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, 2020

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. ☐

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, 2020, based on the last reported sale price of the registrant's common stock of $17.92 per share was $454.4 million. As of February 28, 2021, the registrant had 27,370,038 shares of common stock, no par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Definitive Proxy Statement for its 2021 Annual Meeting of Stockholders scheduled to be held on May 27, 2021, 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, 2020 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. Moreover, we operate in a very competitive and rapidly changing environment and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in 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. You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Moreover, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this Annual Report on Form 10-K to conform these statements to actual results or to changes in our expectations.

RISK FACTORS SUMMARY

An investment in our common stock involves risks. You should consider carefully 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 before investing in our common stock. These risks include, but are not limited to, the following:

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

- the timing or results of clinical trials for the OCS;
- our manufacturing, sales, marketing and clinical support capabilities and strategy;
- attacks against our information technology infrastructure;
- the economic, political and other risks associated with our foreign operations;
- our ability to attract and retain key personnel;
- our ability to protect, defend, maintain and enforce our intellectual property rights relating to the OCS and avoid allegations that our products infringe, misappropriate or otherwise violate the intellectual property rights of third parties;
- the pricing of the OCS, as well as the reimbursement coverage for the OCS in the United States and internationally;
- regulatory developments in the United States, European Union and other jurisdictions;
- the extent and success of competing products that are or may become available;
- the impact of any product recalls or improper use of our products;
- our use of proceeds from our equity offerings; and
- our estimates regarding revenues, expenses and needs for additional financing.

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

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, 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. While there are approximately 67,000 potential donors annually in the United States, Canada, the European Union and Australia, which we refer to as our key geographies, the majority of lungs and hearts donated after brain death, or DBD, go unutilized, and almost no available lungs and hearts donated after circulatory death, or DCD, 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 offers the potential to significantly improve donor organ utilization.

We designed the OCS to be a platform that allows us to leverage core technologies across products for multiple organs. To date, we have developed three OCS products, one for each of lung, heart and liver transplantations, making the OCS the only multi-organ technology platform. Our OCS products have been used for over 1,800 human organ transplants. The OCS Lung has been approved by the FDA, for commercial use in the United States since March 2018 for donor lungs that are currently utilized for transplantation and since May 2019, for donor lungs currently unutilized for transplantation. We also have commercialized the OCS Lung and OCS Heart outside of the United States. We submitted a Pre-Market Approval, or PMA, application to the FDA in December 2018 for the use of the OCS Heart for donor hearts currently utilized and unutilized for transplantation based on the results of our OCS Heart EXPAND Trial, OCS Heart EXPAND Continued Access Protocol, or CAP, Trial and OCS Heart PROCEED II Trial. The FDA will convene an advisory committee meeting, typical for novel technologies, to discuss our OCS Heart PMA application. The FDA advisory committee panel was initially set for April 2020 but was delayed due to the COVID-19 pandemic, and we currently expect it to be held on April 6, 2021. It is possible that the FDA decides that the data from our clinical trials does not support PMA approval or any of the claims we wish to make, or the FDA could require us to gather significant additional clinical data or conduct additional non-clinical testing. In addition, we completed enrollment of the 300 patient OCS Liver PROTECT trial in October 2019, and we submitted a PMA application for the OCS Liver in June 2020 and it is currently under review by the FDA. We also completed enrollment of the 180 patient OCS Heart DCD trial in September 2020. We expect to submit a PMA supplement application for the use of OCS Heart for DCD hearts in 2021.

We are focused on establishing the OCS as the standard of care for solid organ transplantation. Because we believe cold storage is the primary factor limiting donor organ utilization today, we estimate our opportunity based on the existing donor pools and the potential for significantly expanded utilization with the OCS. We estimate the potential pool of DBD and DCD donors in our key geographies to be approximately 67,000 annually, with each donor having the capacity to donate more than one organ, including lung, heart and liver. However, the industry in which we operate is subject to a high degree of uncertainty and risk, and these estimates could change. Based on the utilization rates in our clinical trials and our commercial experience outside the United States, we estimate the potential annual addressable commercial opportunity for the OCS to be approximately $8 billion for lung, heart and liver transplantation combined. Our clinical trials have demonstrated that the OCS may result in improved post-transplant outcomes as compared to cold storage, and we believe this will enable us to capture a significant portion of the expanded transplant opportunity.

The majority of transplant procedures are performed at a relatively small number of hospitals that have specialized organ transplant centers. For example, we estimate that approximately 50 to 55 transplant centers in the United States perform over 70% of the lung, heart and liver transplant volume. The lead transplant surgeons at each of these centers are the primary decision-makers on most aspects of the transplant programs. These surgeons rely primarily on clinical evidence to drive changes in their programs. During our clinical trials, we established relationships with over 65 leading transplant programs in our key geographies and have generated a substantial body of clinical evidence. Our commercial strategy is focused on leveraging these relationships to drive deeper adoption of the OCS at the leading, large-volume academic transplant institutions. We have also initiated a national OCS program that provides turnkey organ retrieval and OCS perfusion services to transplant centers in order to assist transplant programs in overcoming logistical hurdles. We believe this program has the potential to accelerate adoption of the OCS.

We believe the OCS will drive significant benefits to all stakeholders in the field of organ transplantation. For patients, we believe the OCS provides more patients with access to life-saving transplants and allows for quicker recovery following transplantation. For hospitals, we believe the OCS provides a means to increase transplant volume, treat more patients, enhance provider status and improve transplant program economics. Finally, we believe the OCS provides 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 are reimbursed in the United States through existing, standard commercial transplant billing mechanisms. The Medicare program and private payors have been providing reimbursement for the OCS Lung, OCS Heart and OCS Liver during the U.S. pivotal trials and have been providing reimbursement for the OCS Lung following our first FDA approval in March 2018. We believe these established channels will continue to facilitate commercial reimbursement for the OCS Lung and, if they are approved by the FDA, for the OCS Heart and OCS Liver. We are in the process of seeking long-term reimbursement for our products outside of the United States.

Our corporate headquarters, manufacturing and clinical training facilities are located in Andover, Massachusetts. We have additional distribution and commercial operations in Europe and Asia-Pacific. As of December 31, 2020, we employed 110 people, globally, most of which were full-time employees. We generated $25.6 million of net revenue during the fiscal year ended December 31, 2020 and $23.6 million of net revenue during the fiscal year ended December 28, 2019, representing a 9% increase. Growth in our business was negatively impacted by the global COVID-19 pandemic after net revenue growth of 81% in 2019 compared to 2018. 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.

Commercial Opportunity

Demand for Organ Transplants

Incidence of end-stage organ failure has been rapidly rising worldwide due to demographic trends that contribute to chronic disease, including an aging population and obesity. Key disease states resulting in organ failure include chronic obstructive pulmonary disease, or COPD, chronic heart failure, diabetes, chronic liver disease and end-stage renal disease.

Organ Transplantation Represents the Treatment of Choice for End-Stage Organ Failure

We believe organ transplantation is the most effective treatment for end-stage organ failure in terms of both clinical outcomes and health economics. 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.

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.

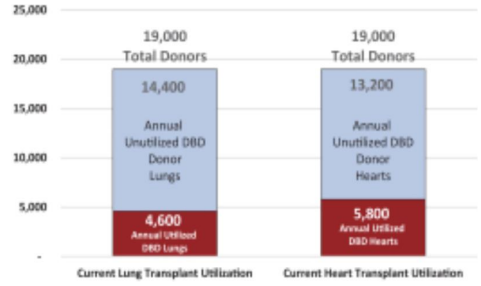
Donor Organs for Transplantation

The supply of donor organs for transplantation comes from two primary sources:

Donation After Brain Death—DBD Donors: DBD donors suffered irreversible brain damage. Because hearts continue to beat naturally for a few days in these donors, the organs continue to be perfused with oxygenated blood until retrieval, allowing transplant clinicians the opportunity to assess organ viability. We estimate that the pool of DBD donors is approximately 19,000 DBD donors annually in our key geographies, with approximately 8,400 DBD donors annually in the United States. While DBD donors represent the vast majority of donor organs transplanted, only approximately 23% of donated lungs and 32% of donated hearts were utilized in the United States in 2016, which we believe is primarily due to the limitations of current organ preservation methods.

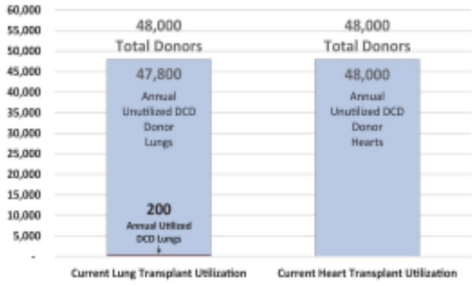
Donation After Circulatory Death—DCD Donors: DCD donors suffered cardiac and circulatory arrest. Because hearts cease to beat in these donors, the organs do not receive oxygenated blood and transplant clinicians are unable to assess organ viability. We estimate that the potential DCD donor pool is approximately 48,000 donors annually in our key geographies, with over 22,000 DCD donors annually in the United States. Despite the large size of this donor pool, we estimate that DCD donor organs are used in fewer than 5% of lung transplants and are not used for heart transplants because current methods for organ preservation are unable to overcome the challenges presented by the lack of perfusion.

Annual Lung and Heart DBD Donor Utilization
United States, Canada, European Union, Australia



Sources: Organ Procurement Transplantation Network; Global Observatory on Donation and Transplantation

Estimated Annual Lung and Heart DCD Donor Utilization
United States, Canada, European Union, Australia



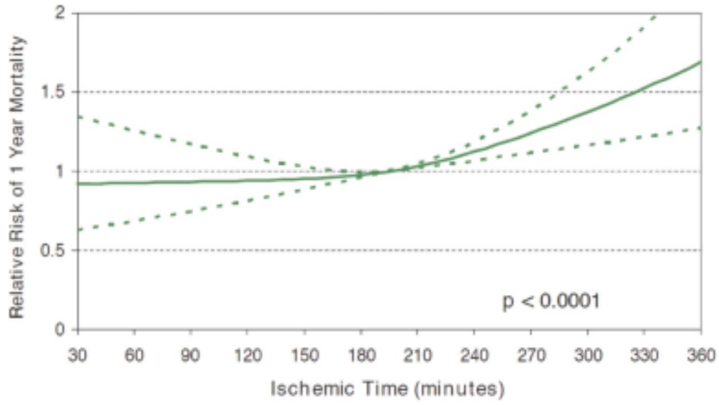
Source: Institute of Medicine of the National Academy of Science (2006)

Limitations of Current Organ Preservation Methods

In recent years, significant innovations have been implemented in most aspects of organ transplantation surgery. However, organ preservation remains primarily limited to cold storage. Cold storage involves flushing the organs with cold pharmaceutical solutions designed to reduce organ temperature and arrest organ function. The donor organ is then placed in a sterile plastic bag and stored on ice in a cooler. This process adversely impacts clinical outcomes and leads to underutilization of viable donor organs due to the following inherent challenges:

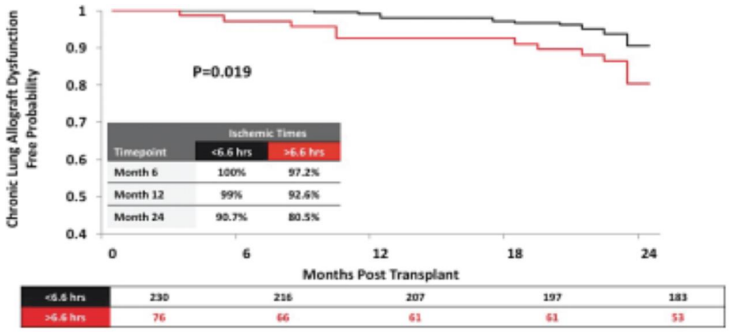
- ***Time-dependent ischemic injury:*** Cold storage subjects donor organs to significant injury due to a lack of oxygenated blood supply, or ischemia. Ischemia has been reported to be an independent predictor of mortality after heart transplantation and development of short-term severe primary graft dysfunction, or PGD, which is associated with long-term complications in lung transplantation. A long-term consequence of PGD3, the most severe form of PGD, is chronic lung allograft dysfunction. Published data from the thoracic transplant registry of the International Society for Heart and Lung Transplantation shows that the risk for post-transplant patient mortality increases dramatically after approximately 190 minutes of injurious ischemic time in heart transplantation. This data highlights that the longer an organ spends on ice, the higher the risk of poor clinical outcomes, including mortality. In addition to resulting in poor transplant outcomes, time-dependent ischemic injury limits the acceptable time that transplant centers permit between organ retrieval and transplantation to four to six hours, resulting in restrictions on geographical distance between donors and transplant recipients.

Ischemic Times Correlates Positively with Increased Risk for Patient Mortality After Heart Transplantation



Dotted lines represent upper and lower confidence bound for the data plotted.

Correlation between Ischemic Injury and Development of Long-Term Complications after Lung Transplantation— Results of the OCS Lung INSPIRE Trial



A p-value is a statistical calculation that relates to the probability that a difference between groups happened by chance. Typically, a p-value less than 0.05 represents statistical significance.

- ***Lack of diagnostic assessment of organ viability or function:*** Cold storage does not support the assessment of organ function or viability because the organs are not functioning or metabolically active during cold storage. This lack of diagnostic assessment largely limits the donor pool to DBD donors, whose organs can be assessed for viability prior to retrieval because their hearts continue to beat. The lack of diagnostic assessment of organ viability during cold storage is the primary reason that DCD organs are rarely used for lung transplants and never used for heart transplants.

- ***Lack of therapeutic or optimization capabilities:*** Clinical studies have demonstrated the clinical benefits of replenishing donor organs with glucose, oxygen, hormones and electrolytes that are significantly altered or depleted during the donation process. Cold storage, however, does not allow for therapeutic intervention to optimize the condition of donor organs, which results in suboptimal post-transplant outcomes. In addition, transplant programs are less likely to accept organs that may appear compromised if they are unable to treat or optimize the organ, which prevents utilization of the vast majority of organs from DBD and DCD donors.

We believe the limitations of cold storage are directly responsible for the severe shortage in donor organ supply, which results in nearly all lungs and hearts from DCD donors, and the majority of lungs and hearts from DBD donors, going unutilized each year. In 2016, approximately 77% of donated lungs and approximately 68% of donated hearts went unutilized in the United States. In addition, we believe the limitations of cold storage are the primary driver of the high rate of severe post-transplant complications that negatively impact both patients' clinical outcomes and transplant economics for payors and providers.

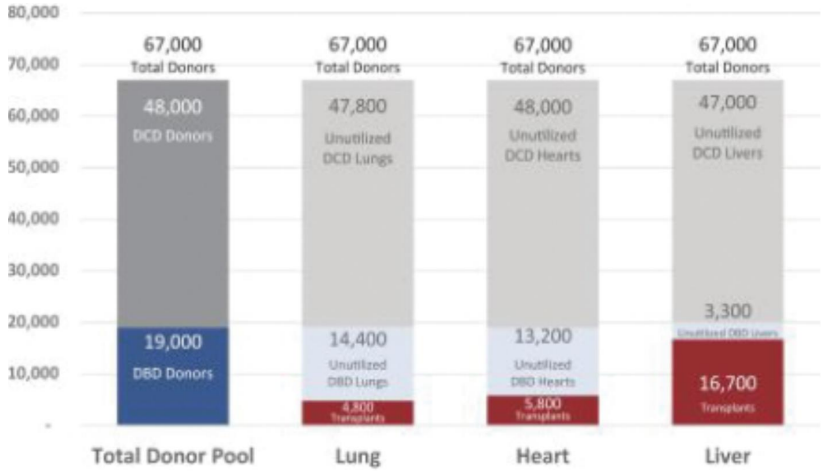
We developed the OCS technology platform to comprehensively address the major limitations of cold storage. The OCS represents a paradigm shift that transforms organ preservation with a dynamic technology that replicates many aspects of an organ's natural state outside of the human body and enables new capabilities of organ optimization and assessment. Because the OCS reduces injurious ischemic time significantly and enables the optimization and assessment of donor organs, it offers the potential to significantly improve organ utilization relative to cold storage and could lead to improved clinical outcomes.

Our Commercial Opportunity

We believe organ transplantation is severely supply constrained by the limitations of cold storage. While there is a national transplant waiting list that represents a snapshot of demand, we believe this waiting list significantly underrepresents the true clinical demand for organ transplants. Because the supply of donor organs has historically been constrained, the waiting list is fairly static, with annual additions to the waiting list typically matching closely the number of transplants performed or patients otherwise removed from the list. We believe that with increased utilization of donor organs for transplant, the waiting list will grow to match any increase in global supply.

We estimate our commercial opportunity based on the existing donor pools and the potential for significantly improved utilization resulting from the use of our OCS technology. We estimate that the potential pool of donors in our key geographies includes approximately 67,000 DBD and DCD donors annually. Our estimates of the potential pools of donors are only estimates and subject to uncertainty, risk and change. Because the OCS reduces injurious ischemic time significantly, allows for therapeutic optimization of the organ's condition and enables diagnostic assessment, we believe the OCS could allow surgeons to utilize the vast majority of the donor pool that is currently unutilized due to the limitations of cold storage.

