of-use asset and lease liability. Rent expense for operating leases is recognized on a straight-line basis over the reasonably assured lease term based on the total lease payments and is included in operating expense in the consolidated statements of operations.

Revenue from leasing arrangements is not subject to the revenue standard for contracts with customers and remains separately accounted for under ASC 842. In accordance with ASC 842, lessors should classify and account for a lease with variable lease payments that do not depend on a reference index or a rate as an operating lease if the lease would have been classified as a sales-type lease or a direct financing lease and the lessor would have otherwise recognized a day-one loss. The Company's OCS Console implied rental agreements qualify as sales-type leases with certain variable payments that meet specified criteria such that a day-one loss would be recognized under ASC 842. Therefore, in accordance with ASC 842, such leases are accounted for as operating leases and the Company does not derecognize the leased asset (the OCS Console) at the time of the sale but depreciates the leased asset over the useful life of the asset.

Fair Value Measurements

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

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

The carrying values of the Company's accounts receivable, accounts payable and accrued expenses approximate their fair values due to the short-term nature of these assets and liabilities. The carrying value of the Company's long-term debt approximates its fair value (a level 2 measurement) at each balance sheet date due to its variable interest rate, which approximates a market interest rate. The Company's 1.50% convertible senior notes, due 2028 (the "Notes") are carried at the face value less unamortized debt discount and issuance costs on the consolidated balance sheets, and the fair value of the Notes is presented at each reporting period for disclosure purposes only (see Note 7).

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 commercialized 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.

Product Warranties

The Company provides a one-year warranty on its OCS Consoles and disposable sets and replaces or repairs any OCS Console or disposable set that does not function in accordance with the product specifications. OCS Consoles returned to the Company may be refurbished and redeployed. Estimated warranty costs are recorded at the time of shipment of the OCS Console or disposable set. Warranty costs are estimated based on the current expected product replacement or repair cost and expected replacement or repair rates based on historical experience. The Company evaluates its warranty accrual at the end of each reporting period and makes adjustments as necessary. As of December 31, 2025 and 2024, the warranty accrual was less than $0.1 million.

Revenue Recognition

The Company generates net product revenue primarily from sales of its single-use, organ-specific disposable sets used on its organ-specific OCS Consoles. To a lesser extent, the Company also generates 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, these customers purchase an additional OCS disposable set for use on their existing organ-specific OCS Console. The Company also generates service revenue by providing outsourced organ procurement, OCS perfusion management and transplant logistics services under its NOP in the United States.

The Company recognizes revenue from sales to customers applying the following five steps: (1) identification of the contract, or contracts, with a customer, (2) identification of the performance obligations in the contract, (3) determination of the transaction price, (4) allocation of the transaction price to the performance obligations in the contract, and (5) recognition of revenue when, or as, performance obligations are satisfied.

Substantially all of the Company’s customer contracts have multiple-performance obligations that contain deliverables consisting of OCS Perfusion Sets and OCS Solutions. Customer contract deliverables may also include organ procurement, OCS perfusion management and transplant logistics services under the Company's NOP or OCS Console, whether sold or loaned to the customer. The Company evaluates each promise within a multiple-performance obligation arrangement to determine whether it represents a distinct performance obligation. The primary performance obligations in the Company’s customer arrangements from which it derives revenue are the OCS Perfusion Sets, the OCS Solutions, the OCS Console, organ procurement, OCS perfusion management and transplant logistics services.

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

Customer orders may include the loan of an OCS Console as well as OCS disposable sets used in each transplant procedure. When the Company loans the OCS Console to the customer, it retains title to the console at all times and does not require minimum purchase commitments from the customer related to any OCS products. In such cases, the Company invoices the customer for OCS disposable sets based on customer orders received for each new transplant procedure and the prices set forth in the customer agreement. Over time, the Company typically recovers the cost of the loaned OCS Console through the customer’s continued purchasing and use of additional OCS disposable sets. For these reasons, the Company has determined that part of the arrangement consideration for the disposable set is an implied rental payment for use of the OCS Console. Therefore, the Company allocates the arrangement consideration between the lease deliverables (i.e., the OCS Console) and non-lease deliverables (i.e., the OCS disposable sets) based on the relative estimated standalone selling price of each distinct performance obligation. To date, the amounts allocated to lease deliverables have been insignificant.

Revenue from sales to customers of OCS Perfusion Sets, OCS Solutions and OCS Consoles is classified as net product revenue in the Company's consolidated statements of operations. Revenue from sales to customers of organ procurement, OCS perfusion management and transplant logistics services is classified as service revenue in the Company’s consolidated statements of operations.

Revenue is recognized when control is transferred to the customer in an amount that reflects the consideration the Company expects to be entitled to in exchange for the product or services. When a customer order includes disposable sets and organ procurement, OCS perfusion management or transplant logistics services, the Company has determined that the disposable sets and services constitute separate performance obligations and recognizes revenue as the disposable sets and services are each delivered to the customer.

Payments Made to Customers

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

Contract Assets and Liabilities

The Company recognizes a receivable at the point in time at which it has an unconditional right to payment. Such receivables are not contract assets. Contract assets arise from unbilled amounts in customer arrangements when revenue recognized exceeds the amount billed to the customer and the Company's right to payment is not just subject to the passage of time. The Company had no contract assets as of December 31, 2025 and 2024.

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

Remaining Performance Obligations

The Company generally satisfies performance obligations within one year of the contract inception date, which amounts are included in deferred revenue and are not material.

Other Revenue Considerations

The Company only includes estimated variable amounts in the transaction price to the extent it is probable that a significant reversal of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is resolved. The Company does not assess whether promised goods or services are performance obligations if they are deemed immaterial in the context of the contract with the customer. Additionally, the Company does not assess whether a contract has a significant financing component if the expectation at contract inception is that the period between payment by the customer and the transfer of the promised goods or services to the customer will be one year or less. Revenue is reported net of taxes.

Distributors

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

Research, Development and Clinical Trials Costs

Research, development and clinical trials expenses consist of costs incurred for research activities, product development, hardware and software engineering and clinical trial activities, including salaries and related costs, including stock-based compensation, facilities costs, laboratory supplies, depreciation, testing, regulatory, data management and consulting costs.

Research, development and clinical trials costs are expensed as incurred. Advance payments for goods or services to be received in the future for use in research, development and clinical trials activities are recorded as prepaid expenses. Such prepaid expenses are recognized as an expense when the related goods have been delivered or the related services have been performed, or when it is no longer expected that the goods will be delivered or the services rendered.

Patent Costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred are classified as selling, general and administrative expenses.

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) and totaled $1.0 million, $(0.7) million and $0.3 million for the years ended December 31, 2025, 2024 and 2023, respectively.

Stock-Based Compensation

The Company accounts for stock-based awards granted to employees, non-employees and directors based on the fair value of the award on the date of grant. The fair value of option awards is measured using the Black-Scholes option-pricing model. The fair value of restricted common stock awards is measured based on the difference between market value of the Company's common stock on date of grant and the purchase price (if any). The Company measures compensation expense for restricted stock units based on the fair value on the date of grant using the market value of the Company's common stock. Generally, the Company issues stock-based awards with only service-based vesting conditions. Compensation expense for those awards is recognized over the vesting period of the respective award using the straight-line method. The Company accounts for forfeitures as they occur and records compensation cost assuming all option holders will complete the requisite service period. When the unvested portion of an award is forfeited, the Company reverses compensation expense previously recognized in the period of the forfeiture. The Company classifies stock-based compensation expense in its consolidated statements of operations in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

Comprehensive Income (Loss) and Accumulated Other Comprehensive Income (Loss)

Comprehensive income (loss) includes net income (loss) as well as other changes in stockholders' equity that result from transactions and economic events other than those with stockholders. The Company's only elements of other comprehensive income (loss) are foreign currency translation adjustments.

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. For periods in which the Company reports a net loss, diluted net loss per common share is the same as basic net loss per common share, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive.

Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the financial statements or in the Company's tax returns. Deferred taxes are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect in the years in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be realized and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by analyzing carryback capacity in periods with taxable income, reversal of existing taxable temporary differences and estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty in income taxes recognized in the financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the financial statements. The amount of benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

Recently Adopted Accounting Pronouncements

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 adopted ASU 2023-09 for the year ended December 31, 2025, and applied the new disclosure requirements prospectively to the current annual period. Prior period disclosures have not been adjusted to reflect the new disclosure requirements.

Recently Issued Accounting Pronouncements

In November 2024, the FASB issued ASU 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40)* to improve financial reporting by requiring that public business entities disclose additional information about specific expense categories in the notes to financial statements at interim and annual reporting periods. ASU 2024-03 is effective for annual periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027, with early adoption permitted. ASU 2023-09 allows for adoption using either a prospective or retrospective method. The Company is currently assessing the impact of the adoption of this guidance on its consolidated financial statements.

In July 2025, the FASB issued ASU 2025-05, Financial Instruments—Credit Losses (Topic 326) to introduce a practical expedient to calculating current expected credit loss by assuming that the current conditions as of the balance sheet date will not change for the remaining life of the asset. This expedient can only be applied to current accounts receivable and current contract assets. ASU 2025-05 is effective for annual reporting periods beginning after December 15, 2025 and interim periods within those annual periods, and this update is applied prospectively. Early adoption is permitted in both interim and annual periods in which financials have not been issued. The Company is currently assessing the impact of the adoption of this guidance on its consolidated financial statements.

In September 2025, the FASB issued ASU 2025-06, Intangibles – Goodwill and Other – Internal-Use Software (Subtopic 350-40): Targeted Improvements to the Accounting for Internal-Use Software, which removes all references to software development project stages and requires entities to start capitalizing software costs when both of the following occur: (i) management has authorized and committed to funding the software project and (ii) it is probable that the project will be completed and the software will be used to perform the function intended. The amendments in ASU 2025-06 are effective for fiscal years beginning after December 15, 2027, and interim periods within those fiscal years, with early adoption permitted as of the beginning of a fiscal year. The amendments can be applied prospectively, retrospectively, or via a modified prospective transition method. The Company is currently assessing the impact of the adoption of this guidance on its consolidated financial statements.

In December 2025, the FASB issued ASU 2025-10, Government Grants (Topic 832): Accounting for Government Grants Received by Business Entities. ASU 2025-10 establishes authoritative guidance for accounting for government grants received by business entities, clarifies the appropriate accounting, in an effort to reduce diversity in practice, and increase consistency of application across business entities. ASU 2025-10 is effective for annual reporting periods beginning after December 15, 2028, and interim reporting periods within those annual reporting periods. Adoption of this guidance can be applied via a modified prospective approach, a modified retrospective approach, or a retrospective approach. Early adoption is permitted. The Company is currently assessing the impact of the adoption of this guidance on its consolidated financial statements.

3. Inventory

Inventory consisted of the following (in thousands):

	December 31,	
	2025	2024
Raw materials	$ 26,249	$ 28,027
Work-in-process	2,006	3,274
Finished goods	20,626	15,253
	$ 48,881	$ 46,554

The Company recorded an immaterial out-of-period adjustment in the fourth quarter of 2024 to reduce inventory by $2.1 million due to inventory-related transactions not being recorded timely and accurately. This adjustment was immaterial for the years ended December 31, 2024 and December 31, 2023.

4. Property, Plant and Equipment, Net

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

	December 31,	
	2025	2024
Transplant aircraft	$ 295,527	$ 252,090
Transplant aircraft equipment	3,100	—
Flight school aircraft	3,717	3,717
OCS Consoles	24,590	19,193
Manufacturing equipment	12,101	10,496
Computer equipment and software	3,376	3,979
Internal-use software	12,413	—
Laboratory equipment	3,698	2,904
Office, trade show and training equipment	5,260	4,698
Leasehold improvements	25,113	22,949
Construction-in-progress	2,174	6,658
Land	2,652	—
	393,721	326,684
Less: Accumulated depreciation and amortization	(66,065)	(40,714)
	$ 327,656	$ 285,970

During the years ended December 31, 2025, 2024 and 2023, total depreciation and amortization expense was $27.0 million, $19.6 million and $8.1 million, respectively. Construction-in-progress as of December 31, 2025 primarily related to the in-process construction of manufacturing equipment. Construction-in-progress as of December 31, 2024 primarily related to capitalized internal-use software that had not yet been placed in service.

The Company capitalized costs associated with the development of internal-use software of $8.1 million and $4.4 million in the years ended December 31, 2025 and 2024, respectively. The Company recorded amortization expense of $1.3 million during the year ended December 31, 2025 related to internal-use software. The Company did not record amortization expense during the year ended December 31, 2024 as no internal-use software assets had been placed into service in 2024. The net book value of internal-use software was $11.2 million and $4.4 million as of December 31, 2025 and 2024, respectively, of which $0.1 million and $4.4 million was included in construction-in-progress as of those respective dates. The Company did not have capitalized costs for internal-use software in the year ended December 31, 2023.

Substantially all of the Company's property, plant and equipment are held in the United States. Land consists of two parcels in Mirandola, Italy.

5. Goodwill and Intangible Assets

The carrying amount of goodwill was $11.5 million as of December 31, 2025 and 2024, and related to the Company's 2023 acquisition of Summit Aviation, Inc. and Northside Property Group, LLC (together "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):

		December 31, 2025		
	Weighted Average Useful Life	Gross Amount	Accumulated Amortization	Carrying Value
	(in years)			
Customer relationship	12	$ 2,320	$ 460	$ 1,860
Other	12	110	22	88
		$ 2,430	$ 482	$ 1,948

		December 31, 2024		
	Weighted Average Useful Life	Gross Amount	Accumulated Amortization	Carrying Value
	(in years)			
Customer relationship	12	$ 2,320	$ 265	$ 2,055
Other	12	110	13	97
		$ 2,430	$ 278	$ 2,152

Amortization expense is recorded within selling, general and administrative expense. Amortization expense for the years ended December 31, 2025, 2024 and 2023 was $0.2 million, $0.2 million and $0.1 million, respectively.

Future amortization expense of the intangible assets as of December 31, 2025, is expected to be as follows (in thousands):

Year Ending December 31,	
2026	$ 203
2027	203
2028	203
2029	203
2030	203
Thereafter	933
	$ 1,948

6. Accrued Expenses and Other Current Liabilities

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

	December 31,	
	2025	2024
Accrued payroll and related expenses	$ 28,443	$ 22,523
Accrued transportation costs	2,700	3,818
Accrued research, development and clinical trials expenses	5,865	4,179
Accrued third-party surgeon costs	3,996	2,546
Accrued professional fees	3,378	2,445
Accrued other	18,358	9,641
	$ 62,740	$ 45,152

7. Long-Term Debt and Financing Arrangements

Convertible Senior Notes

The Notes consisted of the following (in thousands):

	December 31,	
	2025	2024
Principal amount of convertible senior notes	$ 459,996	$ 459,996
Less: Current portion of convertible senior notes	—	—
Convertible senior notes, net of current portion	459,996	459,996
Debt discount, net of accretion	(7,192)	(10,057)
Convertible senior notes, net of discount and current portion	$ 452,804	$ 449,939

As of December 31, 2025, the estimated fair value of the Notes was $693.2 million. The fair value was determined based on the quoted price of the last trade of the Notes prior to the end of the reporting period in an inactive market, which is considered as Level 2 in the fair value hierarchy.

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.

A conditional conversion feature of the Notes was triggered on December 31, 2025, 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 December 31, 2025, and the Notes therefore became convertible at the noteholders' election in the calendar quarter ending March 31, 2026 (and only during this calendar quarter). 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.