Estimated Transplant Pool Underutilization
United States, Canada, European Union, Australia



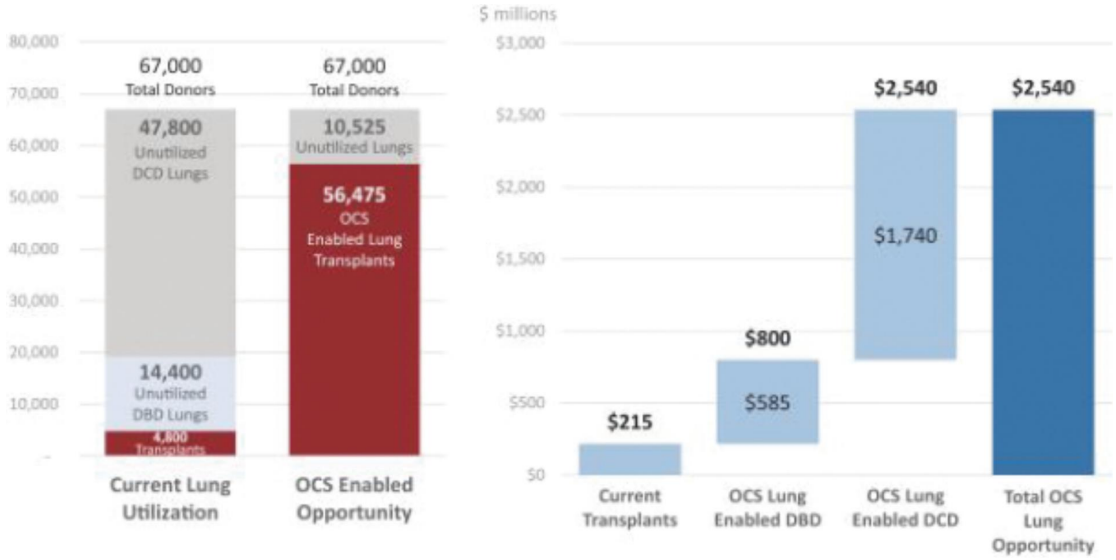
Sources: Organ Procurement and Transplantation Network; Global Observatory on Donation and Transplantation; Institute of Medicine of the National Academy of Science (2006)

We are focused on establishing the OCS as the standard of care for solid organ transplantation. Our clinical trial results have demonstrated that the OCS may result in improved post-transplant outcomes as compared to cold storage. In addition, our clinical trial results and commercial experience outside the United States have demonstrated a significant improvement in donor organ utilization to approximately 87% of DBD and DCD donor lungs, approximately 81% of DBD donor hearts and approximately 80% of DCD donor hearts, with improved post-transplant outcomes compared to cold storage. As a result, we believe that the OCS will also expand the existing pool of utilizable donor organs to include a significant share of the 67,000 potential annual donors and increase the overall number of transplants performed each year. We believe the OCS could be adopted for use in a significant share of transplants; however, certain factors may limit the actual utilization of the OCS, including the need to continue to educate surgeons, transplant centers and private and public payors of the merits of the OCS as compared with cold storage, the requisite training of surgeons prior to their use of the OCS and the overall capacity of transplant centers to perform organ transplants due to factors such as the availability of surgeons. See “Item 1A. Risk Factors—Risks Related to Research and Commercialization—We depend heavily on the success of the OCS and achieving market acceptance. If we are unable to successfully commercialize the OCS, our business may fail” and “—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. Surgeons, transplant centers and private and public payors may require additional clinical data prior to adopting or maintaining coverage of the OCS”.

Lung Opportunity

Only 4,800 donor lungs are utilized annually for transplantation in our key geographies, resulting in approximately 62,200 organs, comprised of 14,400 from potential DBD donors and 47,800 from potential DCD donors, going unutilized each year due to the limitations of cold storage. Our OCS Lung EXPAND Trial demonstrated that the use of the OCS Lung in the types of organs that currently are not transplanted resulted in a blended DBD and DCD utilization rate of approximately 87%, based on 90% DBD utilization and 81% DCD utilization. Applying this 90% utilization rate to DBD donor lungs and 81% utilization rate to DCD donor lungs implies a total potential addressable opportunity of approximately $2.5 billion annually, of which approximately $215 million represents currently transplantable lungs, approximately $585 million represents improved utilization of DBD donors and the remaining approximately $1.7 billion represents utilization of DCD donors.

Estimated Addressable Lung Opportunity
United States, Canada, European Union, Australia



Heart Opportunity

Only 5,800 donor hearts are utilized annually for transplantation in our key geographies, resulting in approximately 61,200 organs, comprised of 13,200 from potential DBD donors and 48,000 from potential DCD donors, going unutilized each year due to the limitations of cold storage. Results from our OCS Heart EXPAND Trial demonstrated that the use of the OCS Heart in the types of organs that are currently unutilized resulted in a DBD utilization rate of approximately 81%. In addition, the results of the OCS Heart DCD commercial activities in Europe and Australia have resulted in a utilization rate of approximately 80% of DCD donor hearts. Applying this 81% utilization rate to DBD donor hearts and 80% utilization rate to DCD donor hearts implies a total addressable opportunity of approximately $2.5 billion annually, of which approximately $260 million represents currently transplantable hearts, approximately $480 million represents improved utilization of DBD donors and the remaining approximately $1.7 billion represents utilization of DCD donors.

Estimated Addressable Heart Opportunity
United States, Canada, European Union, Australia

Liver Opportunity

Only 16,700 donor livers are utilized annually for transplantation in our key geographies, resulting in approximately 50,300 organs, comprised of 3,300 from potential DBD donors and 47,000 from potential DCD donors, going unutilized each year due to the limitations of cold storage. To support an FDA PMA for the OCS Liver, we have completed a pivotal trial, OCS Liver PROTECT, to preserve and assess donor livers from both DBD and DCD donors. The results of the OCS Liver PROTECT Trial demonstrated that the OCS Liver resulted in approximately 98% utilization of DBD and DCD donor livers. Final results from the OCS Liver European REVIVE Trial demonstrated that the OCS Liver resulted in approximately 100% utilization of DBD and DCD donor livers. Applying this 100% utilization rate implies a total potential addressable opportunity of approximately $3.0 billion annually, of which approximately $750 million represents currently transplantable livers, approximately $150 million represents improved utilization of DBD donors and the remaining approximately $2.1 billion represents utilization of DCD donors.

Estimated Addressable Liver Opportunity
United States, Canada, European Union, Australia

Our Technology and Solution

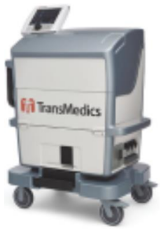
We developed the OCS to comprehensively address the major limitations of cold storage. The OCS is a portable organ perfusion, optimization and monitoring system that utilizes our proprietary and customized technology to replicate near-physiologic conditions for donor organs outside of the human body. 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 multi-organ 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. OCS products for additional organs, including kidneys, are under development.

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 retrieval;
- **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.

For each organ product, the OCS core technologies are supplemented with additional customized and proprietary organ-specific features to meet each organ's requirements. The following table summarizes the key features of our current commercial products.

	OCS Lung	OCS Heart	OCS Liver
Console			
Perfusion set / Solution			
Regulatory status	FDA—PMA approved for donor lungs currently utilized and currently unutilized for transplantation	FDA—Pivotal trial enrollment completed for currently utilized and unutilized DBD donor hearts; PMA application submitted in December 2018. Expect FDA Advisory Committee meeting on April 6, 2021. Pivotal trial enrollment completed for DCD hearts. Expect PMA for DCD hearts to be submitted in 2021.	FDA—Pivotal trial completed enrollment in October 2019. PMA submitted in June 2020 and currently under review. Expect FDA Advisory Committee meeting in 2021.
	CE Marked for console, perfusion set and solutions	CE Marked for console, perfusion set and solutions	CE Marked for console, perfusion set
Key features	**Proprietary and customized ventilation circuit and method** allows the lung to breathe outside of the human body, while maximizing portability	**Proprietary organ chamber** maintains critical valve heart function with embedded EKG sensors to monitor heart viability during preservation	**Proprietary perfusion circuit** enables physiologic dual blood supply of the liver using a single pump and a **bile collection system** assesses liver function during organ preservation
	Customized cannulation enables the lung to be maintained and assessed using standard clinical diagnostics	**Proprietary automated solution delivery system** optimizes condition of the heart perfusion during preservation	**Proprietary automated solution delivery** optimizes condition of the liver perfusion during preservation
	Proprietary nutrient-rich, lung-specific solution improves lung condition from negative effects of brain death	**Proprietary nutrient- and hormone-rich physiologic solutions** replenish and optimize the heart with depleted nutrients	**Customized OCS bile salt solution** replenishes the liver to continue to produce bile

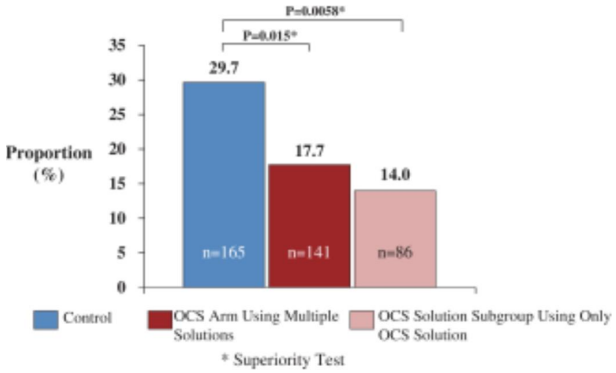
Key Advantages of the OCS Platform

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

Improved Clinical Outcomes

Use of the OCS has demonstrated a substantial reduction in injurious ischemic time in all of our clinical trials. The results of our OCS Lung INSPIRE Trial, which compared the use of the OCS Lung to cold storage, demonstrated a statistically significant reduction of approximately two hours in the amount of time the organ went without oxygenation, or ischemic time. These results were achieved while allowing for an average of 1.5 incremental hours between donor and recipient. This decrease in injurious ischemic time resulted in an approximately 50% reduction relative to cold storage in the most common and severe form of lung transplant complication called primary graft dysfunction grade 3, or PGD3. PGD3 is a dangerous and costly complication as patients with it typically experience longer time on mechanical ventilation and in the intensive care unit, as well as potential long-term negative consequences. We believe these results are consistent with those of our other clinical trials and will support adoption of the OCS.

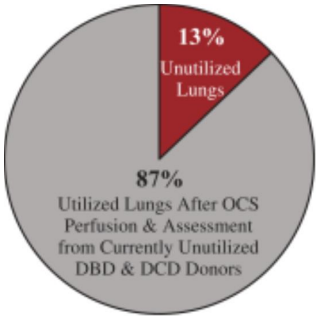
Use of OCS Lung Significantly Reduced Incidence of PGD3
In Lung Transplant Recipients—INSPIRE Trial Results



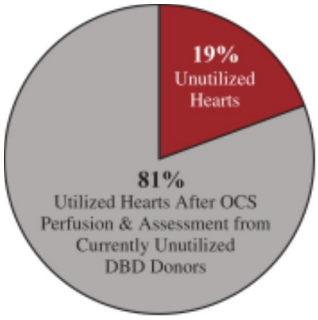
Increased Donor Organ Utilization

In our OCS Lung EXPAND Trial, we evaluated the use of the OCS Lung for donor organs from both DBD and DCD donors that would not otherwise have been utilized, and in the OCS Heart EXPAND Trial, we evaluated the use of the OCS Heart for donor organs from DBD donors that would not otherwise have been utilized. The lungs and hearts that were transplanted in these studies were rejected an average of 35 and 66 times, respectively, by other institutions using cold storage due to a variety of clinical and logistical reasons that may have included donor organ quality, donor age, expected injurious ischemic time or travel distance, or type of donor. In these trials, the use of the OCS resulted in an 87% utilization rate of DBD and DCD donor lungs and an 81% utilization rate of DBD donor hearts that otherwise would have been unutilized. The results of these trials support our belief that the OCS can significantly expand the number of organs that can be transplanted and better serve the large population of patients who need an organ transplant to survive.

OCS Lung EXPAND Trial Utilization Results



OCS Heart EXPAND Trial Utilization Results



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 Centers for Medicare & Medicaid Services, or 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, increasing the utilization of donor organs and improving clinical outcomes.

The key elements of our strategy are:

- **Target and drive deeper adoption of the OCS at leading transplant institutions.** We are focused on driving adoption at leading, high volume transplant programs where we have established strong relationships during our clinical trials. We believe we are well-positioned to leverage these centers' familiarity with the value of the OCS to increase the number of transplants they perform and increase our penetration of their case volumes.
- **Grow our National OCS Program, a turnkey organ retrieval and OCS perfusion service to overcome logistical hurdles and deliver better clinical outcomes.** We have initiated a service program that leverages our clinical and logistical capabilities to provide access to and use of the OCS for transplant centers in certain regions of the United States. We believe we could become a national clinical service provider of organ retrieval and perfusion service to transplant centers throughout the United States. We believe this program has the potential to accelerate adoption of the OCS, maximize utilization of donor organs for transplantation and, by standardizing the quality of use of the OCS, deliver better clinical outcomes.
- **Expand the existing pool of utilizable donor organs by securing additional FDA PMA supplements and new PMAs for expanded indications.** We secured our first PMA approval for the OCS Lung in March 2018 and our second PMA approval for the OCS Lung in May 2019. We have submitted additional PMA applications for the OCS Heart and OCS Liver.
- **Continue to build clinical evidence in the pre- and post-market settings to substantiate the benefits of the OCS and expand clinical transplant indications.** Surgeons affiliated with leading academic transplant centers rely primarily on clinical evidence to drive changes in their practice. We have developed a substantial body of clinical evidence to support our PMA applications, potential PMA applications and other regulatory approvals for the use of the OCS technology in the field of organ transplantation. We plan to expand this body of clinical evidence in the pre- and post-market settings, for example with our ongoing post-market Thoracic Organ Perfusion Registry.

- **Develop the next generation OCS technology platform to improve user experience and facilitate our National OCS Program.** We have initiated the development of the next generation multi-organ platform to improve the usability, incorporate new technology and automation, and facilitate the use of OCS in our national OCS program.
- **Leverage the established commercial reimbursement process and billing mechanisms to accelerate U.S. commercial traction.** Medicare and private payors provided reimbursement for the OCS Lung, OCS Heart and OCS Liver during our U.S. pivotal trials using existing commercial billing and reimbursement processes for organ transplant procedures and have provided reimbursement for the OCS Lung following our first FDA approval in March 2018. We believe these established methods will continue to facilitate commercial reimbursement for the OCS Lung and, if they are approved by the FDA, for the OCS Heart and OCS Liver. We are in the process of seeking long-term reimbursement for our OCS products in several other countries.

Commercialization Strategy & Business Model

Organ Transplant Opportunity Characteristics

The majority of transplant procedures are performed at a relatively small number of hospitals that have specialized organ transplant centers. For example, we estimate that approximately 50 to 55 transplant centers in the United States perform over 70% of the lung, heart and liver transplant volume. Furthermore, there is a high degree of overlap within each center. For example, the top 30 U.S. lung transplant centers, which were responsible for 77% of the total adult lung transplant volume in 2017, also performed a significant portion of heart and liver transplants.

The field of organ transplantation is driven by leading clinical academic institutions. The lead transplant surgeon at each of these institutions is often the primary decision-maker on most aspects of the transplant program, including preservation technology, threshold for accepting donor organs and travel distance for accepting organs. Unlike other specialties for which hospital administrators are more likely to exercise control over purchasing decisions, lead transplant surgeons are typically the primary purchasing decision-makers for new transplant technologies. To effect these changes in their programs, lead transplant surgeons rely primarily on clinical evidence and are focused on the following major factors:

- **Improving post-transplant clinical outcomes** in order to:
  - enhance patients' quality of life,
  - meet CMS post-transplant survival metrics required for reimbursement coverage, and
  - support the financial health of programs; and
- **Increasing the volume of organ transplantation** in order to:
  - facilitate more patients receiving an organ transplant,
  - achieve "Center of Excellence" designation with payors, and
  - drive revenue growth.

Our Commercial Strategy

In light of these dynamics, we designed our commercialization strategy to drive adoption of the OCS at the leading, large-volume academic transplant institutions that were involved with the OCS trials as well as to expand our presence to new centers. We believe our substantial body of clinical evidence has demonstrated the potential benefits of the OCS and we are also focused on continuing to increase our clinical evidence in the post-market setting to maintain a high level of engagement with transplant program directors and enable further penetration of the OCS at transplant programs.

We believe the concentrated nature of organ transplant activity in the United States and the reputation we established during our clinical trials will enable us to rely on a focused commercial team. The sales and clinical adoption team sells our OCS products and provides clinical education for their use in leading academic transplant centers in our key geographies during our clinical trials and commercially where our OCS products are approved. In addition, our team targets new leading transplant centers to expand our user base. We believe the team has established deep knowledge and credibility with our clinical users and customers. We believe the close relationship between transplant surgeons and our team provides us with unparalleled customer access that should enable us to further penetrate these transplant centers.

In addition, we have initiated a national OCS program, which allows us to partner with transplant centers and organ procurement organizations to provide logistical and perfusion solutions to reduce inefficient burdens on both organizations. We believe this program has the potential to accelerate the adoption of the OCS technology throughout the United States.

Business Model

Our business model is characterized by a high level of recurring revenue, which is derived primarily from sales of our single-use OCS Perfusion Sets and OCS Solutions, which we refer to collectively as a disposable set, that are required for each transplant using the OCS. Each OCS product is comprised of three components: the OCS Console, the OCS Perfusion Set and the OCS Solutions.

The OCS Console is either purchased by or loaned to a transplant program depending on individual center arrangements. Given the independent buying power of each transplant program within an institution, as well as the unique organ-specific characteristics of each OCS product, a multi-organ transplant center will require at least one OCS Console for each organ transplant program within the same center. For example, there are several centers that use both the OCS Lung and OCS Heart and centers that use all three of the OCS Lung, OCS Heart and OCS Liver.

Our recurring revenue stream is derived primarily from sales of our single-use OCS disposable sets. In light of the unscheduled nature of transplant procedures, our users replenish OCS disposable sets to maintain a minimum stock of three to five units per OCS product, on average.

We generate a significant amount of our net revenue from a limited number of customers. For the fiscal year ended December 31, 2020, Massachusetts General Hospital accounted for 14% of our net revenue and Duke University accounted for 10% of our net revenue. We expect that sales to relatively few customers will continue to account for a significant percentage of our net revenue in future periods. See “Item 1A. Risk Factors—Risks Related to Research and Commercialization—We depend on a limited number of customers for a significant portion of our net 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 results of operations” in this Annual Report on Form 10-K

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.

Data from the 2017 Milliman U.S. Organ and Tissue Transplant research report estimates the average billed charges per organ transplant, including costs billed to organ acquisition costs. The report estimates that in the United States the overall billed charges for a double-lung transplant are approximately $1.2 million, of which only approximately $130,000 is associated with organ acquisition; overall billed charges for a heart transplant are approximately $1.4 million, of which only approximately $100,000 is associated with organ acquisition; and overall billed charges for a liver transplant are approximately $800,000, of which only approximately $95,000 is associated with organ acquisition.

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 following our first FDA approval in March 2018. This has established multiple years of billing precedent. We believe these established methods will continue to facilitate commercial reimbursement for the OCS Lung and, if they are approved by the FDA, for the 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, national healthcare systems do not reimburse transplant centers for the use of the OCS and reimbursement in international markets may require us to undertake additional clinical studies. However, 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 PMA applications, potential PMA applications and other regulatory approvals for the OCS for lung, heart and liver transplantation. Many of these clinical trials and studies have been published in peer-reviewed clinical journals and several additional studies are ongoing. 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.

OCS Lung Clinical Trials

Below is a summary of our key clinical trials evaluating the OCS Lung.

	OCS Lung INSPIRE Trial For Current Lung Transplants	**OCS Lung EXPAND Trial For Currently Unutilized DBD and DCD Donor Lungs**
FDA Status	PMA approved in March 2018	PMA approved in May 2019
Objectives	International pivotal trial for FDA approval and market access for current lung transplant market Compare OCS Lung clinical outcomes to cold storage	International pivotal trial for FDA approval and market access for currently unutilized DBD and DCD donors Single arm trial to assess the ability of the OCS to improve donor lung utilization from currently unutilized DBD and DCD donors
Number of Patients	320 patients in pre-specified cohort and 29 additional patients as administrative extension	79 patients
Length of Follow-up	24 months post-transplantation	12 months post-transplantation
Number of Centers	21 international centers	8 international centers
Summary Outcomes	Met primary effectiveness and safety endpoints Demonstrated significant reduction of most severe and common form of post-lung transplant complication, PGD3, compared to cold storage controls Demonstrated significant reduction of injurious ischemic time on donor lungs compared to cold storage controls	Did not meet the primary effectiveness endpoint Demonstrated significant increase in donor lung utilization from currently unutilized DBD and DCD donors to 87% utilization Demonstrated good patient survival at one year post-transplantation, comparable to current standard lung transplant outcomes Demonstrated substantial reduction of PGD3 in unutilized DBD and DCD donors, when compared to other published results of similar trials
Publication Status	Warnecke et al., Lancet Respiratory Medicine, April 2018	Loor et al., Lancet Respiratory Medicine, August 2019

Summary Overview of OCS Lung INSPIRE Trial & Results

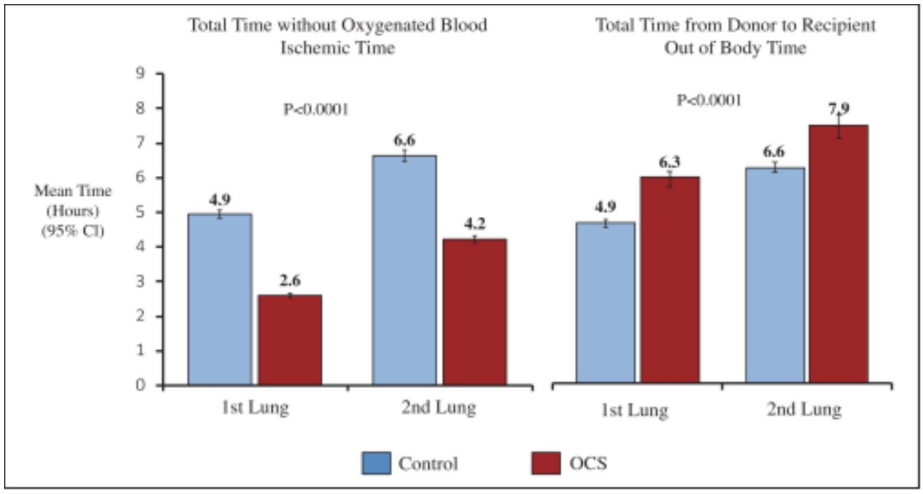
We sponsored the OCS Lung INSPIRE Trial, a randomized, controlled, multi-center study, at 21 leading global academic lung transplant centers. The objective of the OCS Lung INSPIRE Trial was to compare the safety and effectiveness of the OCS Lung to cold storage preservation for lung transplants. The trial inclusion criteria focused on current standard lung transplant donor lung criteria. The trial enrolled 349 patients in total, of which 320 lung transplant recipients were randomized between OCS Lung perfusion and cold storage control. Twenty-nine additional patients were added as an administrative extension.

The OCS Lung INSPIRE Trial protocol allowed donor lungs to be perfused on the OCS Lung device with either OCS Lung Solution or a commercial low potassium dextran, or LPD, solution, both supplemented with packed red blood cells. In addition to comparing the outcomes of all transplants performed with the OCS, our results included a subgroup analysis of the transplants that also used the OCS Solutions. We believe this subgroup is the most clinically relevant given it is the product approved by the FDA for exclusive use in the OCS Lung.

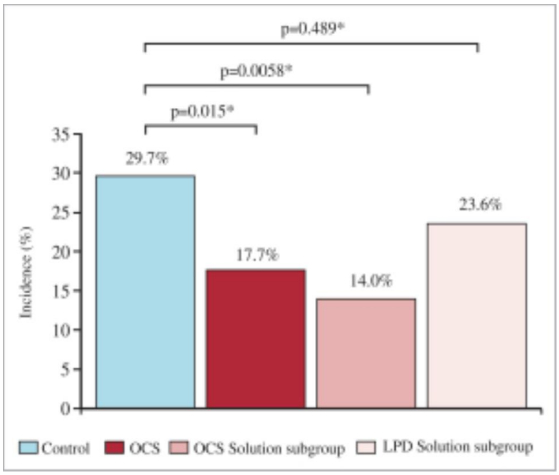
PGD is a form of acute lung injury that is a common and serious complication after lung transplantation. The most severe form of PGD, PGD3, has been shown to be positively correlated with poor short- and long-term transplant outcomes. Generally, in lung transplant procedures, PGD3 is assessed at four distinct timepoints: within a few hours of the transplantation, and at 24 hours, 48 hours and 72 hours following the transplantation. In the OCS Lung INSPIRE Trial, we assessed the incidence of PGD at the same four timepoints during the initial 72 hours following the transplantation.

Summary results of the OCS Lung INSPIRE Trial include:

- ***Significant Reduction of Injurious Ischemic Time on Donor Lungs***: OCS Lung significantly reduced the injurious ischemic time on donor lungs, while permitting the organ to remain out of the body for a significantly longer time compared to cold storage. These clinically significant results marked the first time in organ transplant history that a preservation technology demonstrated the ability to reduce the injurious ischemic time on the donated lung, regardless of the travel distance.



- ***Significant Reduction of PGD3 Post-Lung Transplantation:*** The OCS Lung also significantly reduced PGD3, the most severe and common clinical complication resulting from lung transplantation. PGD3 has been associated with poor short- and long-term outcomes following lung transplantation. We believe the OCS is the only technology or therapy that has demonstrated a significant reduction in this common and severe short-term complication in lung transplantation.



Incidence of PGD3 in the per-protocol analysis
OCS=Organ Care System; LPD=low potassium dextran; *Superiority test

Summary Overview of OCS Lung EXPAND Trial & Results

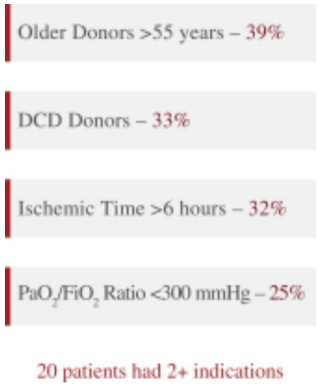
We sponsored the OCS Lung EXPAND Trial, a single arm, multi-center U.S. FDA pivotal trial in eight leading global academic lung transplant centers. The objective of the OCS Lung EXPAND Trial was to demonstrate the ability of the OCS Lung to improve donor lung utilization from currently unutilized DBD and DCD donors and to demonstrate reasonable assurance of effectiveness and safety required for U.S. FDA approval for this indication. The trial inclusion criteria focused on currently unutilized DBD and DCD donor lungs and enrolled 79 lung transplant recipients with donor lungs that would otherwise have been unutilized. In fact, data obtained from the U.S. United Network for Organ Sharing, or UNOS, demonstrated that the U.S. donor lungs used for the OCS Lung EXPAND Trial had been declined for transplantation on average 35 times by other transplant centers before reaching a center participating in the OCS Lung EXPAND Trial due to a variety of clinical and logistical reasons, including donor organ quality, donor age, expected injurious ischemic time or travel distance, or type of donor.

The primary effectiveness endpoint in the OCS Lung EXPAND Trial was a composite of patient survival at day 30 post-transplantation and freedom from PGD3 within the initial 72-hour period post-transplantation. The results of the OCS Lung EXPAND Trial did not meet the pre-specified performance goal that 65% of transplants meet the composite endpoint. The key clinical driver for missing the primary endpoint was the 44.3% rate of PGD3 within the initial 72-hour period post-transplantation due to the challenging nature of the donor lung criteria included in the OCS Lung EXPAND Trial. However, patient survival at day 30 post-transplantation was 98.7%. The primary endpoint of the OCS Lung EXPAND trial was established prior to the initiation of the study and was based on the only published data available for PGD3 within the initial 72-hour period post-transplantation, which reflected data from currently utilized donor lungs. Several recently published studies have demonstrated higher rates of PGD3 within the initial 72-hour period post-transplantation when using donor lungs from currently unutilized DBD and DCD donors. We performed a comparative benchmark analysis against these studies with the results of the OCS Lung EXPAND Trial. Although the analysis was not a head-to-head comparison and thus is not definitive evidence of efficacy, the OCS Lung resulted in significantly lower rates of PGD3 within the initial 72-hour period post-transplantation as compared to similar donor cohorts.

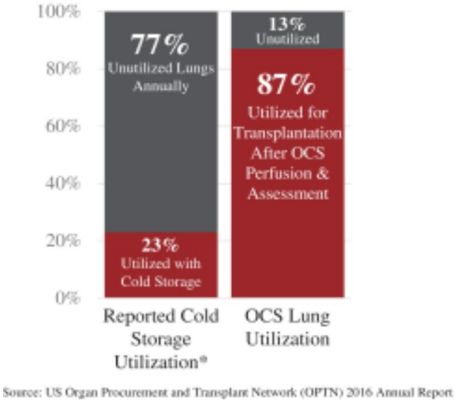
Summary results of the OCS Lung EXPAND Trial include:

- ***Observed 87% Utilization Rate for Lung Transplantation Using OCS Lung:*** The OCS Lung EXPAND Trial included several clinical criteria that would typically result in the rejection of lungs from DBD donors, including donor age above 55 years old, lung oxygenation function assessed by fraction oxygenation index, or PaO2/FiO2, below 300 mmHg and injurious ischemic time greater than six hours. In addition, the trial included DCD donor organs that are seldom utilized for transplantation today. Use of the OCS Lung resulted in successful utilization of 87% of these donor lungs that had been rejected for transplantation by other transplant centers using cold storage. The figure below demonstrates the donor lung criteria and observed rates of successful transplantation in the OCS Lung EXPAND Trial.

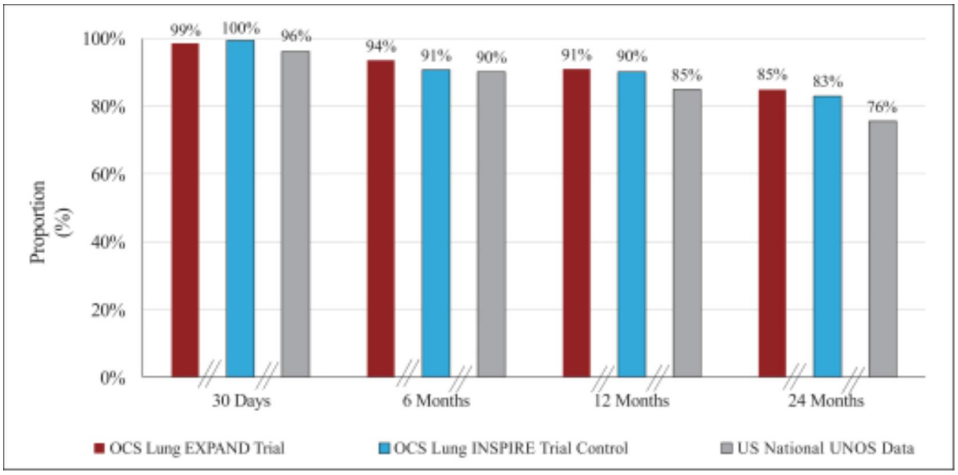
OCS Lung EXPAND Trial Donors Inclusion Criteria



OCS Lung EXPAND Trial Utilization Result



- ***The OCS Lung Resulted in Good Short- and Long-Term Patient Survival at One Year and Two Years Post-Lung Transplantation:*** As indicated in the figure below, the 30-day, 6-month, one-year and two-year survival of patients in the OCS Lung EXPAND Trial was good and compared favorably to the survival rates of patients receiving donor lungs in our OCS Lung INSPIRE Trial as well as to U.S. national averages post-transplantation.



OCS Lung Thoracic Organ Perfusion Post-Approval Study Registry

As a condition of approval for our OCS Lung PMA, we are conducting a post-approval study known as the OCS Lung Thoracic Organ Perfusion Post-Approval Study Registry, or TOP Registry. The TOP Registry will evaluate the short- and long-term safety and effectiveness of the OCS Lung for lung transplantation in a real-world environment. This registry will enroll all consenting patients who receive preserved double-lung transplants using the OCS Lung. Upon approval of the PMA for the OCS Lung for use with currently unutilized donor lungs, the TOP Registry was expanded to include patients from both OCS Lung indications. There are two analysis populations: one that includes 289 double lung transplant recipients with currently utilized donor lungs preserved on the OCS Lung and a second that includes 266 double lung transplant recipients with currently unutilized donor lungs preserved on the OCS Lung. The primary effectiveness endpoint is 12-month patient and graft survival post double-lung transplant. The safety endpoints are the number of lung graft-related serious adverse events through the longer of 30 days post-transplantation or initial hospital stay per patient, survival rate at 30 days post-transplantation and survival rate through initial transplant surgery hospital stay, if longer than 30 days. Enrollment began in the fourth quarter of 2018, and we had enrolled 144 patients as of February 28, 2021.

OCS Heart Clinical Trials

Below is a summary of our key clinical trials evaluating the OCS Heart.

	OCS Heart PROCEED II Trial in Current Donor Hearts	**OCS Heart EXPAND Trial and OCS Heart EXPAND CAP for Currently Unutilized DBD Donors**	**OCS Heart DCD Trial and OCS Heart DCD CAP**
FDA Status	PMA submission in December 2018		Expect PMA submission in 2021
Objectives	International pivotal trial for FDA approval and market access for current heart transplant market Compare OCS Heart clinical outcomes to cold storage and demonstrate non-inferiority of OCS Heart clinical outcomes to cold storage control	U.S. pivotal trial for FDA approval and market access for currently unutilized DBD donors Single arm trial to assess the ability of the OCS to improve donor heart utilization from currently unutilized DBD donors Continued Access Protocol (CAP) to allow access to the OCS Heart System for the same currently unutilized DBD donors while PMA is under review	U.S. pivotal trial for FDA approval and market access for DCD donors. Prior to this trial DCD hearts were never utilized for transplant Randomized trial vs. standard hearts transplanted with ice
Number of Patients	128 patients	150 patients	270 patients
Length of Follow-up	30 days post-transplantation	12 months post-transplantation	12 months post-transplantation
Number of Centers	10 U.S. and international centers	9 U.S. centers	25 U.S. centers

	OCS Heart PROCEED II Trial in Current Donor Hearts	OCS Heart EXPAND Trial and OCS Heart EXPAND CAP for Currently Unutilized DBD Donors	OCS Heart DCD Trial and OCS Heart DCD CAP
Summary Outcomes	Met primary effectiveness and safety endpoints Demonstrated significant reduction of injurious ischemic time on donor hearts compared to cold storage controls In a post-hoc observational analysis of all-cause mortality, through 60 months post-transplant, graft-related deaths in the OCS group were similar to the number in the standard of care group, but overall deaths were higher in the OCS group.	Met the primary effectiveness endpoint of 30-day patient survival and freedom from severe PGD within 24 hours post-transplant Demonstrated significant increase in donor heart utilization from currently unutilized DBD donors to 81% to 84% utilization Demonstrated good patient survival at 6 months and 12 months post-transplantation Low incidence of severe left ventricular or right ventricular PGD	Results to be reported in 2021
Publication Status	Pre-specified trial results published in Ardehali et al., The Lancet Journal, April 2015	Pre-publication	Pre-publication

The OCS Heart PROCEED II Trial was the first FDA trial for machine perfusion technologies for solid organ transplantation and helped identify several trial design and device technology implementation opportunities. These opportunities were addressed in the modified design of the OCS Heart and the design of the OCS Heart EXPAND Trial. As a result, we voluntarily withdrew our original PMA application for the OCS Heart prior to approval in an effort to expand our data to include OCS Heart EXPAND Trial results as well as supplement our OCS Heart PROCEED II Trial results with long-term follow-up data that was not collected as part of the original trial protocol.

Summary Overview of OCS Heart PROCEED II Trial & Results

We sponsored the OCS Heart PROCEED II Trial, a randomized, controlled, multi-center study at 10 leading global academic heart transplant centers. The purpose of this trial was to demonstrate non-inferiority of the OCS Heart compared to cold storage. The trial inclusion criteria focused on current routine donor heart transplant criteria and the trial enrolled 128 heart transplant recipients randomized between the OCS Heart and the control arm, which used cold storage. Summary results of the OCS Heart PROCEED II Trial include:

- ***Met Primary Effectiveness Endpoint of Patient Survival at Day 30 post-Heart Transplantation:*** The OCS met the primary effectiveness endpoint in all analysis populations, demonstrating a greater than 90% survival rate at day 30 post-transplantation. These survival rates were not statistically different from those of the control arm, which potentially support that the OCS is effective in preserving donor hearts for transplantation.
- ***Met Principal Safety Endpoint of Cardiac-Graft Related Serious Adverse Events Relative to the Control Arm:*** The OCS Heart PROCEED II Trial met the secondary endpoint of cardiac-graft related serious adverse events, with no statistically significant difference relative to the control arm. These results support the safety of the OCS Heart for donor heart preservation.