The Company accounts for the Notes as a single liability in accordance with ASC Topic 470-20 as the Company concluded that embedded conversion features within the Notes do not meet the requirements for bifurcation. Initial purchaser discounts and other debt issuance costs related to the Notes totaling $14.6 million were recorded by the Company as a debt discount. The debt discount is reflected as a reduction of the carrying value of the Notes on the Company's consolidated balance sheets and is being accreted to interest expense over the term of the Notes using the effective interest method. During the years ended December 31, 2025, 2024 and 2023, the Company recognized $9.8 million, $9.7 million and $6.2 million, respectively, in interest expense related to the 1.50% cash coupon of the Notes and amortization of the debt issuance costs. During the years ended December 31, 2025, 2024 and 2023, the effective interest rate on the outstanding Notes was approximately 2.1%.

Capped Call Transactions

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

	December 31,	
	2025	2024
Principal amount of long-term debt	$ 60,000	$ 60,000
Less: Current portion of long-term debt	(10,000)	—
Long-term debt, net of current portion	50,000	60,000
Debt discount, net of accretion	(413)	(628)
Long-term debt, net of discount and current portion	$ 49,587	$ 59,372

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 Second Amendment to Credit Agreement, dated as of June 23, 2023, by and among the Company, and CIBC, the Third Amendment to Credit Agreement, dated as of November 9, 2023, by and among the Company, and CIBC (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%. The Company is obligated to repay the outstanding principal amount in equal monthly installments commencing in July 2026 with the remaining balance due on the maturity date in July 2027. At the Company's option, the Company may prepay the outstanding principal amount under the CIBC Credit Agreement, without a prepayment fee.

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

All obligations under the CIBC Credit Agreement are guaranteed by the Company and each of its material subsidiaries. All obligations of the Company and each guarantor are secured by substantially all of the Company's and each guarantor's assets, including their intellectual property, subject to certain exceptions. Under the CIBC Credit Agreement, the Company has agreed to customary representations and warranties, events of default and certain affirmative and negative covenants to which it will remain subject until maturity. The financial covenants include, among other covenants, (x) a requirement to maintain a minimum liquidity amount of the greater of either (i) the consolidated adjusted EBITDA loss (or gain), 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 December 31, 2025, the Company was in compliance with all financial covenants of the CIBC Credit Agreement.

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

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

As of December 31, 2025, the stated interest rate applicable to borrowings under the CIBC Credit Agreement was 5.7%. During the years ended December 31, 2025, 2024 and 2023, the Company recognized $4.0 million, $4.7 million and $4.6 million, respectively, in interest expense related to the variable interest rate on borrowings and amortization of the debt issuance costs. During the years ended December 31, 2025, 2024 and 2023, the weighted average effective interest rate on outstanding borrowings under the CIBC Credit Agreement was approximately 6.8%, 7.7% and 7.7%, respectively.

8. Equity

Preferred Stock

As of December 31, 2025, the Company's articles of organization authorized the Company to issue up to 25,000,000 shares of preferred stock, no par value per share, all of which is undesignated. The preferred stock will have such rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, as shall be determined by the Company's boards of directors upon issuance.

Common Stock

As of December 31, 2025, the Company's articles of organization authorized the Company to issue up to 150,000,000 shares of common stock, no par value per share. Each share of common stock is entitled to one vote on all matters submitted to a vote of the Company's stockholders. The holders of common stock are entitled to receive dividends, if any, as may be declared by the board of directors, as described above. Through December 31, 2025, no dividends had been declared or paid.

Warrants

In April 2024, warrants for the purchase of 14,440 shares of common stock at an exercise price of $17.47 per share were exercised in a cashless exercise resulting in the issuance of 11,735 shares of common stock. As of December 31, 2025 and 2024, the Company had no outstanding warrants.

9. Stock-Based Compensation

2019 Stock Incentive Plan

The 2019 Stock Incentive Plan (the "2019 Plan") provides for the grant of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock, restricted stock units, unrestricted stock, unrestricted stock units, and other stock-based awards to employees, directors, and consultants of the Company and its subsidiaries. The number of shares of common stock of TransMedics Group initially available for issuance under the 2019 Plan was 3,428,571 shares, plus the number of shares underlying awards under the previously outstanding 2014 Stock Incentive Plan (the "2014 Plan"), not to exceed 1,595,189 shares, that expire or are terminated, surrendered, or cancelled without the delivery of shares, are forfeited to or repurchased by TransMedics Group or otherwise become available again for grant. Since the effectiveness of the Company's 2019 Plan in April 2019, no awards have been made 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 2019 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 2019 Plan until June 1, 2033 and (iv) increase the annual limits on non-employee director compensation. As of December 31, 2025, 414,758 shares of common stock were available for issuance under the Amended 2019 Plan.

2021 Inducement Plan

In August 2021, the Company's board of directors approved the TransMedics Group, Inc. Inducement Plan (the "Inducement Plan"). Pursuant to the terms of the Inducement Plan, the Company may grant nonqualified stock options, stock appreciation rights, restricted stock, unrestricted stock, restricted stock unit awards and performance awards to individuals who were not previously employees or directors of the Company or individuals returning to employment after a bona fide period of non-employment with the Company. A total of 1,000,000 shares of the Company's common stock were initially available for issuance under the Inducement Plan. 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 December 31, 2025, 429,145 shares of common stock remained available for issuance under the Inducement Plan.

Awards granted under the Amended 2019 Plan and Inducement Plan vest over periods determined by the board of directors and expire no longer than ten years from the date of the grant. The exercise price for stock options granted is not less than the fair value of common shares based on quoted market prices.

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 common stock of TransMedics Group were initially reserved for issuance under the 2019 ESPP. During the year ended December 31, 2025, 58,996 shares were issued under the 2019 ESPP and as of December 31, 2025, 174,260 shares remained available for issuance under the 2019 ESPP.

Stock Option Valuation

The fair value of stock option grants is estimated using the Black-Scholes option-pricing model. Because there had been no public market for the Company's common stock prior to the Company's initial public offering, there is limited Company-specific historical and implied volatility data. Accordingly, the Company bases its estimates of expected volatility on a combination of the Company's own historical volatility and historical volatility of a group of publicly-traded companies with similar characteristics to itself. For options with service-based vesting conditions, the expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

The following table presents, on a weighted average basis, the assumptions used in the Black-Scholes option-pricing model to determine the grant-date fair value of stock options granted to employees and directors:

	Year Ended December 31,		
	2025	2024	2023
Risk-free interest rate	4.19%	4.25%	4.15%
Expected term (in years)	6.04	6.03	6.03
Expected volatility	71%	68%	69%
Expected dividend yield	0%	0%	0%

The following table summarizes the Company's option activity since December 31, 2024:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Contractual Term	Aggregate Intrinsic Value
			(in years)	(in thousands)
Outstanding as of December 31, 2024	2,773,556	$ 38.88	6.71	$ 76,855
Granted	352,045	82.95		
Exercised	(431,771)	31.84		
Forfeited	(95,723)	65.92		
Expired	(3,677)	71.09		
Outstanding as of December 31, 2025	2,594,430	$ 44.99	6.23	$ 199,697
Vested and expected to vest as of December 31, 2025	2,594,430	$ 44.99	6.23	$ 199,697
Options exercisable as of December 31, 2025	1,937,447	$ 34.63	5.51	$ 168,882

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock. The aggregate intrinsic value of stock options exercised during the years ended December 31, 2025, 2024 and 2023, was $36.3 million, $80.1 million and $31.0 million, respectively. The weighted average grant-date fair value of stock options granted during the years ended December 31, 2025, 2024 and 2023 was $55.04 per share, $57.12 per share and $41.75 per share, respectively.

The Company has not granted any stock-based awards with performance-based vesting conditions.

Restricted Common Stock

Shares of unvested restricted common stock may not be sold or transferred by the holder. If the holder's service to the Company and its affiliates ceases for any reason, unvested shares of restricted common stock held by these individuals will immediately be forfeited for no consideration, as provided in the individual restricted stock agreements.