Summary Overview of OCS Heart EXPAND Trial & Results

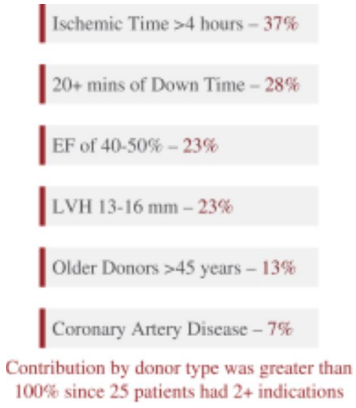
We sponsored the OCS Heart EXPAND Trial, a single arm, multi-center U.S. FDA pivotal trial at nine leading academic U.S. heart transplant centers. The objective of the OCS Heart EXPAND Trial was to demonstrate the ability of the OCS Heart to improve donor heart utilization from currently unutilized DBD donors and to demonstrate reasonable assurance of effectiveness and safety required for U.S. FDA approval for this indication. The trial inclusion criteria focused on currently unutilized DBD donor hearts and enrolled 75 heart transplant recipients with donor hearts that would otherwise have been unutilized from DBD donors. In fact, data obtained from UNOS demonstrated that U.S. donor hearts used for the OCS Heart EXPAND Trial had been declined for transplantation an average of 66 times by other transplant centers before reaching a center participating in the OCS Heart EXPAND Trial due to variety of clinical and logistical reasons, including donor organ quality, donor age, expected injurious ischemic time or travel distance, or type of donor.

After conclusion of enrollment of the OCS Heart EXPAND Trial, we began enrollment of the OCS Heart EXPAND CAP trial. A CAP trial is approved by the FDA to allow continued usage of a medical technology for those hospitals that were in the original clinical trial, using the same protocol as the original EXPAND trial. This allows patients to receive access to this critical lifesaving technology during the review of the PMA. As of February 28, 2021, we have enrolled 62 patients in the OCS Heart EXPAND CAP trial.

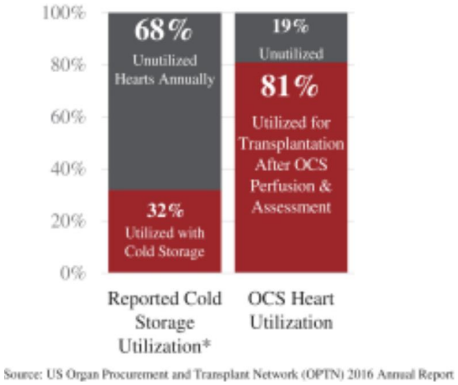
Summary results of the OCS Heart EXPAND Trial:

- ***Observed 81% Utilization Rate for Heart Transplantation Using OCS Heart Technology***: The OCS Heart EXPAND Trial included several clinical criteria that would typically result in the rejection of hearts from DBD donors, including older donor age, lower than acceptable cardiac ejection fraction, or EF, donor with prolonged cardiac arrest/down time requiring resuscitation, donor hearts with thick left ventricle hypertrophy, or LVH, donor hearts with non-specific coronary artery disease, or CAD, and long injurious ischemic time greater than four hours. Use of the OCS Heart resulted in successful utilization of 81% of these donor hearts that had been rejected for transplantation by other transplant centers using cold storage. The figure below demonstrates the donor heart characteristics and observed rates of successful transplantation in the OCS Heart EXPAND Trial. When the patients transplanted in the OCS Heart EXPAND CAP are combined with the OCS Heart EXPAND patients, the utilization rate was 84%

OCS Heart EXPAND Trial Donors Type



OCS Heart EXPAND Trial Utilization Results



- ***Good Short- and Mid-Term Patient Survival at Six Months Post-Heart Transplantation:*** Despite the higher risk profile associated with the donor hearts used in the OCS Heart EXPAND Trial, the trial demonstrated short- and mid-term survival rates of 94.7%, 88.0% and 83.8% at 30 days, six months and 12 months, respectively. When the results for the OCS Heart EXPAND CAP are combined with the results for the OCS Heart EXPAND Trial, the survival rates were 94.7%, 88.0% and 83.8% at 30 days, six months and 12 months, respectively.
- ***Low Incidence of Severe Primary Graft Dysfunction:*** In addition to good rates of survival, patients in the OCS Heart EXPAND Trial experienced 10.7% severe left ventricular, or LV, or right ventricular, or RV, PGD. Recently published studies of standard heart transplants have demonstrated higher rates of severe LV or RV PGD.

We have received FDA approval for a CAP for the OCS Heart EXPAND Trial. This trial follows the same protocol as the OCS Heart EXPAND Trial and is intended to allow patient access to the OCS Heart while the OCS Heart PMA is under review. As of February 28, 2021, we have enrolled 62 out of 75 patients in this study.

OCS Heart DCD Trial

In September 2020, we completed enrollment of 180 patients in the first U.S. trial of DCD hearts for transplantation. The objective of the study is to evaluate the effectiveness of the OCS Heart to resuscitate, preserve, and assess hearts donated after circulatory death for transplantation to increase the pool of donor hearts available for transplantation. The primary endpoint is a non-inferiority comparison of patient survival at 6 months post-transplant between recipients of DCD donor hearts preserved on the OCS Heart and concurrent recipients of standard criteria donor hearts preserved using cold storage, adjusting for risk factors. We have completed enrollment in this trial and have transplanted 90 patients with DCD donor hearts and 90 patients with standard of care hearts preserved on cold storage. This trial is currently in the follow-up phase and we anticipate submission of a PMA supplement for this trial in 2021.

Similar to the OCS EXPAND Heart trial, once enrollment was complete, we initiated the OCS DCD Heart CAP trial. As of February 28, 2021, we have enrolled 28 patients in the OCS Heart DCD CAP trial.

Summary of Key Ex-U.S. Studies Supporting OCS Heart for DCD Donors

The OCS Heart is the only portable medical technology capable of resuscitating, preserving and assessing hearts from DCD donors. Outside of the United States, the OCS has been used to successfully transplant over 140 hearts from DCD donors. As such, in addition to our clinical trials that potentially support the FDA approval process for the OCS Heart, there are several scientific and clinical publications from Australia and the U.K. that may provide additional support for demonstrating the safety and efficacy of the OCS Heart in the transplantation of DCD donor hearts.

A single-center observational matched cohort study in the U.K. compared the outcomes of consecutive patients who received transplants of DCD donor hearts between February 1, 2015 and March 31, 2017 to matched recipients who received transplants of DBD donor hearts between February 1, 2013 and March 31, 2017. The DCD donor hearts were transported and perfused on the OCS Heart, while the DBD hearts were preserved with cold storage. There was no difference in the protocol for implant technique or immunosuppressive regimens during this period. In this study, the use of the OCS Heart resulted in an 87% rate of successful utilization of DCD donor hearts for transplantation and resulted in one-year post-transplantation survival rates that were comparable to those of the matched DBD donor hearts that were transplanted with cold storage. This study was published in the Journal of Heart and Lung Transplantation in December 2017.

Similarly, a publication by Dhital et al. in April 2015 in The Lancet Journal described the experience of using the OCS Heart to preserve DCD donor hearts at St. Vincent's Hospital in Sydney, Australia. The DCD program at this institution began in July 2014 with all DCD donor hearts being perfused with the OCS Heart. As reported in October 2018, there had been 17 DCD donor heart transplants utilizing 71% of DCD donor hearts. Of the reported results available on 16 of the 17 patients, all 16 patients were alive and had normal biventricular function.

Chew, et al. 2019 reported on the use of the OCS Heart to preserve 23 DCD donor hearts. A total of 33 DCD donor hearts were retrieved for potential transplant and of these, 23 were transplanted, yielding a utilization rate of 70%. Overall survival of these transplant recipients was 95% at each of one month, one year and two years.

OCS Liver Clinical Trials

Summary Overview of OCS Liver PROTECT Trial & Results

In October 2019, we completed enrollment of patients in our U.S. pivotal Investigational Drug Exemption, or IDE trial, the OCS Liver PROTECT Trial, to support U.S. FDA approval and market access for the OCS Liver. The OCS Liver PROTECT Trial is a prospective, randomized trial to evaluate the effectiveness of the OCS Liver to preserve and assess donor livers intended for transplantation. This is a two-armed, multi-center, randomized, controlled pivotal trial with participants assigned to the OCS treatment arm or the control arm, which uses cold storage.

Summary Results of the OCS Liver PROTECT Trial:

- Observed a 98.1% utilization rate.
- Lower incidence of EAD compared to control across both DBD donor and DCD donor cohorts in the trial.

We have received FDA approval for a CAP for the OCS Liver PROTECT Trial. This study follows the same protocol as the OCS Liver PROTECT Trial and is intended to allow patient access to the OCS Liver while the OCS Liver PMA is under preparation and review. As of February 28, 2021, we have enrolled 74 patients in this trial.

Summary Overview of OCS Liver REVIVE Trial

Additionally, our OCS Liver European REVIVE Trial, which was a single arm, prospective trial of 25 transplanted liver recipients, evaluated the safety and performance of the OCS Liver. The primary performance endpoint was the number of donor livers preserved by the OCS Liver in a near-physiologic state. The primary safety endpoint was the number of events directly related to the use of the OCS Liver that led to the donor liver being deemed not clinically acceptable and, consequently, not transplanted. Results from the OCS Liver European REVIVE Trial demonstrated that the OCS Liver resulted in 100% utilization of DBD and DCD donor livers.

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, 2020, our owned and licensed patent portfolio consisted of approximately 248 issued patents and pending patent applications worldwide, including in the United States, Australia, Europe, Canada, China, Israel, New Zealand and Japan. Our licensed portfolio includes one issued unexpired United States patent licensed from the Veteran's Administration, or VA. Several other licensed U.S. and international patents expired in 2018. The issued unexpired licensed VA patent includes claims directed to portable perfusion apparatus for preserving a harvested donor organ in a viable state. 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 27 issued patents and 9 pending applications. Outside the United States, our owned portfolio includes about 161 issued patents and 51 pending applications. Issued patents in our portfolio are expected to expire between 2020 and 2036, 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 2025 and 2036, excluding any potential additional patent term for patent term adjustments or patent term extensions, if applicable.

As of December 31, 2020, our patent portfolio relating to the OCS Lung includes a family 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, Australia, Belgium, Canada, China, 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 New Zealand. These patents, and any patents issued from pending patent applications, are expected to expire in 2029, excluding any potential additional patent term for patent term adjustments or patent term extensions, if applicable.

As of December 31, 2020, our patent portfolio relating to the OCS Heart includes a family 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, Australia, Belgium, Canada, China, 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, Canada, China, Europe, Hong Kong, Israel, Japan, and New Zealand. These patents, and any patents issued from pending patent applications, are expected to expire in 2025, excluding any potential additional patent term for patent term adjustments or patent term extensions, if applicable.

As of December 31, 2020, our patent portfolio relating to the OCS Liver 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 and Australia, and applications are pending in the United States, Australia, Canada, China, Europe, Hong Kong, Israel, Japan and New Zealand. 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.

As of December 31, 2020, our patent portfolio relating to the OCS Solutions includes a family 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, Australia, China, Israel, Japan, New Zealand and patent applications are pending in the United States, Canada, China, Europe, Hong Kong, and New Zealand. These patents, and any patents issued from pending patent applications, are expected to expire in 2025, 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. We cannot assure you that patents will be issued from any of our pending applications or that, if patents are issued, they will 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.

Department of Veterans Affairs License

In August 2002, we entered into a license agreement with the VA under which the VA granted us an exclusive, worldwide license under specified patents to make, use, sell and import perfusion apparatuses for our portable organ preservation systems and disposable perfusion modules for use in these apparatuses and a non-exclusive, worldwide license to make, use, sell and import solutions for use in or with those systems. Prior to September 23, 2017, our license rights under the VA patents included at least 20 issued United States and international patents and patent applications pending in the United States, Canada and Japan. Dr. Hassanein, our President and Chief Executive Officer and founder, is a co-inventor on all of these patents. During his cardiac surgery research fellowship at West Roxbury VA Medical Center prior to founding TransMedics, Dr. Hassanein performed much of the research and other work that resulted in the inventions and claims that subsequently became the subject of patents and patent applications currently held by the VA. The majority of the licensed U.S. patents expired in 2017, and the foreign patents expired in September 2018. However, we have requested patent term extension for one U.S. patent covered by the VA license agreement, U.S. Patent No. 6,100,082. We have been granted an interim patent term extension until September 23, 2021 for this patent and have requested an extension to May 2022. However, the length of the patent term extension is currently being determined by the United States Patent and Trademark Office (USPTO) based on input from the FDA. On February 8, 2021, the FDA provided to the USPTO a determined regulatory review period for the OCS Lung. Under the FDA’s analysis, the patent term extension of the ’082 patent would be until November 6, 2021. Our rights under the license agreement will continue until the expiration of the last to expire of the licensed patents, which will be the ’082 patent. Our license includes the right to grant sublicenses, subject to approval by the VA and other restrictions, and is subject to the U.S. government’s right to practice the licensed patents on its own behalf without payment of a royalty and an obligation to grant certain sublicenses as necessary to fulfill public health, welfare and safety needs. During its term, our license agreement with the VA also requires us to make our products covered by the licensed patents available to the public on reasonable terms and to provide the U.S. government such products at the lowest price. During the term, we must manufacture our products covered by the licensed patents in the United States to the extent practicable.

As consideration for the licenses granted by the VA, we paid a one-time five figure amount to the VA and are obligated to pay tiered royalties ranging from a low single-digit to a mid single-digit percentage on net sales of each product covered by a licensed patent (subject to a minimum aggregate royalty payment of less than $0.1 million per year during each of the first five years after the first commercial sale, after which no minimum is required). Royalties will be paid by us on a licensed product-by-licensed product and country-by-country basis, beginning on the first commercial sale of such licensed product in such country until expiration of the last valid patent claim covering such licensed product in such country. Our license agreement with the VA provides that so long as our license remains exclusive, we have the first right to amend, prosecute and maintain the licensed patents at our own expense, and, subject to prior written approval of the U.S. Department of Justice or, if required by law, jointly with the VA, the first right to enforce the licensed patents with respect to infringement relating to perfusion apparatuses. Our license agreement with the VA can be terminated by us or the VA only if the other party fails to cure its material breach within a specified period after receiving notice of such breach.

Research, Development and Clinical Trial Operations

Our research, development and clinical trial operations function consists of a dedicated clinical trial team that has trial management, data collection and biostatistics expertise. Our product engineering function consists of a multi-disciplinary engineering team that has electrical, mechanical, systems and software engineering expertise. Our regulatory function includes a team with both U.S. and international medical device regulatory expertise and is supported by senior FDA regulatory advisors and legal counsel. For the fiscal years ended December 31, 2020 and December 28, 2019 our research, development and clinical trials expenses were $18.8 million and $19.9 million, respectively.

This team is focused on the following research, development and clinical trial activities:

- expanding the body of clinical evidence supporting the use of the OCS platform through pre-market clinical trials, post-market registries and scientific publications;
- improving incrementally the technology and manufacturing efficiency of our current platform;
- developing the next generation OCS; and
- conducting research to investigate new clinical applications and uses for the OCS platform.

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 or 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.

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 and XVIVO Perfusion AB, both of which offer single-organ systems for the liver and lung, respectively.

We believe that our principal competitive factors include:

- strong clinical evidence from large trials demonstrating safety, effectiveness and clinical benefits;
- regulatory approvals for broad clinical indications of use;
- ease of integration into current organ retrieval 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.

Manufacturing, Supply and Operations

We design and assemble our OCS Consoles and disposable OCS Perfusion Sets at our facility in Andover, Massachusetts. We believe our current facility's capacity using a single shift is sufficient to cover the next two to three years of forecast demand, and we also have the ability to increase capacity significantly with additional shifts. We manufacture our sterilized disposable OCS Perfusion Sets in a class 10,000 cleanroom. 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 expires in April 2022 and automatically extends for subsequent periods of 24 months each, unless terminated by either party at least 12 months prior to the end of the initial term or 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 operations team includes production and test employees, manufacturing engineers and field service technicians.

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 authorities in the European Union. EU laws in relation to CE marking also apply in Norway, Lichtenstein and Iceland. EU laws in relation to Conformité Européenne marking, or CE, will apply in Switzerland and Turkey at least until May 26, 2021 due to mutual recognition agreements, and thereafter it is anticipated that a new mutual recognition agreement with Switzerland and a Customs Union with Turkey will allow application to continue, although potentially with some interruption. 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. Whether or not we have or are required to obtain FDA clearance or approval for a product, we will be required to obtain authorization before commencing clinical trials and to obtain marketing authorization or approval of our products under the comparable regulatory authorities of countries outside of the United States before we can commence clinical trials or commercialize our products in those countries. The approval processes outside the European Union, although to a significant extent harmonized across 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.

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 are those for which safety and effectiveness can be assured by adherence to the FDA's General Controls for medical devices, which include compliance with the applicable portions of the Quality System Regulation, or QSR, facility registration and product listing, reporting of adverse medical events, 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.

Devices deemed by the FDA to pose the greatest risks, such as life-sustaining, life-supporting and most 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. Pre-amendment Class III devices require a PMA only after FDA publishes a regulation calling for PMA submissions, and prior to the PMA effective date are subject to the FDA's 510(k) premarket notification and clearance process in order to be commercially distributed.

Each of our OCS products is a Class III device. We received PMA approval for the OCS Lung in March 2018 for the preservation of donor lungs currently utilized for double-lung transplantation, and we received PMA approval for the OCS Lung for preservation of donor lungs currently unutilized for double-lung transplantation in May 2019. In the future, we also hope to obtain PMA approvals for the OCS for preservation of donor hearts currently utilized and unutilized for transplantation, and donor livers currently utilized and unutilized for transplantation.