The following table summarizes the Company's restricted common stock activity since December 31, 2024:

	Shares	Weighted Average Grant Date Fair Value
Unvested restricted common stock as of December 31, 2024	4,160	$ 156.00
Issued	1,737	129.35
Vested	(1,280)	156.00
Forfeited	(2,880)	156.00
Unvested restricted common stock as of December 31, 2025	1,737	$ 129.35

The aggregate fair value of restricted stock that vested during the years ended December 31, 2025, 2024 and 2023 was $0.2 million, $1.4 million and $1.7 million, respectively. The Company granted restricted common stock during the years ended December 31, 2025, 2024 and 2023 with a weighted average grant-date fair value of $129.35, $156.00 and $72.75 per share, respectively.

Restricted Stock Units

The following table summarizes the Company's restricted stock unit activity since December 31, 2024:

	Shares	Weighted Average Grant Date Fair Value
Unvested restricted stock units as of December 31, 2024	430,250	$ 78.09
Granted	389,342	82.99
Vested	(161,417)	76.95
Forfeited	(51,692)	84.52
Unvested restricted stock units as of December 31, 2025	606,483	$ 81.00

The aggregate fair value of restricted stock units that vested during the years ended December 31, 2025 and 2024 was $14.2 million and $11.3 million, respectively. There was no restricted stock units vesting during the year ended December 31, 2023. The Company granted restricted stock units during the years ended December 31, 2025, 2024 and 2023 with a weighted average grant-date fair value of $82.99, $89.60 and $63.74 per share, respectively.

Stock-Based Compensation

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

	Year Ended December 31,		
	2025	2024	2023
Cost of revenue	$ 1,360	$ 1,480	$ 438
Research, development and clinical trials expenses	4,741	4,194	2,823
Selling, general and administrative expenses	30,760	27,550	16,530
	$ 36,861	$ 33,224	$ 19,791

The Company recognized income tax benefits related to stock-based compensation expense of $8.9 million as a component in calculating its income tax benefit for the year ended December 31, 2025. The Company did not record income tax benefits related to stock-based compensation expense for the years ended December 31, 2024 and 2023 due to the full valuation allowance against deferred tax assets.

As of December 31, 2025, total unrecognized compensation cost related to unvested share-based awards was $63.1 million, which is expected to be recognized over a weighted-average period of 2.2 years.

10. Income Taxes

Income (Loss) Before Income Taxes

The domestic and foreign components of income (loss) before income taxes were as follows (in thousands):

	Year Ended December 31,		
	2025	2024	2023
United States	$ 106,352	$ 35,318	$ (27,038)
Foreign	1,170	462	367
	$ 107,522	$ 35,780	$ (26,671)

Tax Provision Components

The components of income taxes were as follows (in thousands):

	Year Ended December 31,		
	2025	2024	2023
Current income tax expense:			
Federal	$ —	$ —	$ —
State	718	216	25
Foreign	56	100	24
Deferred income tax expense (benefit):			
Federal	(65,562)	—	(1,292)
State	(17,981)	—	(400)
Foreign	—	—	—
Income tax expense (benefit)	$ (82,769)	$ 316	$ (1,643)

The Company adopted ASU 2023-09 on a prospective basis beginning with the year ended December 31, 2025. The following table presents required disclosure pursuant to ASU 2023-09 and reconciles the U.S. federal statutory income tax amount and rate to the Company's effective amount and rate for the year ended December 31, 2025 (dollar amounts in thousands):

	Year Ended December 31, 2025	
	Amount	Percent
Federal statutory income tax rate	$ 22,580	21.0%
State and local income tax, net of federal (national) income tax effect(1)	(17,685)	(16.4)%
Effect of changes in tax laws or rates enacted in the current period	273	0.3%
Federal tax credits	5,887	5.5%
Changes in federal valuation allowance	(116,448)	(108.3)%
Nontaxable or nondeductible items		
Permanent differences	172	0.2%
Executive compensation	1,015	0.9%
Federal net operating loss adjustments	27,416	25.5%
Tax attribute true up	(1,415)	(1.3)%
Stock-based compensation expense	(4,367)	(4.1)%
Other adjustments	(197)	(0.3)%
Effective income tax rate	$ (82,769)	(77.0)%

(1) State income tax expense is impacted primarily by the release of the state valuation allowance of $31.5 million, partially offset by the impact of the 382 assessment on the Company's Massachusetts net operating loss carryforwards and Massachusetts research and development tax credits, totaling $12.1 million.

The One Big Beautiful Bill Act (“OBBBA”) was signed into law on July 4, 2025, which, among other provisions, permanently repeals the requirement to capitalize domestic research expenditures for federal income tax purposes for taxable years beginning after December 31, 2024, and allows for the accelerated deduction of any remaining unamortized domestic research expenditures over one or two years. Foreign research expenditures are still required to be capitalized and amortized ratably over 15

years. The OBBBA also allows the option to claim 100% accelerated depreciation deductions on qualified property. In accordance with ASC 740, the impacts of the OBBBA are reflected in the Company's income tax benefit for the year ended December 31, 2025.

The following table presents the required disclosures prior to adoption of ASU 2023-09 and reconciles the U.S. federal statutory income tax rate to the effective income tax rate for the years ended December 31, 2024 and 2023:

	Year Ended December 31,	
	2024	2023
Federal statutory income tax rate	21.0%	(21.0)%
State taxes, net of federal benefit	(2.2)%	(7.1)%
Federal and state research and development tax credits	(12.0)%	(10.2)%
State deferred tax adjustment	(1.3)%	(27.5)%
Nondeductible items	3.1%	1.2%
Stock-based compensation expense	(38.5)%	(5.7)%
Deferred tax effect of change in state blended rate	6.2%	(5.9)%
Return to provision	2.5%	(1.5)%
Other	0.1%	(0.1)%
Change in deferred tax asset valuation allowance	22.0%	71.6%
Effective income tax rate	0.9%	(6.2)%

Net deferred tax assets consisted of the following (in thousands):

	December 31,	
	2025	2024
Deferred tax assets:		
Net operating loss carryforwards	$ 95,572	$ 106,684
Capitalized research and development expense	1,307	23,157
Acquired in-process research and development expenses	5,797	6,181
Research and development tax credit carryforwards	10,967	20,232
Accrued expenses	6,281	5,820
Stock-based compensation expense	12,713	8,103
Lease liability	1,622	2,180
Section 163(j) interest	—	280
Other	489	578
Total deferred tax assets	134,748	173,215
Deferred tax liabilities:		
Property, plant and equipment	(45,815)	(22,256)
Right-of-use assets	(3,329)	(1,554)
Intangible assets	(1,182)	(546)
Total deferred tax liabilities	(50,326)	(24,356)
Valuation allowance	(879)	(148,859)
Net deferred tax assets	$ 83,543	$ —

As of December 31, 2025, the Company had federal net operating loss carryforwards of $370.9 million, which may be available to offset future taxable income, of which $74.0 million expire at various dates between 2030 and 2037, while the remaining $296.9 million do not expire but are limited in their usage to an annual deduction equal to 80% of taxable income. As of December 31, 2025, the Company had state net operating loss carryforwards of $261.6 million, which may be available to offset future taxable income and expire at various dates between 2030 and 2045. As of December 31, 2025, the Company had U.S. federal and state research and development tax credit carryforwards of $7.3 million and $4.0 million, respectively, which may be available to offset future tax liabilities and expire at various dates between 2026 and 2045. As of December 31, 2025, the Company had no foreign net operating loss carryforwards.

Utilization of the U.S. federal and state net operating loss carryforwards and research and development tax credit carryforwards may be subject to limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, and corresponding provisions of state law, due to ownership changes that have occurred previously. Future ownership changes could result in

additional limitations. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income or tax liabilities. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain stockholders or public groups in the stock of a corporation by more than 50% over a three-year period. During 2025, the Company completed a 382 assessment and determined that the Company underwent multiple ownership changes since inception. Net operating loss carryforwards and development tax credit carryforwards were limited by these changes. The Company recorded a reduction to its gross U.S. deferred tax assets of $44.7 million during the year ended December 31, 2025 relating to these limitations, with a corresponding decrease to its valuation allowance.