PMA Pathway

Class III devices require an approved PMA before they can be marketed, although some pre-amendment Class III devices for which the FDA has not yet required a PMA are cleared through the 510(k) process. 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. Following receipt of a PMA, the FDA determines whether the application is sufficiently complete to permit a substantive review. 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' and/or suppliers' manufacturing facility or facilities to ensure compliance with the QSR 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. Grounds for PMA denial include the lack of a showing of reasonable assurance that the device is safe or effective under the conditions of use prescribed, recommended or suggested in the proposed labeling; a finding that the methods used in, or the facilities or controls used for, the manufacture, processing, packing or installation of such device do not conform to the requirements of the QSR; or a finding that the proposed labeling is false or misleading in any particular. If none of the grounds for PMA denial identified in FDA's laws and regulations exist, the FDA will approve the PMA. 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. In such cases, the manufacturer might be required to follow certain patient groups for a number of years and to make periodic reports to the FDA on the clinical status of those patients. For our currently marketed OCS Lung, as part of the conditions of approval, we must complete three PMA post-approval studies, or PAS: the OCS Lung INSPIRE Continuation PAS, which is a two-arm observational study intended to evaluate long-term outcomes of the OCS Lung INSPIRE Trial patients, the OCS Lung EXPAND Continuation PAS, which is a single-arm study intended to evaluate long-term outcomes of the OCS Lung EXPAND Trial patients, and our TOP Registry, 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. The OCS Lung INSPIRE Continuation PAS, the OCS Lung EXPAND Continuation PAS and the TOP Registry entail submission of regular reports to the FDA. 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 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. 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 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. A significant risk device is one that presents a potential for serious risk to the health, safety or welfare of a patient and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject. 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. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies the company that the investigation may not begin. 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.

In addition, 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. If an IDE application is approved by the FDA and one or more IRBs, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate approval from the FDA, but must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements. 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.

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. The clinical investigators in the clinical study are also subject to FDA regulations and must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device, and comply with all reporting and recordkeeping requirements. Additionally, 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.

Currently, we are conducting, under IDEs, a Continued Access Protocol to the OCS Heart Study for the preservation of certain donor hearts that do not meet the current standard donor heart acceptance criteria for transplantation, a Continued Access Protocol to the OCS Heart DCD study for the preservation of hearts donated after circulatory death, and a Continued Access Protocol to the OCS Liver study for the preservation of currently utilized donor livers and certain donor livers that are currently unutilized for transplantation.

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;
- QSR 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, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or 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 QSR, 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 QSR also requires, among other things, maintenance of a device master record, device history file, and complaint files. 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 QSR or other applicable regulatory requirements (for example, if we fail to re-certify our products under the new Medical Devices Regulation in time) 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 or import approvals 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 our medical devices in the European Union is harmonized such that EU countries follow the standards set out in the applicable medical devices directive (93/42/EEC). However, the competent authorities in each member state have the right to enforce the standards set out in that directive against the manufacturer selling medical devices in the member state.

All medical devices placed on the market in the European Union must meet the applicable essential requirements laid down in Directive 93/42/EEC concerning medical devices, or the Medical Devices Directive. Similar to the U.S. system, medical devices are classified into one of four classes: I, IIa, IIb and III, with class I representing the lowest risk products and class III the highest risk products. The most fundamental essential requirement 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. In addition, the device must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in a suitable manner. The European Commission has adopted various standards applicable to medical devices. These include standards governing common requirements, such as sterilization and safety of medical electrical equipment, and product standards for certain types of medical devices. There are also harmonized standards relating to design and manufacture. While not mandatory, compliance with these standards is often viewed as the easiest way to satisfy the essential requirements as a practical matter. Compliance with a standard developed to implement an essential requirement also creates a rebuttable presumption that the device satisfies that essential requirement.

To demonstrate compliance with the essential requirements laid down in Annex I to the Medical Devices Directive, medical device manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Conformity assessment procedures require an assessment of available clinical evidence, literature data for the product and post-market experience in respect of similar products already marketed.

Except for low-risk medical devices (Class I non-sterile, non-measuring devices), where the manufacturer can self-declare the conformity of its products with the essential requirements (except for any parts that relate to sterility or metrology), a conformity assessment procedure requires the intervention of a notified body. Notified bodies are private entities and are authorized or licensed to perform such assessments by government authorities. The notified body must audit and examine a product's technical dossiers and the manufacturers' quality system. If satisfied that the relevant product conforms to the relevant essential requirements, 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 apply the CE Mark to the device, which allows the device to be placed on the market throughout the European Union. Once the product 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 the medical device. The notified body has on-going audit rights and must be notified of all significant changes to the device.

On April 5, 2017, the European Parliament passed the Medical Devices Regulation (Regulation 2017/745), or MDR, which repeals and replaces the EU Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the EU member states, the regulations would be directly applicable without the need for adoption of EU member state laws implementing them, in all EU member states and are intended to eliminate current differences in the regulation of medical devices among EU member states. The Medical Devices Regulation, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the European Union for medical devices and ensure a high level of safety and health while supporting innovation.

While the regulatory process is essentially the same as described above, the requirements of MDR are significantly more onerous than under the EU Medical Devices Directive and requires much preparatory work by our regulatory team in advance of May 26, 2021. The increased regulation includes the following:

- strengthening of the rules on placing devices on the market, by requiring more evidence substantiating safety and efficacy of the device and more detailed content in the technical documentation for each device;
- requiring a structured post-market clinical follow-up program for every medical device;
- necessitating more thorough post-market surveillance program, with an emphasis on active gathering and analyzing the data;
- establishing explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market and new responsibilities for distributors and importers;
- improving the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;

- setting up a central database into which manufacturers and other economic operators are required to input data with the goal of providing EU competent authorities as well as provide patients, healthcare professionals and the public with comprehensive information on products available in the European Union; and
- strengthening rules for the assessment of certain high-risk devices, such as implants, which may have to undergo an additional check by experts before they are placed on the market.

Our regulatory function is working toward being compliant with MDR prior to May 26, 2021. Because of the permitted transition periods under MDR, each of our medical devices will require recertification prior to September 19, 2022.

Clinical Investigations

In order to demonstrate safety and efficacy for their medical devices, manufacturers must conduct clinical investigations in accordance with the requirements of Annex X to the Medical Devices Directive, and applicable European and International Organization for Standardization standards, as implemented or adopted in the European Union member states. Clinical trials commencing after May 26, 2021 will be regulated under the more onerous provisions of MDR. Clinical investigations for medical devices cannot proceed without a positive opinion of an ethics committee and approval by or notification to the national regulatory authorities. Both regulators 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 that accompany the affixing of the CE Mark to medical devices and which will be even stricter beginning on May 26, 2021. These include the obligation to report serious adverse events within a specified time period and to provide periodic safety reports and updates. Serious adverse events will, in the future, have to also be reported via the EU database, which will enable EU competent authorities to be alerted more quickly and across the whole of the EU and will enable the competent authorities to act more in concert than is currently the case.

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 as advertising and promotion law is not harmonized in the European Union.

New Developments: Brexit

Our notified body, BSI, previously issued from its U.K. entity the certificates which allow CE marking of the OCS products. Following the U.K.'s withdrawal from the European Union, certificates issued by U.K. notified bodies will no longer be recognized. Our notified body is based in the Netherlands and issues the certificates that allow CE marking of the OCS products. In addition, we have engaged with a new Authorized Representative covering both the U.K. as well as Europe in separate arrangements in compliance with both region regulations.

Regulations Applicable to Transport of Organs Intended for Transplantation

In the European Union, the Directive 2010/53/EU (formerly Directive 2010/45/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 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;
- 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 clearance by foreign countries may be longer or shorter than that for FDA clearance, and requirements for licensing a product in a foreign country may differ significantly from FDA requirements.

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 in the European Union.

Internationally, the approaches to product defects will vary. A product may be recalled in one country but not in others. However, within the European Union, competent authorities share adverse event information and cooperate with each other and a recall in one EU member state is more likely to lead to recalls in the rest of the European Union.

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 U.K. are governed by the code of Association of British Healthcare Industries, 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 2010 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 offences, which in the U.K. and in the United States include the offence of bribing a foreign public official.

Data Privacy and Security Laws

We are, or 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, proscribes 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 may be 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, which took effect on January 1, 2020, gives California consumers (defined to include all 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. We expect additional federal and state legislative and regulatory efforts to regulate consumer privacy in the future.

In the European Economic Area, or EEA, we may be subject to laws relating to our collection, control, processing and other use of personal data, such as data relating to an identifiable living individual. 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 each of them. Each EU member state has transposed the requirements laid down by the Data Protection Directive and E-Privacy Directive into its own national data privacy regime and therefore the laws may differ by jurisdiction, sometimes significantly. 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. We need to ensure compliance with the rules in each jurisdiction where we are established or are otherwise subject to local privacy laws. For example, we may be subject to the GDPR for processing personal data in connection with offering goods or services to persons located in the EEA or monitoring the behavior of persons located in the EEA.

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, secure, not be transferred outside of the EEA unless certain steps are taken to ensure an adequate level of protection and 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), 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. In particular, in order to process such data, explicit consent to the processing (including any cross-border transfer) usually 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 or scientific research.

The GDPR also imposes potentially onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and policies. It requires data controllers to be transparent and disclose to data subjects (in a concise, intelligible and easily accessible form) how their personal information is to be used, imposes limitations on retention of information, increases requirements pertaining to pseudonymized (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 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, 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. 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 to the U.S., has led to increased scrutiny on data transfers from the EEA to the U.S. generally and may increase our costs of compliance with data privacy legislation.

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 have a practice of entering into contractual arrangements 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, our policy is that it is done so in compliance with applicable data export requirements. Any failure by us or third parties to follow these policies or practices, or otherwise comply with applicable data laws, could lead to a security or privacy breach, regulatory enforcement, or regulatory 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.

The implementation of the Affordable Care Act in the United States, for example, has changed healthcare financing and delivery by both governmental and private insurers substantially, and affected medical device manufacturers significantly. The Affordable Care Act imposed, among other things, a 2.3% federal excise tax, with limited exceptions, on any entity that manufactures or imports Class I, II and III medical devices offered for sale in the United States that began on January 1, 2013, however the tax was suspended in 2016 and permanently repealed in 2019. The Affordable Care Act also implemented payment system reforms, including bundled payment models and Medicare value-based purchasing plans. Additionally, the Affordable Care Act has expanded eligibility criteria for Medicaid programs and provided incentives to programs that increase the federal government’s comparative effectiveness research, including the creation of a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. There have been ongoing judicial and Congressional challenges seeking to repeal, modify or invalidate some or all of the provisions of the Affordable Care Act, and we expect additional challenges and amendments in the future. In November 2020, the U.S. Supreme Court heard argument in Texas v. Azar, which challenges the constitutionality of the Affordable Care Act. Pending resolution of the litigation, all of the Affordable Care Act but the individual mandate to buy health insurance remains in effect. The effect of the transition from the Trump administration to the Biden administration in January 2021 on the Affordable Care Act is unknown at this time. If the Affordable Care Act is repealed, replaced or modified, additional regulatory risks may arise and our future financial results could be adversely and materially affected.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, the Budget Control Act of 2011, as amended, among other things, included reductions to Medicare (but not Medicaid) payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030 (except May 1, 2020 to March 31, 2021) unless additional Congressional action is taken. Additionally, the American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

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.

Employees

As of December 31, 2020, we employed 110 people globally, most of which were full-time employees. Except for certain European employees, our employees are not subject to collective bargaining agreements, and we believe that we have good relations with our employees.

Corporate Information and Organizational Transactions

TransMedics Group, Inc., was incorporated in the Commonwealth of Massachusetts in October 2018 to facilitate our 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.

On May 6, 2019, immediately prior to the completion of our initial public offering, the Company engaged in a series of transactions whereby TransMedics, Inc. became a wholly owned subsidiary of TransMedics Group, Inc. As part of the transactions, shareholders of TransMedics, Inc. exchanged their shares of TransMedics, Inc. for shares of TransMedics Group, Inc. on a 3.5-for-one basis.

See “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Note 1. Nature of the Business and Basis of Presentation” to the consolidated financial statements included in Part II, Item 8 in this Annual Report on Form 10-K for more information about the above-mentioned transactions.

We are an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012. We will remain an emerging growth company until the earlier of: (i) the last day of the fiscal year (a) following the fifth anniversary of the completion of the IPO, (b) in which we have total annual gross revenue of at least $1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of the prior June 30th, and (ii) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

We are also a “smaller reporting company,” as defined in Regulation S-K. We may continue to be a smaller reporting company if either (i) market value of our stock held by non-affiliates is less than $250 million or (ii) our annual revenue is less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million as of the last business day of our second fiscal quarter. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Prior to 2020, our fiscal year ended on the last Saturday in December, and we reported fiscal years using a 52/53-week convention. Under this convention, certain fiscal years contained 53 weeks. Each fiscal year was typically composed of four 13-week fiscal quarters, but in years with 53 weeks, the fourth quarter was a 14-week period. The fiscal year ended December 28, 2019 included 52 weeks. In February 2020, we changed the end of its fiscal year end from the last Saturday in December to December 31.

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. You should consider carefully the following risks and all of the other information contained in this Annual Report on Form 10-K 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 you could lose all or part of your 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

We have incurred substantial losses since our inception and anticipate that we will continue to incur losses in the future.

Since our inception, we have incurred significant operating losses. Our ability to generate net revenue sufficient to achieve profitability will depend on the successful further development and commercialization of our OCS products. We generated net revenue of $25.6 million and $23.6 million for the fiscal years ended December 31, 2020 and December 28, 2019, respectively, and incurred net losses of $28.7 million and $33.5 million for these same years. As of December 31, 2020, we had an accumulated deficit of $398.2 million. To date, we have funded our operations primarily with proceeds from sales of equity, borrowings under loan agreements and revenue from clinical trials and commercial sales of our OCS products. Our losses have resulted principally from costs incurred in connection with our research and development, clinical trials, manufacturing and commercialization activities.

We expect to continue to incur net losses for the foreseeable future as we focus on growing commercial sales of our products in both the U.S. and select non-U.S. markets, including growing our sales and clinical adoption team, which will pursue increasing commercial sales and clinical adoption of our OCS products; scaling our manufacturing operations; continuing research, development and clinical trial efforts; and seeking regulatory clearance for new products and product enhancements, including new indications, in both the U.S. and select non-U.S. markets. Further, following the closing of our IPO in May 2019, we have incurred and expect to continue to incur additional costs associated with operating as a public company. As a result, we will need substantial additional funding for expenses related to our operating activities, including selling, general and administrative expenses and research, development and clinical trials expenses. Because of the numerous risks and uncertainties associated with product development and commercialization, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve or maintain profitability. Although we fund a portion of our operations from net revenue from sales of our OCS products for use in clinical trials and from commercial sales, we expect that we will need to finance our operations through a combination of equity offerings, debt financings and strategic alliances until such time, if ever, that we can generate substantial net revenue sufficient to achieve profitability. We may be unable to raise additional funds or enter into such other agreements or arrangements, when needed, on favorable terms or at all. If we are unable to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back or discontinue the further development and commercialization efforts of one or more of our products, or may be forced to reduce or terminate our operations.

We 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.

As we continue to pursue and increase commercial sales of our OCS products, we expect our costs and expenses to increase in the future, particularly as we expand our sales and clinical adoption team, scale our manufacturing operation, continue research, development and clinical trial efforts, and seek regulatory clearance for new products and product enhancements, including new indications, both in the United States and in select non-U.S. markets. The timing and amount of our operating and capital expenditures will depend on many factors, including:

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

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 cease or reduce development or commercialization activities, sell or license to third parties some or all of our assets or merge with another entity, any of which could result in a loss of all or part of your investment.

In addition, if we raise additional funds through the issuance of equity or convertible securities, the issuance of these securities could dilute your 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.

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

As of December 31, 2020, we had $35.0 million of outstanding long-term debt under our credit agreement with OrbiMed Royalty Opportunities II, LP, or OrbiMed, which we refer to as the Credit Agreement. We could incur additional indebtedness in the future. Our payment obligations under the Credit Agreement reduce cash available to fund working capital, capital expenditures, research and development and general corporate needs. In addition, indebtedness under the 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.

Our obligations under the Credit Agreement are secured by substantially all of our assets and the assets of our wholly-owned subsidiaries. The security interest granted over our assets could limit our ability to obtain additional debt financing. In addition, the Credit Agreement contains negative covenants restricting our activities, including limitations on dispositions, mergers or acquisitions; encumbering our intellectual property; incurring indebtedness or liens; paying dividends or redeeming stock or making other distributions; making certain investments; liquidating our company; modifying our organizational documents; entering into sale-leaseback arrangements and engaging in certain other business transactions. In addition, we are required to maintain a minimum liquidity amount of $3.0 million and are required, on an annual basis, to deliver to OrbiMed annual audited financial statements with an unqualified audit opinion from our independent registered public accounting firm. Failure to comply with the covenants in the Credit Agreement, including the minimum liquidity and unqualified audit opinion covenants, could result in the acceleration of our obligations under the Credit Agreement, and, if such acceleration were to occur, it would materially and adversely affect our business, financial condition, operating results, cash flows and prospects.

We may not have sufficient funds, and may be unable to arrange for additional financing, to pay the amounts due under our debt arrangements. The obligations under the Credit Agreement are subject to acceleration upon the occurrence of specified events of default, including payment default, change in control, bankruptcy, insolvency, certain defaults under other material debt, certain events with respect to 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, OrbiMed may declare all or any portion of the outstanding principal amount of the borrowings plus accrued and unpaid interest to be due and payable. Upon the occurrence of certain events of bankruptcy or insolvency, all of the outstanding principal amount of the borrowings plus accrued and unpaid interest will automatically become due and payable.

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

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 timing of patient enrollment in and regulatory approvals for our clinical trials, the availability of donor organs for transplantation, which is unpredictable and could impact the volume of transplant procedures performed at transplant centers using the OCS, and foreign currency exchange rates. We expect that revenue from sales will 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. 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 you should not rely on our past results as an indication of our future performance. Because the timing of organ transplant procedures is generally unpredictable, we have not experienced seasonality in our business from quarter to quarter and do not expect to do so in the foreseeable future.

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

As of December 31, 2020, we had U.S. federal and state net operating loss, or NOL, carryforwards of $322.0 million and $252.7 million, respectively, which may be available to offset future taxable income and begin to expire in 2021 and 2030, respectively. The Company’s federal net operating losses include $108.0 million, which can be carried forward indefinitely. As of December 31, 2020, we also had U.S. federal and state research and development tax credit carryforwards of $7.6 million and $5.0 million, respectively, which may be available to offset future tax liabilities and begin to expire in 2021 and 2024, respectively. A material portion of these NOL and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. In addition, in general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an “ownership change,” generally defined 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, its research and development credit carryforwards and its disallowed interest expense carryovers to offset future taxable income. Our existing NOLs and research and development credit carryforwards may be subject to limitations arising from previous ownership changes. In addition, future changes in our stock ownership, some of which might be beyond our control, could result in an ownership change under Section 382 of the Code. Our NOLs and credits may also be impaired under state law. For these reasons, if we determine that an ownership change has occurred or in the event we experience a change of control, we may not be able to utilize a material portion of the NOLs, research and development credit carryforwards or disallowed interest expense carryovers incurred prior to 2018.

Furthermore, our ability to utilize our NOLs or credits is conditioned upon our attaining profitability and generating U.S. federal and state taxable income. As described above, we have incurred significant net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future; and therefore, we do not know whether or when we will generate the U.S. federal or state taxable income necessary to utilize our NOL or credit carryforwards. Under the Tax Cuts and Jobs Act, or TCJA, NOLs arising in taxable years beginning after December 31, 2017 will not be subject to expiration. In addition, the deduction for NOLs in any taxable year is limited to 80% of annual taxable income in respect of NOLs generated during or after 2018. The TCJA also reduced the corporate income tax rate to 21%, from a prior rate of 35%. This may cause a reduction in the potential economic benefit of our NOLs and other available deferred tax assets.

The transition away from LIBOR may adversely affect our cost to obtain financing.

On July 27, 2017, the U.K. Financial Conduct Authority announced that it intends to stop persuading or compelling banks to submit London Interbank Offered Rate, or LIBOR, rates after 2021. The Financial Conduct Authority and the ICE Benchmark Administration recently announced that LIBOR may continue for legacy contracts until June 2023. While there is no certainty as to what rate or rates may become accepted alternatives to LIBOR, the Alternative Reference Rates Committee, a steering committee comprised of U.S. financial market participants, selected and the Federal Reserve Bank of New York started in May 2018 to publish the Secured Overnight Finance Rate, or SOFR, as an alternative to LIBOR. SOFR is a broad measure of the cost of borrowing cash in the overnight U.S. treasury repo market. The manner and impact of the transition to SOFR or another alternative rate may materially adversely affect the trading market for LIBOR-based securities, which may result in an increase in borrowing costs under our Credit Agreement. Any replacement for LIBOR may result in an effective increase in the applicable interest rate on our current or future debt obligations, including our Credit Agreement.

Risks Related to Research and Development and Commercialization

We depend heavily on the success of the OCS and achieving market acceptance. If we are unable to successfully commercialize the OCS, our business may fail.

We have invested all of our 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 and providing services related to the OCS. While the OCS Lung has received PMA from the FDA for the preservation of donor lungs currently utilized and currently unutilized for double lung transplantation, and our OCS products have received the CE Mark and several other international regulatory approvals for lung, heart and liver for sales outside the United States, we might not be able to commercialize successfully the OCS for the 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 become profitable depends solely on sales of OCS Perfusion Sets and OCS Solutions, which we refer to collectively as disposable sets, and OCS Consoles. 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.

In order to achieve market acceptance for the OCS, we expect that we will need 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. Data from our ongoing or future clinical trials may not demonstrate that the OCS provides these benefits. Our estimates of the potential pools of donors are only estimates and subject to uncertainty, risk and change. In addition, the medical community might not consider data collected from our patient registry meaningful or compelling, or the data collected from our patient registry or any clinical or commercial experience could indicate that the OCS is unsafe, which would substantially undermine our commercialization efforts.

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. We expect that the cost of the OCS will significantly exceed the cost of cold storage preservation. In addition, 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. Based on these and other factors, transplant center program directors, organ procurement organizations and private and public payors may decide that the benefits of the OCS do not outweigh its costs. 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.

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

In order to obtain PMA approval for a device, the sponsor must conduct clinical trials, often well-controlled clinical studies, designed to assess the safety and effectiveness of the product. Conducting clinical trials is a complex and expensive process, can take many years and outcomes are inherently uncertain. We 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 are necessary to support PMA applications and may be necessary to support PMA supplements for modified versions of our marketed device products. Trials often require enrollment of large numbers of subjects, who may be difficult to identify, recruit and maintain as participants in the clinical trial. We have obtained PMA approval for the OCS Lung for the preservation of donor lungs currently utilized and currently unutilized for transplants in the United States. As a condition of this PMA approval, we are required to conduct two post-market studies. 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, like kidney, and 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 our clinical trials:

- we have been required and, prior to collecting clinical data in the future to support new PMA applications, will 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 products or conducting clinical trials on our behalf, 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, IRBs or other reviewing bodies may 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.

Patient enrollment in clinical trials and completion of patient follow-up depend on many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial, patient compliance, competing clinical trials clinicians' and patients' perceptions as to the potential advantages of the product being studied in relation to other available products or services, and the ongoing COVID-19 pandemic. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and effectiveness of a product, or they may be persuaded to participate in contemporaneous clinical trials of a competitor's product. In addition, patients participating in our clinical trials may drop out before completion of the trial or experience adverse medical events unrelated to our products. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may delay commencement or completion of the clinical trial, cause an increase in the costs of the clinical trial and delays, or result in the failure of the clinical trial.

Clinical trials must be conducted in accordance with the regulations of the FDA and other applicable regulatory authorities' legal requirements and regulations and are subject to oversight by these governmental agencies and IRBs at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with supplies of our devices produced under certain requirements of the QSR, and other regulations. Furthermore, we rely on clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities, we have limited influence over their actual performance. We depend on transplant centers to conduct our clinical trials in compliance with good clinical practice, or GCP, requirements. To the extent that transplant centers fail to enroll participants for our clinical trials, fail to conduct the study to GCP standards or are delayed for a significant time in the execution of trials, including achieving full enrollment, we may be affected by increased costs, program delays or both. In addition, clinical trials that are conducted in countries outside the United States may subject us to further delays and expenses as a result of increased shipment costs, additional regulatory requirements and the engagement of non-U.S. institutions, as well as expose us to risks associated with clinical investigators who are unknown to the FDA, and different standards of diagnosis, screening and medical care.

Failure can occur at any stage of clinical testing. For example, our clinical studies may produce negative or inconclusive results, and, 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 the PMA for the OCS Lung. While we believe we responded in full to the FDA's requests with respect to the PMA application for the OCS Heart, including by submitting short and longer-term data from the OCS Heart EXPAND Trial and OCS Heart EXPAND Continued Access Protocol, the FDA could ask us to conduct additional clinical trials or submit additional evidence to support the OCS Heart PMA application, or other PMA applications in the future, if the FDA does not believe the data we have already submitted is sufficient. Our failure to adequately demonstrate the safety and effectiveness of the OCS or 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 approval by regulatory authorities in those countries. 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.

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. Surgeons, transplant centers and private and public payors may require additional clinical data prior to adopting or maintaining coverage of the OCS.

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. 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. 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. Currently, universal national healthcare systems 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 beyond one to three years 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.

Our long-term growth depends on our ability to improve the OCS platform, including by expanding into new indications and developing the next generation of our products, and expanding access to the OCS, including through the potential development of a turnkey perfusion service for transplant centers.

Our business plan contemplates that we will continue to improve the OCS platform, including by expanding into additional organs and developing the next generation of our products. 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 sales and marketing effort.

We also are developing a turnkey perfusion service that would facilitate organ retrieval and transportation to transplant centers, which we believe would expand access and use of the OCS. We may not be successful in the development of such a service, which will depend on recruiting and retaining qualified surgeons and coordinating with regional organ procurement organizations. 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 depend on a limited number of customers for a significant portion of our net 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 net revenue from a limited number of customers. For the fiscal year ended December 31, 2020, Massachusetts General Hospital accounted for 14% of our net revenue and Duke University accounted for 10% of our net revenue. We expect that sales to relatively few customers will continue to account for a significant percentage of our net revenue in future periods. However, these customers or any of our other customers may not continue to utilize our products 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 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 one of our key customers or have a key customer significantly reduce its 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.

We depend on single-source suppliers and, in a few cases, sole-source suppliers for many of the components used in the OCS.

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 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. 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 may also face regulatory delays or be required to seek additional regulatory clearances or approvals if we experience any delay or deficiency in the quality of products obtained from suppliers or if we have to replace our suppliers. 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.

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. Our inability to obtain sufficient quantities of components for the OCS also could adversely affect clinical development 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.

We will need to increase our manufacturing 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 increase our manufacturing capabilities. 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. Commercial scale production of the OCS on a continuing basis also will require us 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. 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 conducted at a single facility in Andover, Massachusetts. 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 relocation expense, 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.

Risks Related to Our Business and Industry

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. Their products or technologies could make the OCS obsolete or noncompetitive. Other companies may also obtain FDA or other regulatory approval or clearance for their products sooner than we may obtain approval or clearance for the OCS. 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.

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 a diverse and inclusive environment, along with our perceived trustworthiness and ethics. Allegations of misconduct by employees, particularly leaders, erode trust and confidence and cause reputational damage. Negative public opinion can result from actual or alleged conduct by the Company or those currently or formerly associated with the Company. Issues can arise in any number of circumstances, including employment-related offenses such as workplace harassment and discrimination, regulatory noncompliance, and failure to properly use and protect data and systems, 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, 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 management, product development tasks, clinical data, donor and patient data, customer service and technical support functions. Our information technology systems are vulnerable to damage or interruption from earthquakes, fires, floods and other natural disasters; terrorist attacks; cyber-based attacks; attacks by computer viruses or hackers; power losses, computer system or data network failures; security breaches and data corruption. Federal, state and international laws and regulations, such as the General Data Protection Regulation (EU) 2016/679 (GDPR), can expose us to enforcement actions and investigations by regulatory authorities, and potentially result in regulatory penalties and significant legal liability, if our information technology security efforts fail. 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.

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, cash flows and prospects.

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 fiscal years ended December 31, 2020 and December 28, 2019, 25% and 31%, respectively, of our net revenue was generated from customers located outside of the United States. Even if we are successful in commercializing the OCS in the United States, we anticipate that international sales will represent a meaningful 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, including any potential impact resulting from the U.K.'s exit from the European Union;
- 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 U.K. Bribery Act of 2010, or 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, the impacts of the COVID-19 pandemic 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 and to our efforts to develop and commercialize the OCS. 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. In addition, it will be an event of default under our Credit Agreement if Dr. Hassanein ceases to be our President and Chief Executive Officer and we do not hire a replacement that is reasonably acceptable to OrbiMed within 120 days. We maintain $1.0 million of "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 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 capabilities, information technology infrastructure and financial and accounting systems and controls. Our growth could 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, such as kidney. Our intended development of a turnkey perfusion service for transplant centers may also require additional capital expenditures or divert attention of our management away from development and commercialization of our OCS products. 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.

The outbreak of the novel strain of coronavirus (COVID-19) impacts our business, financial condition, operating results, cash flows and prospects.

The COVID-19 pandemic, including efforts to contain the spread of the coronavirus, has impacted, and may continue to impact, our business, financial condition, operating results and cash flows. Impacts to our business as a result of COVID-19 include the temporary disruption of transplant procedures at many of the organ transplant centers who purchase OCS products; disruptions to our manufacturing operations and supply chain caused by facility closures, reductions in operating hours, staggered shifts and other social distancing efforts; labor shortages; decreased productivity and unavailability of materials or components; restrictions on or delays of our clinical trials and studies; delays of reviews and approvals by the FDA and other health authorities; limitations on our employees' and customers' ability to travel; and delays in product installations, trainings or shipments to and from affected countries and within the United States. Since April 2020, we have taken several steps to protect the health and safety of our employees, to establish a process to support the continuous supply of our OCS products at transplant centers globally and to maintain financial flexibility. These actions include reducing near-term expenses, such as reducing non-essential discretionary expenses. We also deferred a portion of executive and employee compensation from April 2020 through August 31, 2020.

Additionally, to protect the health of our employees and their families, and our communities, and in accordance with direction from state and local government authorities, we have restricted access to our facilities to personnel and third parties who must perform critical activities that must be completed on-site, limited the number of such personnel that can be present at our facilities at any one time, and requested that most of our personnel work remotely. Also, our sales and clinical adoption team has been restricted from visiting many transplant centers in person. In addition, we temporarily reduced the manufacturing and distribution of our OCS products at our facility in Andover, Massachusetts. Starting in May 2020, we resumed manufacturing and distribution operations to pre-COVID levels. In the event that governmental authorities were to further modify current restrictions, our employees conducting manufacturing activities may not be able to access our manufacturing facilities, and our core activities may be significantly limited or curtailed, possibly for an extended period of time. We also may be faced with limitations in employee resources that would otherwise be focused on our commercial, manufacturing or clinical activities, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people.

In response to the pandemic, healthcare providers have, and may need to further, reallocate resources, such as physicians, staff, hospital beds and intensive care unit facilities, as they prioritize limited resources and personnel capacity to focus on the treatment of patients with COVID-19 and implement limitations on access to hospitals and other medical institutions due to concerns about the potential spread of COVID-19 in such settings. These actions significantly delay the provision of other medical care such as organ transplantation and reduce the number of transplant procedures that are performed, which negatively impacts our revenue and clinical trial activities. These measures and challenges may continue for the duration of the COVID-19 pandemic, which is highly uncertain, and may significantly reduce our revenue and cash flows while the pandemic continues. We have observed recovery in the frequency of transplant procedures, but not yet at the same activity level as prior to the disruption of business and economic activities resulting from COVID-19. In addition, while the number of transplant procedures performed has declined during the COVID-19 pandemic, organ transplantations are non-elective, life-saving procedures and we believe that the need for these procedures will persist. However, as interventions to contain the spread of the virus are lifted or reduced, new COVID-19 outbreaks may result in new or heightened restrictions, which could again cause disruptions to our customers' operations and adversely impact organ transplant procedures. OCS product sales have been negatively impacted by the COVID-19 pandemic since the first quarter of 2020 and we anticipate OCS product sales will continue to be impacted in 2021; however, the length and extent of the pandemic, its consequences, and containment efforts will determine the future impact on our operations and financial condition.

An adverse impact on the volume and availability of transplant procedures impacts our clinical trials and enrollment in our post-approval studies, and the COVID-19 pandemic has impacted operations at the FDA and other health authorities, resulting in delays of reviews and approvals, including with respect to our OCS Heart PMA application, and may affect other potential PMA applications.

The COVID-19 pandemic has also impacted, and may continue to impact, our third party suppliers, including through the effects of facility closures, reductions in operating hours, staggered shifts and other social distancing efforts, labor shortages, decreased productivity and unavailability of materials or components. While we maintain an inventory of finished products and raw materials used in our OCS products, a prolonged pandemic could lead to shortages in the raw materials necessary to manufacture our products. The extent to which COVID-19 impacts our operations and those of our third-party partners will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the pandemic, additional or modified government actions, new information which may emerge concerning the severity and incidence of COVID-19, actions to contain the virus or treat its impact, periodic spikes in infection rates, new strains of the virus that cause outbreaks of COVID-19, and the broad availability of effective vaccines. In particular, the speed of the continued spread of COVID-19 globally, and the magnitude of interventions to contain the spread of the virus, such as government-imposed quarantines, including shelter-in-place mandates, sweeping restrictions on travel, mandatory shutdowns for non-essential businesses, requirements regarding social distancing, and other public safety measures, will determine the impact of the pandemic on our business, financial condition, operating results, cash flows and prospects. If we experience a prolonged disruption in our manufacturing, supply chains, clinical trial or commercial operations, or if demand for our products is significantly reduced as a result of the COVID-19 pandemic, we would expect to experience a material adverse impact on our business, financial condition, results of operations and prospects.

Additionally, the extent and duration of the impact of the COVID-19 pandemic on our stock price and on those of other companies in our industry is highly uncertain and may make us look less attractive to investors and, as a result, there may be a less active trading market for our common stock, our stock price may be more volatile, and our ability to raise capital could be impaired, which could in the future negatively affect our liquidity and financial position.

Risks Related to Our Intellectual Property

If we fail to maintain our license to patents covering the OCS, we will lose the right to manufacture, market and sell the OCS and our business would be harmed.

Our business depends, in part, on our license from the VA, that covers the OCS. We have a license under certain patent rights relevant to our right to manufacture, market and sell the OCS, including the OCS Perfusion Sets and OCS Solutions specific to the lung, heart, liver and kidney for use in the OCS, pursuant to a license agreement with the VA. For more information, see “Item 1. Business—Intellectual Property—Department of Veterans Affairs License” in this Annual Report on Form 10-K. Our license agreement requires us, among other things, to pay royalties, determined as a percentage of our net sales of products covered by the licensed patents. If we fail to make these payments or otherwise fail to comply with the terms of our license agreement, the VA would have the right to terminate our license, in which case we would lose our right to manufacture, market and sell products covered by the licensed patents, which would materially and adversely affect our business, financial condition, operating results, cash flows and prospects.

The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the agreement. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our license agreement with the VA or any other licensing arrangements on acceptable terms, or are insufficient to provide us the necessary rights to use the intellectual property, we may be unable to successfully develop and commercialize the OCS or other affected products. If we or our licensors fail to adequately protect our licensed intellectual property, our ability to commercialize our products could suffer. Any disputes with our licensor or any termination of the licenses on which we depend could have a material adverse effect on our business, financial condition, results of operations and prospects.

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, there is no assurance that a court would 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, there is no assurance that a court of competent jurisdiction would 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 or have an exclusive license under several patents and patent applications in the United States and corresponding patents and patent applications in a number of foreign jurisdictions. All but one of the issued United States patents under the VA license expired in 2017 and the issued international patents expired in 2018. With respect to the unexpired, issued U.S. patent licensed from the VA, we have been granted an interim patent term extension until September 23, 2021 and we have requested an extension until May 2022. However, the length of the patent term extension is currently being determined by the United States Patent and Trademark Office (USPTO) based on input from the FDA. On February 8, 2021, the FDA provided to the USPTO and determined the regulatory review period for the OCS Lung System. Under the FDA's analysis, the patent term extension would be until November 6, 2021. 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 2037, assuming all required fees are paid.