As required by ASC 740, management evaluated positive and negative evidence when assessing the realizability of its deferred tax assets, which are comprised principally of net operating loss carryforwards. During the fourth quarter of 2025, the Company concluded that it is more likely than not that the Company will realize substantially all its net U.S. Federal and state deferred tax assets and accordingly, recognized a benefit to income tax expense of $103.3 million related to the release of its valuation allowance against deferred tax assets. Management relied primarily on cumulative income over the preceding twelve quarters, recent operating profits and, to a lesser extent, expected future profits in its assessment to release the valuation allowance. A valuation allowance of $0.9 million was maintained on certain state tax attributes as it was considered more-likely-than-not that these tax attributes would expire before realization. As of December 31, 2024, the Company had a full valuation allowance against its U.S. federal and state deferred tax assets.

Changes in the valuation allowance for deferred tax assets during the year ended December 31, 2025 related to the valuation allowance release described above. Changes in the valuation allowance for deferred tax assets during the year ended December 31, 2024 related primarily to federal and state net operating losses generated, capitalized research and development costs, and federal and state research and development tax credits generated, partially offset by an increase in deferred tax liabilities related to depreciation expense. Changes in the valuation allowance for deferred tax assets during the year ended December 31, 2023 related primarily to current year federal and state net operating losses generated, acquired IPR&D and capitalized research and development costs.

The changes in the valuation allowance were as follows (in thousands):

	Year Ended December 31,		
	2025	2024	2023
Valuation allowance as of beginning of year	$ (148,859)	$ (140,986)	$ (121,891)
Decreases recorded as benefit to income tax provision	147,980	—	—
Increases recorded to income tax provision	—	(7,873)	(19,095)
Valuation allowance as of end of year	$ (879)	$ (148,859)	$ (140,986)

As of December 31, 2025 and 2024, the Company had no uncertain tax positions and no accrued interest or penalties related to uncertain tax positions. The Company's policy is to record any interest or penalties related to income taxes as part of the income tax provision.

The Company files income tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. There are currently no pending federal or state tax examinations. The Company has open tax years subject to examination in the United States from fiscal year 2022 to present. To the extent that the Company has carryforward attributes, the tax years in which the attribute was generated may still be adjusted upon examination by federal, state or local tax authorities if they either have been or will be used in the future.

Income taxes paid (net of refunds received) for the year ended December 31, 2025 were as follows (in thousands):

	Year Ended December 31, 2025
Aggregated state and local jurisdictions	$ 145
Disaggregated state and local jurisdictions:	
California	802
Texas	200
Total	$ 1,147

During the years ended December 31, 2024 and 2023, income taxes paid were not material.

11. Leases

The Company leases its office, laboratory and manufacturing space under two noncancelable leases that expire in December 2027 and include a lease incentive, fixed payment escalations, and rent holidays. The leases include an option to renew for an additional five years. The option to extend the lease term was not included in the right-of-use asset and the lease liability as it was not reasonably certain of being exercised. The Company classified the leases as operating leases under ASC 842. Annual base rent increases at an average rate of 2.5% each year until the end of the term. The Company is also obligated to pay the landlord certain costs, taxes, and operating expenses, subject to certain exclusions. As these costs are generally variable in nature, they are not included in the measurement of the right-of-use asset and related lease liability. In June 2023, the Company amended one of its lease agreements to add space through the remainder of the lease term and under the existing terms of the lease.

In connection with the acquisition of Summit, the Company acquired a 20-year operating lease with one 10-year renewal option, for space at the Bozeman Yellowstone International Airport in Bozeman, Montana where the Company constructed a commercial aircraft hangar.

In June 2024, the Company entered into a lease for office and hangar space in Dallas, Texas that expires June 30, 2027, subject to certain early termination provisions. Fixed monthly payments total $1.7 million over the three-year term of the lease. The Company is also obligated to pay the landlord certain variable costs. The Company recorded a right-of-use asset and related lease liability of $1.5 million in the third quarter of 2024, upon commencement of the lease.

The Company also leases office space for its NOP and hangar space for its aircraft at various locations in the U.S. under both short-term and long-term leases, and leases space for distribution and commercial operations in Europe.

The components of the Company's lease expense under ASC 842 are as follows (in thousands):

	Year Ended December 31,		
	2025	2024	2023
Operating lease cost	$ 2,682	$ 2,215	$ 1,692
Short-term lease cost	2,408	1,861	1,606
Variable lease cost	2,620	1,920	1,495
	$ 7,710	$ 5,996	$ 4,793

Supplemental disclosure of cash flow information related to the leases were as follows (in thousands):

	Year Ended December 31,		
	2025	2024	2023
Cash paid for amounts included in the measurement of operating lease liabilities	$ 3,447	$ 2,916	$ 2,246

The weighted-average remaining lease term as of December 31, 2025 and 2024 was 2.8 years and 3.7 years, respectively. The weighted-average discount rate as of December 31, 2025 and 2024 was 6.8% and 6.9%, respectively. Because the interest rate implicit in the leases was not readily determinable, the Company's estimated incremental borrowing rate was used to calculate the present value of the leases. In determining its incremental borrowing rate, the Company considered its credit quality and assessed interest rates available in the market for similar borrowings, adjusted for the impact of collateral over the term of the leases.

Future payments for the Company's operating lease liabilities as of December 31, 2025 are as follows (in thousands):

Year Ending December 31,	
2026	$ 3,677
2027	3,341
2028	132
2029	25
2030	25
Thereafter	559
Total future minimum lease payments	7,759
Less: imputed interest	(872)
Total operating lease liabilities	$ 6,887

The following table represents operating lease liabilities on the consolidated balance sheets (in thousands):

	December 31, 2025
Current operating lease liabilities	$ 3,310
Operating lease liabilities, net of current portion	3,577
Total operating lease liabilities	$ 6,887

In January 2026, the Company entered into a new lease agreement and purchased land in Somerville, Massachusetts to eventually replace its existing headquarters in Andover, Massachusetts (see Note 16).

12. Commitments and Contingencies

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 years ended December 31, 2025, 2024 and 2023, the Company recorded expense of $3.9 million, $3.3 million and $1.4 million, respectively, related to these matching contributions.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to customers, 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, negligence or willful misconduct, 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 and executive officers 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 December 31, 2025 and 2024.

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 December 31, 2025 was $4.0 million.

Legal Proceedings

On February 14, 2025, a class action captioned Jewik v. TransMedics Group, Inc., et al., Case No. 1:25-cv-10385, was filed against the Company and certain of its current and former officers in the U.S. District Court for the District of Massachusetts. The complaint purported to assert claims pursuant to Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), as amended, and SEC Rule 10b-5 promulgated thereunder, seeking unspecified damages on behalf of a putative class of investors who purchased or otherwise acquired the Company's shares between February 28, 2023 and January 10, 2025 (the "Class Period"). On April 2, 2025, another purported stockholder filed a putative class action lawsuit against the Company and certain of its current and former officers, also in the U.S. District Court for the District of Massachusetts (Collins v. TransMedics Group, Inc., et al., Case No. 1:25-cv-10778). The Collins complaint alleged claims substantially similar to those alleged in the Jewik action and also sought unspecified damages. On May 22, 2025, the court consolidated the Jewik and Collins actions and appointed the Peace Officers' Annuity and Benefit Fund of Georgia and Oguzhan Altun as lead plaintiffs (the "Lead Plaintiffs").

On August 8, 2025, Lead Plaintiffs filed a consolidated amended complaint. Like the earlier-filed complaints, the amended complaint purports to assert claims pursuant to Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5, on behalf of a putative class of investors who purchased or otherwise acquired the Company's shares during the Class Period. Lead Plaintiffs seek unspecified damages allegedly caused by purported misstatements and omissions contained in our 2022 Annual Report, certain earnings calls, and other public statements. The amended complaint claims these alleged statements and omissions operated to artificially inflate the price paid for our common stock during the Class Period. On October 7, 2025, defendants filed a motion to dismiss the amended complaint for failure to state a claim. Lead Plaintiffs' filed their response to the motion on November 21, 2025, and defendants' filed a reply in further support of their motion on December 22, 2025. The Company cannot anticipate when the court will rule on that motion.