However, we cannot provide any assurances that any of our patents have, or that any of our pending patent applications that mature into issued patents will 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 limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act. For example, we currently have a pending patent term extension request based on the recently approved OCS Lung that, if granted, would increase the term of one of our patents by up to five years, through May 2022. 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 during 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 exercise due diligence during the testing phase or regulatory review process, to fail to apply within applicable deadlines or prior to expiration of relevant patents or otherwise to fail to satisfy applicable requirements. Moreover, the time period of the extension or the scope of patent protection afforded could be less than we request. Only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval and only those claims covering 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 or restoration or the term of any such extension is less than we request, the period during which we can enforce our patent rights for the applicable product will be shortened and our competitors may obtain approval of competing products following our patent expiration. As a result, our ability to generate revenues could be materially adversely affected. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and 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, there can be no assurance that we would 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

If we fail to adequately respond to the FDA follow-up inquiries or to obtain or maintain necessary FDA approval for each use of the OCS, or if such approval is delayed, 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 PMA approval for the OCS Lung for both the preservation of donor lungs currently utilized for transplantation and donor lungs that are currently unutilized for transplantation, but the OCS has not yet attained PMA approval for preservation of heart and liver donor organs.

In the United States, before we can market the OCS products for each organ, we must first receive PMA approval from the FDA. This process can be expensive and lengthy and entail significant costs. The process of obtaining PMA approval requires significant clinical trial data. It generally takes one year, or even longer, from the time the PMA application is submitted to the FDA until an FDA action date. Despite the time, effort and cost involved in this process, the FDA might not approve the OCS products for use in preservation or transplantation or of donor hearts, livers, or other organs.

Furthermore, unforeseen requirements or delays in obtaining clearances or approvals from the FDA for any future products could result in unexpected and significant costs for us and consume management's time and other resources. The COVID-19 pandemic may result in delayed review and approval timelines. The pandemic has and may continue to cause disruptions in global regulatory agencies' daily operations. Any delay in regulatory review resulting from such disruptions could materially affect our development and commercialization plans, which could adversely affect our business and results of operations. The duration and severity of the COVID-19 pandemic is unpredictable and difficult to assess.

Moreover, the FDA could ask us to supplement our submissions, collect additional non-clinical data, conduct additional clinical trials or engage in other costly and time-consuming actions, or it could simply deny our PMA application or, if we were to seek any 510(k) clearance for a product, issue a not substantially equivalent determination for a 510(k) device. For example, in 2015, we voluntarily withdrew our original PMA application for the OCS Heart in an effort to expand our data to include OCS Heart EXPAND Trial results as well as to supplement our OCS Heart PROCEED II Trial results with long-term follow-up data that was not collected as part of the original trial protocol. In addition, even if we obtain PMA approval, the approval could be withdrawn or other restrictions imposed if post- market data demonstrate safety issues or inadequate performance. For 510(k) cleared devices, the FDA can use its enforcement authorities to require removal of a device from the market in case of safety issues.

We are currently investigating the safety and effectiveness of the OCS in multiple IDE investigations. Specifically, we completed enrollment in the OCS Liver PROTECT Trial under an IDE and received IDE approval for and are enrolling patients in the OCS Liver PROTECT CAP Trial. We also received IDE approval for a study of the use of the OCS Liver for certain donor livers that are donated after circulatory death that have extended warm ischemia time or older donor age. In addition, we completed the OCS Heart EXPAND Trial under an IDE and received IDE approval for the OCS Heart EXPAND CAP Trial. We also completed enrollment in the OCS Heart DCD trial for donor hearts that are donated after circulatory death under an IDE and received IDE approval for the OCS Heart DCD CAP Trial.

As is typical to the PMA review process, during the course of its initial PMA review and in most cases within 90 calendar days of the company's PMA filing date, the FDA communicates issues that it has identified and views as deficiencies through a substantive interaction, which in most cases is a letter. That letter is technically referred to as a "major deficiency letter," and it provides the applicant with an opportunity to address the FDA's questions. After completing its review of a PMA application, the FDA will take one of the following actions: an approval, an approvable letter, a not approvable letter, or, in rare instances, a denial. We have received a "major deficiency letter" for each PMA application that we have submitted to the FDA, and we believe our responses have been thorough and comprehensive, including most recently with respect to the OCS Liver. The FDA will convene an advisory committee of experts from outside the FDA to review and evaluate our OCS Heart PMA currently under review and to provide recommendations to the FDA as to the safety, effectiveness, risk and benefit of the device. It is not uncommon for the FDA to seek advice from an outside expert panel when considering an application for a novel technology. The FDA ultimately decides whether to approve or disapprove the PMA application and may or may not follow the advisory committee's recommendation, even if favorable. Notwithstanding a favorable recommendation, the FDA could determine that the data from our clinical trials does not support PMA approval or the claims we wish to make, or the FDA could require us to gather significant additional clinical data or conduct additional non-clinical testing. The FDA had scheduled the advisory committee meeting regarding our OCS Heart PMA application for the second quarter of 2020. However, due to the COVID-19 pandemic, the FDA postponed the advisory committee meeting to October 2020, and in September 2020, the FDA further postponed the advisory committee meeting to allow the FDA to review additional, already collected, short and longer-term data from the OCS Heart EXPAND Trial and OCS Heart EXPAND CAP Trial. The FDA advisory committee panel is expected to be held on April 6, 2021.

The approval process involving the OCS for each organ is subject to many of the same risks and uncertainties. If we are not able to obtain the necessary regulatory approvals for the OCS, or 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. Even if the FDA grants PMA approval for the OCS Heart and OCS Liver for preservation of donor hearts and livers for transplantation, respectively, the claims approved by the FDA may be significantly narrower than those we are seeking.

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.

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. We have CE Marks for each of the OCS Heart, the OCS Lung, and the OCS Liver, which were renewed in September 2017. These CE Marks are valid for five years, so they will expire in September 2022. In order to be able to continue to use the CE Mark in the same manner after May 2021, we will have to meet the conditions set out in the transitional provisions in the Medical Devices Regulation (Regulation 2017/745) (MDR), and the in vitro Diagnostic Medical Device Regulations (2017/746) (IVDR). In Great Britain (England, Wales and Scotland), the devices will be required to conform to the UK MDR 2002 in order to be registered with the Medicines and Healthcare Products Regulatory Agency (MHRA). Unlike Great Britain, the Medical Device Regulations (2017/745) and the in vitro Diagnostic Medical Device Regulations (2017/746) will apply in Northern Ireland from 26 May 2021, and 26 May 2022 respectively, in line with the EU's implementation timeline. The MHRA will remain the competent Authority for medical devices in Northern Ireland. Before expiry of these certificates, we will need to apply for their re-certification under the new Medical Devices Regulation. We might not be able to continue to use the CE Mark for any current use of the OCS. If:

- we are not able to obtain re-certification of our products for their current use;
- we are not able to do so in time before the certificates expire;
- our technical files for our products do not meet the new (and more stringent) requirements under the Medical Devices Regulation; or
- any variation in the uses for which the CE Mark has been affixed to the OCS requires us to perform further research or to modify the technical documentation required to affix the CE mark, our revenues 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 and Great Britain.

Additionally, we have appointed a U.K. responsible person and will register with the Medicines and Healthcare Products Regulatory Agency in the U.K. Failure to do so may mean that we will be unable to lawfully sell our products in the U.K.

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, our prospects for generating revenue and achieving profitability will suffer materially.

Our prospects for generating revenue and achieving 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.

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 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. During OCS clinical trials, even before the OCS had been approved by the FDA, the Medicare program reimbursed transplant centers for their use of the OCS for lung, heart and liver transplantation. We believe, though cannot be assured, that the costs incurred by transplant centers for the organ-specific OCS Console, OCS Perfusion Sets and OCS Solutions will be classified as organ acquisition costs for which Medicare will provide 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 sufficient for this purpose in a coverage determination by CMS or a Medicare contractor. 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 are likely to require that we 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. Adoption of our products in the European Union may be hindered if they impede 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. In these countries, reimbursement and pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for 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 never become profitable.

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 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 the indications that are necessary or desirable for successful commercialization or could require clinical trials to support any modification to the device or our 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.

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, 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 premarket approval 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.

We are currently 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 to provide periodic summary and trend reports. 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.

For our currently marketed OCS Lung, as part of the conditions of approval, we must complete three PMA post-approval studies: the OCS Lung INSPIRE Continuation PAS, which is a two-arm observational study intended to evaluate long-term outcomes of the OCS Lung INSPIRE Trial patients, the OCS Lung EXPAND Continuation PAS, which is a single arm study intended to evaluate long-term outcomes of the OCS Lung EXPAND Trial patients, and our OCS Lung Thoracic Organ Perfusion PAS Registry, or TOP Registry, 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. The OCS Lung INSPIRE Continuation PAS, the OCS Lung EXPAND Continuation PAS and the TOP Registry entail submission of regular reports to the FDA. Failure to comply with the conditions of approval can result in material adverse enforcement action, including withdrawal of the approval.

In addition, certain changes and other events with respect to regulatory approvals may cause an event of default under our Credit Agreement, including the initiation of a regulatory enforcement action or issuance of a warning letter with respect to the Company or any of its products or manufacturing facilities that causes the discontinuance of marketing or withdrawal of any products or causes delay in manufacturing. See “Item 7. Management’s Discussion and Analysis —Long-Term Debt,” in this Annual Report on Form 10-K.

If we fail to comply with the FDA’s QSR, or FDA or EU requirements that pertain to clinical trials or investigations, the FDA or the competent EU 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 QSR. The QSR 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 QSR through periodic inspections and unannounced “for cause” inspections.

We are subject to periodic FDA inspections to determine compliance with QSR 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 industrial standards bodies, such as the International Organization for Standardization. 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 QSR (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.

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 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 actions as 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 report the recalls when they were conducted, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device approval, seizure of our products or delay in clearance or approval of future products.

We have voluntarily recalled certain OCS products from customer 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. For example, most recently, in July 2018, we implemented a correction to the OCS Heart and Liver Consoles to address a loss of connection between the OCS Console and Perfusion Sets that was caused by incomplete cleaning, and in March 2018, after identifying out-of-specification plastic components used in the manufacturing of the OCS Lung Console, we recalled the affected units from customer sites and replaced them with known, good product, and we made required notifications to the FDA and foreign regulatory agencies.

Internationally, the approaches to product defects will vary. A product may be recalled in one country but not in others. However, within the European Union, competent authorities are known to communicate with each other, therefore a recall in one EU member state may lead to recalls in the rest of the European Union.

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. Although we have been able to affix the CE Mark to the OCS Lung, OCS Heart and OCS

Liver in the European Union, we may not be able to maintain such CE Marking, including as a result of the need to re-certify our products, under the new Medical Devices Regulation and the Medical Devices Regulations 2002 (UK MDR 2002) in Great Britain. Our notified body in the Netherlands, BSI, could determine either itself or at the request of a competent authority that our OCS products do not meet the regulatory requirements for CE marking, which would result in withdrawal of the certificates that allow the CE marking required to market the OCS products in the European Union. 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. Our most recent inspection by our EU Notified Body was in January 2021, which resulted in one minor observation. While we are implementing corrective and preventive action to address the observation, this previous observation may not be closed out. Additionally, 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. For example, most recipients of heart transplants experience one or more serious adverse events during their transplant and post-operative care, including in some cases, death. In our OCS Lung INSPIRE Trial of donor lungs, 24% of patients experienced serious lung graft related adverse events and in our OCS Heart PROCEED II Trial of donor hearts, 13% of patients experienced serious heart graft related adverse events. 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.

Additionally, if the number of adverse events experienced by patients in clinical trials of the OCS is greater than expected, our clinical trials could be delayed or terminated by us or regulatory authorities. In our OCS Lung INSPIRE Trial of currently utilized donor lungs, 5.3% of patients died within 30 days of transplant, and in our OCS Heart PROCEED II Trial of currently utilized donor hearts, 6% of patients died within 30 days of transplant. Additionally, in a post-hoc observational analysis of all-cause mortality at 60 months post-transplantation for OCS Heart PROCEED II Trial patients, overall deaths were higher in the OCS group compared to the standard of care group. 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, the study could be delayed or halted, 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 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 in Belgium, Germany, Australia and the U.K. with coverage ranging from €2.5 million to €10.0 million per occurrence as required by the applicable country. 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 warned that the threat of cyberattacks on medical devices is no longer theoretical. 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.

Certain OCS products have been approved by regulatory authorities 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 sales and clinical adoption team to not promote the OCS for uses outside of the approved indications for use, 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 approved by any foreign regulatory body 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 an untitled letter, which is used for violations that do not necessitate a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action under other regulatory authority, such as false claims 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 are often 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.

The European Parliament passed the MDR, which repeals and replaces the European Union Medical Devices Directive and the Active Implantable Medical Devices Directive, which will become effective in May 2021. The EU MDR and EU IVDR will fully apply in the EU Member States from May 26, 2021 and May 26, 2022. Unlike directives, which must be implemented into the national laws of the European Economic Area, or EEA, member states, regulations would be directly applicable, (i.e., without the need for adoption of EEA member state laws implementing them) in all EEA member states and are intended to eliminate current differences in the regulation of medical devices among EEA member states. The provisions contained within the EU MDR and EU IVDR will not be transposed into law in Great Britain and will not be implemented in Great Britain. Medical Devices in Great Britain are governed under the UK Medical Device Regulations 2002. Under the terms of the Northern Ireland Protocol, the rules for placing medical devices on the Northern Ireland market differ from those applicable to Great Britain (England, Wales and Scotland). The EU MDR and EU IVDR will apply in Northern Ireland from May 26, 2021 and May 26, 2022, respectively. The MDR, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices and ensure a high level of safety and health while supporting innovation.

The regulations, among other things:

- strengthen the rules on placing devices on the market and reinforce surveillance once they are available;
- establish explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- improve the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- set up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the European Union; and
- strengthen rules for the assessment of certain high-risk devices, such as implants, which may have to undergo an additional check by experts before they are placed on the market.

Our products may be affected by these rules, which may mean longer or more burdensome assessment of our products. These modifications may have an effect on the way we conduct our business in the EEA.

We recognize that our products will have to be re-certified under the MDR and we are in the process of updating internal procedures to ensure compliance with the new MDR and have added international regulatory personnel to assist with the transition.

In addition, there are significant concerns associated with whether EU Notified Bodies will be able to re-certify all devices in their care in time. If we do not manage to re-certify our products under this regulation or cannot rely on the transitional provisions, we may have to take our products off the EU market until this is the case.

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 Sunshine Act under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the Affordable Care 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 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, 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 U.K. 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 providers and entities 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 exposed to trade and economic sanctions and other restrictions imposed by the United States, the European Union and other governments and organizations. The U.S. Departments of Justice, Commerce, State and U.S. Treasury and other federal agencies and authorities have a broad range of civil and criminal penalties they may seek to impose against corporations and individuals for violations of economic 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, as well as bribery across both private and public sectors. The substantive offences of offering or receiving a bribe will be committed by an individual where either the bribery takes place in the U.K, or the person paying or receiving the bribe has a close connection with the U.K. An organization which is either incorporated in or carries on part of its business in the U.K will be liable under the Bribery Act if a person associated with the organization (being persons performing services for it) pays a bribe anywhere in the world intending to obtain or retain business for the organization. This is a strict liability offense with the only defenses available being that the organization implemented "adequate procedures" to prevent bribery or it was reasonable for it to not have such procedures in place. Under these laws and regulations, as well as other anti-corruption laws, anti-money laundering laws, export control laws, customs laws, sanctions laws and other laws governing our operations, various government agencies may require export licenses, 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 compliance costs, and may subject us to fines, penalties and other sanctions. A violation of these laws or regulations would negatively affect our business, financial condition and results of operations. Due to sales of 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 relevant law.

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. We cannot assure you, however, that our policies and procedures are or will be sufficient or that directors, officers, employees, representatives, consultants and agents have not engaged and will not engage in conduct for which we may be held responsible, nor can we assure you that our business partners have not engaged and will not engage in conduct that could materially affect their ability to perform their contractual obligations to us or even result in our being held liable for such conduct. 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 we may be subject to other 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. 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 European Union also has laws and regulations dealing with the collection, use and processing of personal data concerning individuals who are located in the European Union, which are often more restrictive than those in the United States. We are subject to the requirements of the GDPR because we are processing personal data in the European Union or offering goods to, or monitoring the behavior of, individuals who are located in the European Union. The GDPR implements more stringent administrative requirements for controllers and processors of personal data, including, for example, shortened timelines for data breach notifications, limitations on retention of information, increased requirements pertaining to health data and pseudonymized (i.e., key-coded) data, additional obligations when we contract with service providers, and more robust rights for individuals over their personal data. The GDPR provides that EU member states may make their own further laws and regulations, including laws and regulations limiting the processing of genetic, biometric or 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, including substantial fines and 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 led to increased scrutiny of data transfers from the EEA to the United States generally and may increase our costs of compliance with data privacy legislation. We rely on a mixture of mechanisms to transfer personal data from our EU 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.

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 Data Protection Act 2018; (iii) the 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 in the field of 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.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, the Affordable Care Act, which was enacted in 2010:

- established a new Patient-Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical effectiveness research in an effort to coordinate and develop such research;

- implemented payment system reforms, including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models; and
- expanded the eligibility criteria for Medicaid programs.

We do not yet know the full impact that the Affordable Care Act, and more recent measures impacting the healthcare system, will have on our business. The taxes imposed by the Affordable Care Act may result in decreased profits to us, lower reimbursement by payors to hospitals and transplant centers, and/or reduced medical procedure volumes, all of which may have a material adverse effect on our business, financial condition and results of operations. Under the former Trump Administration, there were ongoing efforts to repeal, modify, or invalidate provisions of the Affordable Care Act. For example, federal legislation repealed penalties for not complying with the individual mandate to carry health insurance. Additionally, the Affordable Care Act has been subject to judicial challenge. The case Texas v. Azar, which challenges the constitutionality of the Affordable Care Act was argued before the Supreme Court in November 2020. Pending resolution of the litigation, all of the Affordable Care Act but the individual mandate to buy health insurance remains in effect. The repeal of all or a portion of the Affordable Care Act could result in lower numbers of insured individuals, reduced coverage for insured individuals and adversely affect our business.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. The Budget Control Act of 2011, as amended, for example, reduced Medicare payments to providers by 2% per fiscal year, and will remain in effect through 2030 (except for the period from May 1, 2020 to March 31, 2021), when no reduction occurred) unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012 also reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates and a new system of incentive payments that are based on various performance measures and physicians' participation in alternative payment models such as accountable care organizations, which took effect in 2019. It is unclear what effect new quality and payment programs, such as MACRA, may have on our business, financial condition, results of operations or cash flows.