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. At this time, the Company is unable to predict the outcome of the class action litigation or reasonably estimate a range of possible losses. The Company expenses as incurred the costs related to such legal proceedings.

13. Revenue and Segment Information

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):

	Year Ended December 31,		
	2025	2024	2023
OCS transplant revenue by country by organ(1)(2):			
United States			
Lung total revenue	$ 13,443	$ 15,755	$ 10,548
Heart total revenue	111,839	96,663	59,080
Liver total revenue	459,415	309,462	151,719
Total United States OCS transplant revenue	584,697	421,880	221,347
All other countries			
Lung revenue	1,418	1,926	1,272
Heart revenue	14,169	13,198	14,012
Liver revenue	1,113	158	104
Total all other countries OCS transplant revenue	16,700	15,282	15,388
Total OCS transplant revenue	$ 601,397	$ 437,162	$ 236,735

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

(2) Service revenue unrelated to OCS transplant, which was $4.1 million, $4.4 million and $4.9 million for the years ended December 31, 2025, 2024 and 2023, respectively, is not included in this table.

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. The Company records the reduction of revenue and a corresponding accrual for its estimate of the payments in the same period as the revenue is recognized. The Company updates its accrual estimates as information related to these payments is received with a corresponding adjustment to revenue.

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

	Year Ended December 31,		
	2025	2024	2023
Gross product revenue from sales to customers	$ 372,401	$ 273,680	$ 176,047
Less: clinical trial payment estimates	—	(186)	(22)
Total net product revenue	$ 372,401	$ 273,866	$ 176,069

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 years ended December 31, 2025, 2024 and 2023, the Company recorded $6.1 million, $6.0 million and $2.4 million, respectively, of operating expense related to these costs.

Segment Information

The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. 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 (the "CODM"), in deciding how to allocate resources and assess performance. The CODM of the Company is the Chief Executive Officer. The CODM assesses performance and allocates resources based on the Company's consolidated statements of operations and the Company's operations are managed on a consolidated basis to decide where to allocate and invest additional resources within the business to continue growth. The CODM also utilizes the consolidated balance sheet for resource allocation and segment asset information is not provided to the CODM to allocate resources.

As a single reportable segment entity, the Company's segment performance measure is net income (loss). Significant segment expenses, as provided to the CODM, are presented below (in thousands):

	Year Ended December 31,		
	2025	2024	2023
Total revenue	$ 605,494	$ 441,540	$ 241,623
Less:			
Cost of net product revenue	77,822	58,345	41,015
Cost of service revenue	164,866	121,114	46,515
Research, development and clinical trials:			
Personnel related (including stock-based compensation expense)	25,720	21,927	15,489
Laboratory supplies and research materials	17,550	13,990	7,939
Consulting and third-party services	15,492	12,920	5,788
Clinical trials costs	1,459	478	1,077
Facility related and other	8,834	6,653	5,762
Acquired in-process research and development expenses	—	—	27,212
Selling, general and administrative:			
Personnel related (including stock-based compensation expense)	114,506	109,475	72,717
Professional and consultant fees	25,936	18,313	17,401
NOP support	6,826	12,289	11,985
Tradeshows and conferences	4,316	4,328	4,575
Facility related and other	33,584	24,212	12,875
Other segment items(1)	(81,708)	2,032	(3,699)
Net income (loss)	$ 190,291	$ 35,464	$ (25,028)

(1) Other segment items include interest income, interest expense, foreign currency exchange gains and losses and income taxes, including an income tax benefit of $82.8 million for the year ended December 31, 2025. See the consolidated financial statements for other financial information regarding the Company's operating segment.

14. 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):

	Year Ended December 31,		
	2025	2024	2023
Numerator:			
Net income (loss)	$ 190,291	$ 35,464	$ (25,028)
Add: Interest expense, net of tax, attributable to assumed conversion of convertible senior notes	7,285	—	—
Net income (loss), diluted	$ 197,576	$ 35,464	$ (25,028)
Denominator:			
Weighted average basic common shares outstanding	33,993,468	33,229,953	32,517,372
Effect of dilutive securities:			
Convertible senior notes	4,893,805	—	—
Options to purchase common stock	1,406,848	1,783,507	—
Restricted stock units	241,805	193,476	—
Warrants to purchase common stock	—	3,470	—
Restricted stock awards	410	3,197	—
Employee stock purchase plan	4,358	3,234	—
Weighted average dilutive common shares outstanding	40,540,694	35,216,837	32,517,372
Net income (loss) per share:			
Basic	$ 5.60	$ 1.07	$ (0.77)
Diluted	$ 4.87	$ 1.01	$ (0.77)

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:

	Year Ended December 31,		
	2025	2024	2023
Convertible senior notes	—	4,893,838	3,150,834
Options to purchase common stock	482,985	371,502	2,595,161
Employee stock purchase plan	9,373	10,170	13,262
Restricted stock units	52,305	9,912	141,906
Restricted stock awards	1,018	1,125	13,586
Warrants to purchase common stock	—	—	14,440
	545,681	5,286,547	5,929,189

15. Related Party Transactions

Employment of Dr. Amira Hassanein

Dr. Amira Hassanein, who serves as Product Director for the Company's OCS Lung program, is the sister of Dr. Waleed Hassanein, the Company's President, Chief Executive Officer and a member of the Company's board of directors. The Company paid Dr. Amira Hassanein $0.8 million, $0.5 million and $0.4 million in total compensation in the years ended December 31, 2025, 2024 and 2023, respectively, for her services as an employee.

16. Subsequent Events

On January 8, 2026, the Company entered into a lease agreement (the "Lease") with BioMed Realty (the "Landlord") for the lease of approximately 498,286 square feet of space in Somerville, Massachusetts for the Company's principal executive offices and for research and development, laboratory, manufacturing and assembly, vivarium, office and related uses (the "Premises") to ultimately replace its existing headquarters in Andover, Massachusetts. Base rent begins to accrue on the latter of: (a) January 1, 2028, and (b) the date that is twenty-four (24) months after term commencement date (but in no event later than February 1, 2028). The Lease will expire one hundred ninety-two (192) months from date base rent begins to accrue, unless earlier terminated (the "Initial Term"). The Lease includes a one-time purchase option, which may be exercised by the Company within a defined time period.

The annual base rent under the Lease will initially be approximately $23.9 million. Base rent will increase by 2% annually during the first three years of the Initial Term and by 3% annually for each year thereafter during the remainder of the Initial Term. The Company will also be responsible for a pro rata share of the payment of additional rent to cover the Company's share of the annual operating and tax expenses for the Premises, with the Company's share estimated to be approximately 100%. The Company holds two consecutive options to extend the Initial Term for additional periods of ten years each, exercisable by written notice delivered not less than 18 months prior to the expiration of the then-current term and subject to customary conditions, including that no default then exists. The Company also holds an option to extend the Lease term for a period of six months, exercisable by written notice delivered not less than 18 months prior to the expiration of the then-current term and subject to customary conditions, including that no default then exists.

The Company has delivered a security deposit to the Landlord in the form of a letter of credit for approximately $18.0 million, which may be drawn down by the Landlord to be applied for certain purposes upon the Company's breach of certain provisions under the Lease. The Lease also contains customary provisions allowing the Landlord to terminate the Lease if the Company fails to remedy a breach of any of its obligations within specified time periods, or upon bankruptcy or insolvency of the Company.

On January 8, 2026, the Company acquired two parcels adjacent to the Premises in Somerville, Massachusetts from BRE-BMR Assembly Innovation I LLC and BRE-BMR Middlesex LLC, respectively. The purchase price was $15.0 million for each property, plus related costs, title company expenses, and tax payments.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None

Item 9A. 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 officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2025. 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 December 31, 2025, our President and Chief Executive Officer and our Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were not effective due to the material weakness in internal control over financial reporting described below. Notwithstanding the material weakness, and based on the additional analyses and other procedures management performed, we have concluded that our consolidated financial statements included in this Annual Report on Form 10-K present fairly, in all material respects, our financial position and results of operations and cash flows as of each of the dates, and for each of the periods, presented therein in accordance with generally accepted accounting principles in the United States of America.

Management's Annual Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our board of directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP.

Internal control over financial reporting includes policies and procedures that: (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect transactions and disposition of assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that receipts and expenditures are being made only in accordance with the authorization of its management and directors; and (3) provide reasonable assurance regarding the prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on its financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of the effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies and procedures may deteriorate.

Our management conducted an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2025 based on the criteria described in "Internal Control-Integrated Framework" (2013) issued by the Committee of Sponsoring Organization of the Treadway Commission. Based on this assessment, management concluded that, as of December 31, 2025, our internal control over financial reporting was not effective due to the material weakness described below.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company's annual or interim financial statements will not be prevented or detected on a timely basis. The Company did not design and maintain effective controls over inventory movement within its manufacturing network. Specifically, while effective controls are in place to verify the existence and accuracy of inventory as of year-end, effective controls were not designed and maintained to verify that inventory movements are appropriately recorded during interim periods. The material weakness resulted in immaterial misstatements to inventory, accounts payable, cost

of net product revenue, selling, general and administrative expenses and research and development expenses, in the interim consolidated financial statements for the quarterly period ended March 31, 2025 and the quarterly and year-to-date periods ended March 31, 2024, June 30, 2024 and September 30, 2024. Additionally, the material weakness could result in a misstatement of the aforementioned accounts and disclosures that would result in a material misstatement to the interim consolidated financial statements that would not be prevented or detected.

The effectiveness of our internal control over financial reporting as of December 31, 2025 has been audited by PricewaterhouseCoopers, LLP, an independent registered public accounting firm, as stated in their report which appears in Item 8 of this Form 10-K.

Remediation Plan

Management has developed and is in the process of implementing the remediation plan to address the material weakness, which includes the design and implementation of new control activities, including system-based controls, to ensure the movement of inventory is timely and accurately recorded throughout the course of the year, as well as strengthening review and approval procedures. The material weakness will not be considered remediated until management has completed the design and implementation of the applicable controls and they operate for a sufficient period of time for management to conclude, through testing, that controls are operating effectively.

Changes in Internal Control over Financial Reporting

No changes 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 December 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

During our fiscal quarter ended December 31, 2025, certain of our directors and officers entered into a contract, instruction or written plan for the purchase or sale of our securities that is 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)(3)	Covers Purchase Or Sale
Tamer Khayal	Adoption 12/11/2025	16-Mar-26	17-Mar-27	Common Stock	22,928	Sale

(1) The 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) The maximum number of securities to be sold pursuant to the Rule 10b5-1 Trading Plan is equal to 22,928, plus shares that may be received by Dr. Khayal in connection with vesting of restricted stock units prior to the scheduled termination date and carryover shares from a prior 10b5-1 plan.

Item 9C. Disclosures Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item 10 will be included in our Definitive Proxy Statement to be filed with the Securities and Exchange Commission, or SEC, with respect to our 2026 Annual Meeting of Stockholders and is incorporated herein by reference.

The Company has adopted an insider trading policy governing the purchase, sale and other dispositions of the Company's securities that applies to the Company's directors, officers, employees, and other covered persons. The Company's insider trading policy also applies to transactions by the Company in its securities. The Company believes that its insider trading policy is reasonably designed to promote compliance with insider trading laws, rules and regulations, and exchange listing standards applicable to the Company. A copy of the Company's insider trading policy is filed as Exhibit 19.1 to our 2024 Annual Report on Form 10-K and incorporated by reference herein.

Item 11. Executive Compensation.

The information required by this Item 11 will be included in our Definitive Proxy Statement to be filed with the Securities and Exchange Commission, or SEC, with respect to our 2026 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this Item 12 will be included in our Definitive Proxy Statement to be filed with the Securities and Exchange Commission, or SEC, with respect to our 2026 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this Item 13 will be included in our Definitive Proxy Statement to be filed with the Securities and Exchange Commission, or SEC, with respect to our 2026 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this Item 14 will be included in our Definitive Proxy Statement to be filed with the Securities and Exchange Commission, or SEC, with respect to our 2026 Annual Meeting of Stockholders and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(1) Financial Statements

The following documents are included on pages 80 through 114 attached hereto and are filed as part of this Annual Report on Form 10-K.

(2) Financial Statement Schedules:

All financial statement schedules have been omitted because they are not applicable, not required or the information required is shown in the financial statements or the notes thereto.

(3) Exhibits.

The following is a list of exhibits filed as part of this Annual Report on Form 10-K.

Exhibit Number	Description
3.1	Restated Articles of Organization (incorporated by reference to Exhibit 3.1 to the Registrant's Annual Report on Form 10-K (File No. 001-38891) filed with the SEC on March 17, 2020)
3.2	Second Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-38891) filed with the SEC on November 4, 2022)
4.1	Specimen stock certificate evidencing shares of common stock (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019).
4.2	Description of Registered Securities (incorporated by reference to Exhibit 4.5 to the Registrant's Annual Report on Form 10-K (File No. 001-38891) filed with the SEC on March 17, 2020)
4.3	Indenture, dated as of May 11, 2023, by and between TransMedics Group, Inc. and U.S. Bank Trust Company, National Association (including the form of the 1.50% Convertible Senior Note due 2028) (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-38891) filed with the SEC on May 11, 2023).
4.4	Form of Note (included in Exhibit 4.1) (incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K (File No. 001-38891) filed with the SEC on May 11, 2023).
10.1	Ninth Amended and Restated Investor Rights Agreement, dated as of May 6, 2019, by and among TransMedics Group, Inc., TransMedics, Inc. and the shareholders party thereto (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-38891) filed with the SEC on May 1, 2019)
10.2	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers (incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)
10.3#	Amended and Restated 2004 Stock Incentive Plan (incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)

10.4#	Form of Incentive Stock Option Agreement under 2004 Stock Incentive Plan (incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)
10.5#	Amended and Restated 2014 Stock Incentive Plan (incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)
10.6#	Form of Incentive Stock Option Agreement under 2014 Stock Incentive Plan (incorporated by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)
10.7#	Form of Non-Qualified Stock Option Agreement under 2014 Stock Incentive Plan (incorporated by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)
10.8#	Form of Restricted Stock Agreement under 2014 Stock Incentive Plan (incorporated by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)
10.9#	Amended and Restated 2019 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-38891) filed with the SEC on May 26, 2023)
10.10#	Form of Incentive Stock Option Agreement under 2019 Stock Incentive Plan (incorporated by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 22, 2019)
10.11#	Form of Non-Statutory Stock Option Agreement under 2019 Stock Incentive Plan (incorporated by reference to Exhibit 10.11 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 22, 2019)
10.12#	Form of Restricted Stock Unit Award under 2019 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-38891) filed with the SEC on February 24, 2023).
10.13#	2019 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 22, 2019)
10.14#	2019 Cash Incentive Plan (incorporated by reference to Exhibit 10.13 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 22, 2019)
10.15#	TransMedics Group, Inc. Inducement Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-38891) filed with the SEC on August 9, 2021)
10.16#	Form of Inducement Restricted Stock Unit Award (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 001-38891) filed with the SEC on February 24, 2023).
10.17#	Executive Retention Agreement, dated as of November 15, 2007, by and among the Registrant and Waleed H. Hassanein, M.D. (incorporated by reference to Exhibit 10.14 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)
10.18#	Executive Retention Agreement, dated as of November 15, 2007, by and among the Registrant and Tamer I. Khayal, M.D. (incorporated by reference to Exhibit 10.15 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)
10.19	Lease Agreement, dated as of June 25, 2004, between the Registrant and 200 Minuteman Limited Partnership (incorporated by reference to Exhibit 10.17 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)
10.20	First Amendment to Lease, dated as of September 28, 2004, between the Registrant and 200 Minuteman Limited Partnership (incorporated by reference to Exhibit 10.18 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)
10.21	Second Amendment to Lease, dated as of November 29, 2005, between the Registrant and 200 Minuteman Limited Partnership (incorporated by reference to Exhibit 10.19 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)

10.22	Third Amendment to Lease, dated as of June 12, 2006, between the Registrant and 200 Minuteman Limited Partnership (incorporated by reference to Exhibit 10.20 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)
10.23	Fourth Amendment to Lease, dated as of February 1, 2007, between the Registrant and 200 Minuteman Limited Partnership (incorporated by reference to Exhibit 10.21 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)
10.24	Fifth Amendment to Lease, dated as of April 30, 2010, between the Registrant and 200 Minuteman Limited Partnership (incorporated by reference to Exhibit 10.22 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)
10.25	Lease Agreement, dated as of June 25, 2004, between the Registrant and 30 Minuteman Limited Partnership (incorporated by reference to Exhibit 10.23 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)
10.26	Second Amendment to Lease, dated as of November 29, 2005, between the Registrant and 30 Minuteman Limited Partnership (incorporated by reference to Exhibit 10.24 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)
10.27	Third Amendment to Lease, dated as of April 30, 2010, between the Registrant and 30 Minuteman Limited Partnership (incorporated by reference to Exhibit 10.25 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)
10.28	Omnibus Amendment #1 to Lease Agreement, dated January 9, 2020, by and among the Company, Whetstone 200 Minuteman Park, LLC and Whetstone 30 Minuteman Park, LLC (incorporated by reference to Exhibit 10.26 to the Registrant's Annual Report on Form 10-K (File No. 001-38891) filed with the SEC on March 17, 2020)
10.29	Credit Agreement, dated as of July 25, 2022, by and among TransMedics Group, Inc., the lenders party thereto and Canadian Imperial Bank of Commerce, as administrative agent and collateral agent (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-38891) filed with the SEC on July 29, 2022)
10.30	First Amendment to Credit Agreement, dated as of May 8, 2023, by and among TransMedics Group, Inc., the lender party thereto and Canadian Imperial Bank of Commerce, as administrative agent (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-38891) filed with the SEC on May 9, 2023).
10.31	Second Amendment to Credit Agreement, dated as of June 23, 2023, by and among TransMedics Group, Inc., the lenders party thereto and Canadian Imperial Bank of Commerce, as administrative agent (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-38891) filed with the SEC on June 29, 2023).
10.32	Third Amendment to Credit Agreement, dated as of November 9, 2023, by and among TransMedics Group, Inc., the lenders party thereto and Canadian Imperial Bank of Commerce, as administrative agent (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-38891) filed with the SEC on November 13, 2023).
10.33++	Assumption Agreement, dated as of December 22, 2023, by Summit Aviation, Inc. and Northside Property Group, LLC in favor of Canadian Imperial Bank of Commerce, as administrative agent and collateral agent for lenders party to the Credit Agreement, dated as of July 25, 2022, by and among TransMedics Group, Inc., the lenders party thereto and Canadian Imperial Bank of Commerce, as administrative agent (incorporated by reference to Exhibit 10.34 to the Registrant's Annual Report on Form 10-K (File No. 001-38891) filed with the SEC on February 27, 2024).
10.34	Guarantee and Collateral Agreement, dated as of July 25, 2022, by and among TransMedics Group, Inc., TransMedics, Inc., TransMedics B.V. and Canadian Imperial Bank of Commerce (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-38891) filed with the SEC on July 29, 2022).
10.35+	Development and Supply Agreement dated as of May 24, 2005 by and between the Registrant and Fresenius Kabi AB (incorporated by reference to Exhibit 10.32 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)
10.36+	Contract Manufacturing Agreement dated as of April 1, 2015 by and between the Registrant and Fresenius Kabi Austria GmbH (incorporated by reference to Exhibit 10.33 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)

10.37	Omnibus Amendment #2 to Lease, dated as of June 1, 2020, by and among the Company and Whetstone 200 Minuteman Park, LLC and Whetstone 30 Minuteman Park, LLC (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38891) filed with the SEC on August 7, 2020).
10.38	Form of Call Option Transaction Confirmation (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 001-38891) filed with the SEC on May 11, 2023).
10.39#	Transition Agreement, by and between TransMedics, Inc. and Stephen Gordon, dated December 2, 2024 (incorporated by reference to Exhibit 10.41 to the Registrant's Annual Report on Form 10-K (File No. 001-38891) filed with the SEC on February 27, 2025)
10.40#	Offer Letter dated as of November 26, 2024, by and between TransMedics, Inc. and Gerardo Hernandez (incorporated by reference to Exhibit 10.42 to the Registrant's Annual Report on Form 10-K (File No. 001-38891) filed with the SEC on February 27, 2025)
10.41#	Executive Retention Agreement, dated as of November 26, 2024, by and between the Registrant and Gerardo P. Hernandez Omana (incorporated by reference to Exhibit 10.43 to the Registrant's Annual Report on Form 10-K (File No. 001-38891) filed with the SEC on February 27, 2025)
10.42++	Lease Agreement, dated as of January 8, 2026, by and between the Registrant and BioMed Realty (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-38891) filed with the SEC on January 12, 2026).
19.1*	TransMedics Group, Inc. Insider Trading Policy (incorporated by reference to Exhibit 19.1 to the Registrant's Annual Report on Form 10-K (File No. 001-38891) filed with the SEC on February 27, 2025)
21.1*	Subsidiaries of the Registrant
23.1*	Consent of PricewaterhouseCoopers LLP, independent registered public accounting firm.
31.1*	Certification of Principal Executive Officer 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.
31.2*	Certification of Principal Financial Officer 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.
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.
97.1	TransMedics Group Inc. Policy for Recoupment of Incentive Compensation (incorporated by reference to Exhibit 97.1 to the Registrant's Annual Report on Form 10-K (File No. 001-38891) filed with the SEC on February 27, 2024)
101.INS*	Inline 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 (formatted as Inline XBRL and contained in Exhibit 101)

* Filed herewith.

** Furnished herewith.

Indicated a management or compensatory plan, contract or arrangement.

+ Confidential treatment has been granted as to certain portions, which portions have been omitted and submitted separately to the SEC.

++ Certain schedules (or similar attachments) have been omitted pursuant to Item 601(a)(5) or Item 601(b)(2) of Regulation S-K. The registrant agrees to furnish copies of such schedules (or similar attachments) to the U.S. Securities and Exchange Commission upon request.

Item 16. Form 10-K Summary.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

TransMedics Group, Inc.

Date: February 24, 2026

By: /s/ Gerardo Hernandez
Gerardo Hernandez
Chief Financial Officer and Treasurer

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Waleed H. Hassanein, M.D. **Waleed H. Hassanein**	President, Chief Executive Officer, Director	February 24, 2026
/s/ Gerardo Hernandez **Gerardo Hernandez**	Chief Financial Officer and Treasurer	February 24, 2026
/s/ James R. Tobin **James R. Tobin**	Chairman of the Board of Directors	February 24, 2026
/s/ Edward M. Basile **Edward M. Basile**	Director	February 24, 2026
/s/ Thomas J. Gunderson **Thomas J. Gunderson**	Director	February 24, 2026
/s/ Edwin M. Kania, Jr. **Edwin M. Kania, Jr.**	Director	February 24, 2026
/s/ David Weill, M.D. **David Weill, M.D.**	Director	February 24, 2026
/s/ Merilee Raines **Merilee Raines**	Director	February 24, 2026
/s/ Stephanie Lovell **Stephanie Lovell**	Director	February 24, 2026