We expect additional state and federal healthcare policies and reform measures to be adopted in the future, including following in the wake of the transition from the Trump administration to the Biden administration, any of which could limit 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, future reimbursement to hospitals and transplant centers could affect demand for the OCS, which in turn could have a material adverse effect on our business, financial condition and results of operations.

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.

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.

Since the shares were sold in our IPO in May 2019 at a price of $16.00 per share and through March 9, 2021, the price per share of our common stock has ranged from as low as $10.10 to as high as $44.12. 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 clinical trials relating to 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.

An active trading market may not be sustained.

You may not be able to sell your shares quickly or at a recently reported market price if trading in our common stock does not remain active. The lack of an active market may also reduce the fair market value of your shares. An inactive market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration.

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 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, 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.

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, which may adversely affect investor confidence in our company.

Although we are required to annually assess our internal controls over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act and disclose changes that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting on a quarterly basis, as an emerging growth company, our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 until the date we are no longer an emerging growth company. At such time, our independent registered public accounting firm may issue a report that is adverse in the event it is not satisfied with the level at which our controls are documented, designed or operated.

To comply with the requirements of being a public company, we have undertaken certain actions, such as implementing new internal controls and procedures and hiring additional accounting staff. We may also need to undertake certain other actions in the future, including the hiring of internal audit staff or additional accounting staff. Testing and maintaining internal controls can divert our management's attention from other matters that are important to the operation of our business. In addition, when evaluating our internal controls over financial reporting, we may identify material weaknesses that we may not be able to remediate in time to meet the applicable deadline imposed upon us for compliance with the requirements of Section 404. If we identify any material weaknesses in our internal controls over financial reporting or we are unable to comply with the requirements of Section 404 in a timely manner or assert that our internal controls over financial reporting is effective, or if our independent registered public accounting firm expresses an adverse opinion as to the effectiveness of our internal controls over financial reporting once we are no longer an emerging growth company, investors may lose confidence in the accuracy and completeness of our financial reports. As a result, the market price of our common stock could be materially adversely affected.

We are an "emerging growth company" and "smaller reporting company," and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and may remain an emerging growth company until the last day of our fiscal year following the fifth anniversary of our IPO, subject to specified conditions. We would cease to be an emerging growth company prior to such date if we have more than $1.07 billion in annual revenue, we have more than $700 million in market value of our stock held by non-affiliates or we issue more than $1 billion of non-convertible debt securities over a three-year period. For so long as we remain an emerging growth company, we are permitted, and intend, to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include reduced disclosure obligations regarding executive compensation and no requirements to hold non-binding advisory votes on executive compensation and golden parachute payments, to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and to comply with certain requirements of Auditing Standard 3101 relating to providing a supplement to the auditor's report regarding critical audit matters. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption, and the reported results of operations contained in our financial statements may not be directly comparable to those of other public companies. Accordingly, we will incur additional costs in connection with complying with the accounting standards applicable to public companies at such time or times as they become applicable to us.

We are also a "smaller reporting company," as defined under Regulation S-K. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than $250 million or (ii) our annual revenue is less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million as of the last business day of our second fiscal quarter. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

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 2. Properties.

Our corporate headquarters and manufacturing and clinical training facilities are located in Andover, Massachusetts, where we lease 105,479 square feet of space, including a 10,500 square foot laboratory and training facility and a 2,400 square foot class 10,000 re-configurable 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.

We believe that our current 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.

We are not currently subject to any material legal proceedings. From time to time, we may be involved in 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.

Holders of Our Common Stock

As of February 28, 2021, there were approximately 28 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 2021 Annual Meeting of Stockholders and is incorporated herein by reference.

Recent Sales of Unregistered Equity Securities

None.

Use of Proceeds from Initial Public Offering

Our IPO was effected through a Registration Statement on Form S-1 (File No. 333-230736), which was declared effective by the SEC on May 1, 2019 and a registration statement on Form S-1MEF (File No. 333-231166), which was automatically effective upon filing with the SEC on May 1, 2019. The net offering proceeds to us, after deducting underwriting discounts and commissions and other offering expenses, were $91.4 million. None of the net proceeds were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning 10.0% or more of any class of our equity securities or to any other affiliates, other than payments in the ordinary course of business to officers for salaries and to non-employee directors as compensation for board or board committee service. As of December 31, 2020, we estimate that we have used approximately $47.4 million of the net proceeds from our IPO for commercialization of OCS Lung, research and development, and general corporate purposes. We are holding a significant portion of the remaining net proceeds in money market funds, U.S. Treasury securities and U.S. government agency bonds. There has been no material change in our planned use of the net proceeds from the IPO as described in the final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act, with the SEC, on May 2, 2019.

Issuer Purchases of Equity Securities

We did not purchase any of our registered equity securities during the period from September 30, 2020 to December 31, 2020.

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

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

We designed the OCS to be a platform that allows us to leverage core technologies across products for multiple organs. To date, we have developed three OCS products, one for each of lung, heart and liver transplantations, making the OCS the only multi-organ technology platform. Our OCS products have been used for over 1,800 human organ transplants. We have commercialized the OCS Lung and OCS Heart outside of the United States and received our first PMA from the FDA in March 2018 for the use in the United States of the OCS Lung for donor lungs currently utilized for transplantation and since May 2019, for donor lungs currently unutilized for transplantation.

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

Since our inception, we have incurred significant operating losses. Our ability to generate net revenue sufficient to achieve profitability will depend on the successful further development and commercialization of our products. We generated net revenue of $25.6 million and $23.6 million for the fiscal years ended December 31, 2020 and December 28, 2019, respectively. We incurred net losses of $28.7 million and $33.5 million, respectively, for those same years. As of December 31, 2020, we had an accumulated deficit of $398.2 million. We expect to continue to incur net losses for the foreseeable future as we focus on growing commercial sales of our products in both the United States and select non-U.S. markets, including growing our sales and clinical adoption team, which will pursue increasing commercial sales and clinical adoption of our OCS products; scaling our manufacturing operations; continuing research, development and clinical trial efforts; and seeking regulatory clearance for new products and product enhancements, including new indications, in both the United States and select non-U.S. markets. Further, following the closing of our IPO we have incurred and expect to continue to incur additional costs associated with operating as a public company. As a result, we will need substantial additional funding for expenses related to our operating activities, including selling, general and administrative expenses and research, development and clinical trials expenses.

On May 6, 2019, we completed our IPO, pursuant to which we issued and sold 6,543,500 shares of common stock, inclusive of 853,500 shares we sold pursuant to the full exercise of the underwriters' option to purchase additional shares. The aggregate net proceeds received by us from the IPO were $91.4 million, after deducting underwriting discounts and commissions as well as other offering costs of $6.0 million.

On May 26, 2020, we completed an underwritten public offering of our common stock, which resulted in the sale of 5,750,000 shares of common stock, inclusive of 750,000 shares we sold pursuant to the full exercise of the underwriters' option to purchase additional shares. The aggregate net proceeds received by us from the offering were $75.1 million, after deducting underwriting discounts and commissions as well as other offering costs of $0.6 million.

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

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

COVID-19

The impact of the COVID-19 pandemic has been and will likely continue to be extensive in many aspects of society, which has resulted in and will likely continue to result in significant disruptions to the global economy, as well as businesses and capital markets around the world. Impacts to our business as a result of COVID-19 include the temporary disruption of transplant procedures at many of the organ transplant centers who purchase OCS products; disruptions to our manufacturing operations and supply chain caused by facility closures, reductions in operating hours, staggered shifts and other social distancing efforts; labor shortages; decreased productivity and unavailability of materials or components; restrictions on or delays of our clinical trials and studies; delays of reviews and approvals by the FDA and other health authorities; limitations on our employees' and customers' ability to travel, and delays in product installations, trainings or shipments to and from affected countries and within the United States. In response to the pandemic, healthcare providers have, and may need to further, reallocate resources, such as physicians, staff, hospital beds and intensive care unit facilities, and these actions significantly delay the provision of other medical care such as organ transplantation and reduce the number of transplant procedures that are performed, which has a negative impact on our revenue and clinical trial activities. Our sales and clinical adoption team has been and may continue to be restricted in visiting many transplant centers in person. Customer delays or reductions in capital expenditures and operating budgets also have a negative impact on our product sales. We plan to maintain these or similar restrictions until we believe employees can fully resume such activities in accordance with federal, state and local requirements. The COVID-19 pandemic also has impacted operations at the FDA and other health authorities, resulting in delays of reviews and approvals, including with respect to our OCS Heart PMA application, and may affect other potential PMA applications. For example, although the FDA had scheduled an advisory committee of experts from outside the FDA to review and evaluate our OCS Heart PMA application in the second quarter of 2020, due to the COVID-19 pandemic the advisory committee meeting was postponed to October 2020. However, this meeting was further postponed to allow the FDA to review additional, already collected, short and longer-term data from the OCS Heart EXPAND Trial and OCS Heart EXPAND CAP trial. The FDA advisory committee meeting is expected to be held on April 6, 2021.

In April 2020, we announced several steps to respond to the COVID-19 pandemic. These steps are intended to protect the health and safety of our employees, to establish a process to support the continuous supply of our OCS products at transplant centers globally and to maintain financial flexibility. These actions include transitioning most employees to a remote work environment, except for those who are deemed essential to product supply and reducing near-term expenses, such as reducing non-essential discretionary expenses. We also deferred a portion of executive and employee compensation from April 2020 through August 31, 2020. While the COVID-19 pandemic did not significantly impact our business or results of operations during the first quarter of 2020, OCS product sales have been negatively impacted by the COVID-19 pandemic since the second quarter of 2020 and we anticipate a negative impact to OCS product sales in 2021. The extent of the future impact on our operations and financial condition will depend on the length and severity of the pandemic, its consequences, and containment and vaccination efforts. While the FDA approved emergency use authorization of vaccines in December 2020, it is expected to take several months for widespread vaccinations to occur and it is not yet known how vaccination efforts will impact the COVID-19 pandemic.

We have observed recovery in the frequency of transplant procedures, but not yet at the same activity level as prior to the disruption of business and economic activities resulting from COVID-19. In addition, while the number of transplant procedures performed has declined during the COVID-19 pandemic, organ transplantations are non-elective, life-saving procedures and we believe that the need for these procedures will persist. However, as interventions to contain the spread of the virus are lifted or reduced, new COVID-19 outbreaks may result in new or heightened restrictions, which could again cause disruptions to our customers' operations and adversely impact organ transplant procedures.

We continue to monitor developments regarding the COVID-19 pandemic and its impact on our business, financial condition, results of operations and prospects. However, we are unable to predict the extent of the impact with confidence due to the uncertainty of future developments, such as the duration of the pandemic, additional or modified government actions, new information which may emerge concerning the severity and incidence of COVID-19 and actions to contain the virus or treat its impact. In particular, the speed of the continued spread of COVID-19 globally, and the magnitude, duration and frequency of interventions to contain the spread of the virus, such as government-imposed quarantines, including shelter-in-place mandates, sweeping restrictions on travel, mandatory shutdowns for non-essential businesses, requirements regarding social distancing, and other public health safety measures, will determine the impact of the pandemic on our business.

Components of Our Results of Operations

Net Revenue

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

All of our revenue has been generated by sales to transplant centers in the United States, Europe and Asia-Pacific, or, in some cases, to distributors selling to transplant centers in select countries. Substantially all of our customer contracts have multiple-performance obligations that contain promises consisting of OCS Perfusion Sets and OCS Solutions. In some of those contracts, the promises also include an OCS Console, whether sold or loaned to the customer.

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

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

Under some of our customer clinical trial agreements, we make payments to our customers for reimbursements of clinical trial materials and for specified clinical documentation related to their use of our OCS products. Because some of these payments do not provide us with a separately identifiable benefit, we record such payments as a reduction of revenue from the customer, resulting in our net revenue presentation. We recorded reimbursable clinical trial costs as a reduction of revenue of $2.7 million and $2.2 million for the fiscal years ended December 31, 2020 and December 28, 2019, respectively.

In March 2018, we received our first FDA PMA for the OCS Lung, and we began commercial sales of this product in the United States during the fourth quarter of 2018. In May 2019, we received our second FDA PMA for the OCS Lung for additional clinical indications. Therefore, our net revenue in the United States for the OCS Lung is now derived primarily from commercial sales and consists of sales of OCS disposable sets and, to a much lesser extent, sales of OCS Consoles. In 2019, we also recorded revenue from clinical trial sales of the OCS Lung for our OCS Lung EXPAND II Trial, which stopped enrollment as of June 24, 2019 since we received FDA PMA for the OCS Lung EXPAND indication.

In the United States, we expect to continue to only have clinical trial sales for our OCS Heart and OCS Liver products until we receive similar FDA PMA for those products. Our net revenue in the United States for OCS Heart and OCS Liver products fluctuates from period to period as a result of the timing of patient enrollment in our clinical trials. Historically, our net revenue during periods of patient enrollment has been higher due to the sale of OCS disposable sets for use during these clinical trials, as compared to periods during which our clinical trials were not actively enrolling. Our OCS Heart EXPAND Trial began patient enrollment in September 2015 and completed patient enrollment in March 2018. Our OCS Liver PROTECT trial began enrollment in January 2016 and completed enrollment in October 2019. Our OCS Heart EXPAND CAP trial began patient enrollment in May 2019 and is currently enrolling patients. Our OCS Heart DCD trial began patient enrollment in December 2019 and has completed enrolling patients. Our OCS Heart DCD CAP trial has been approved by the FDA and we began enrolling patients in December 2020. Our OCS Liver PROTECT CAP trial began patient enrollment in February 2020 and has completed initial enrollment; however, we have applied to the FDA to enroll additional patients in this trial. Our net revenue may continue to fluctuate from period to period as a result of the timing of ongoing clinical trials in which our OCS products are used.

Through December 31, 2020, all of our sales outside of the United States have been commercial sales (unrelated to any clinical trials) and our net revenue has been generated primarily from sales of OCS disposable sets and, to a much lesser extent, sales of OCS Consoles. Commercial sales of OCS disposable sets generally have a higher average selling price than clinical trial sales of OCS disposable sets.

We expect that our net revenue will increase over the long term as a result of receiving our first two FDA PMAs for the OCS Lung in the United States in March 2018 and May 2019 and any potential future FDA approvals in the United States for OCS Heart and OCS Liver. We also expect that our net revenue will increase over the long term as a result of anticipated growth in non-U.S. sales if national healthcare systems begin to reimburse transplant centers for the use of the OCS, if transplant centers utilize the OCS in more transplant cases, and if more transplant centers adopt the OCS in their programs. We expect that net revenue will continue to be negatively impacted in 2021 a result of the COVID-19 pandemic.

Cost of Revenue, Gross Profit and Gross Margin

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

We expect that cost of revenue will increase or decrease in absolute dollars primarily as, and to the extent that, our net revenue increases or decreases.

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

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

Operating Expenses

Research, Development and Clinical Trials Expenses

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

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

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

Selling, General and Administrative Expenses

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

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

Other Income (Expense)

Interest Expense

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

Change in Fair Value of Preferred Stock Warrant Liability

Prior to our IPO in May 2019, we had outstanding warrants to purchase preferred stock. We classified these warrants as a liability on our consolidated balance sheet that we remeasured to fair value at each reporting date, and we recognized changes in the fair value of the warrant liability as a component of other income (expense) in our consolidated statements of operations.

On May 6, 2019, immediately prior to the closing of our IPO, the warrants to purchase preferred stock were converted into warrants to purchase common stock, and the fair value of the warrant liability at that time was reclassified to common stock. As a result, subsequent to the closing of our IPO, we no longer remeasure the fair value of the warrant liability at each reporting date.

Other Income (Expense), Net

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

Interest income consists of interest earned on our invested cash balances. Foreign currency transaction gains and losses result from intercompany transactions as well as transactions with customers or vendors denominated in currencies other than the functional currency of the legal entity in which the transaction is recorded.

Provision for Income Taxes

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

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

Results of Operations

Prior to 2020, our fiscal year ended on the last Saturday in December, and we reported fiscal years using a 52/53-week convention. Under this convention, certain fiscal years contained 53 weeks. Each fiscal year was typically composed of four 13-week fiscal quarters, but in years with 53 weeks, the fourth quarter was a 14-week period. Our fiscal year ended December 28, 2019 included 52 weeks. In February 2020, we changed the end of our fiscal year from the last Saturday in December to December 31.

Comparison of the Fiscal Years Ended December 31, 2020 and December 28, 2019

The following table summarizes our results of operations for the fiscal years ended December 31, 2020 and December 28, 2019:

	Fiscal Year Ended		
	December 31, 2020	December 28, 2019	Change
	(in thousands)		
Net revenue	$ 25,639	$ 23,604	$ 2,035
Cost of revenue	9,004	9,741	(737)
Gross profit	16,635	13,863	2,772
Operating expenses:			
Research, development and clinical trials	18,831	19,870	(1,039)
Selling, general and administrative	24,188	23,596	592
Total operating expenses	43,019	43,466	(447)
Loss from operations	(26,384)	(29,603)	3,219
Other income (expense):			
Interest expense	(3,985)	(4,353)	368
Change in fair value of preferred stock warrant liability	—	(341)	341
Other income, net	1,653	790	863
Total other expense, net	(2,332)	(3,904)	1,572
Loss before income taxes	(28,716)	(33,507)	4,791
Provision for income taxes	(32)	(40)	8
Net loss	$ (28,748)	$ (33,547)	$ 4,799

Net Revenue

	Fiscal Year Ended		
	December 31, 2020	December 28, 2019	Change
	(in thousands)		
Net revenue by geography:			
United States	$ 19,239	$ 16,253	$ 2,986
Outside the U.S.	6,400	7,351	(951)
Total net revenue	$ 25,639	$ 23,604	$ 2,035
Net revenue by OCS product:			
OCS Lung net revenue	$ 6,194	$ 8,664	$ (2,470)
OCS Heart net revenue	14,196	11,442	2,754
OCS Liver net revenue	5,249	3,498	1,751
Total net revenue	$ 25,639	$ 23,604	$ 2,035

Net revenue from customers in the United States was $19.2 million in the fiscal year ended December 31, 2020 and increased by $3.0 million in the fiscal year ended December 31, 2020 compared to the fiscal year ended December 28, 2019. The increase in net revenue from customers in the United States was primarily due to sales of OCS disposable sets for use in our OCS Heart EXPAND CAP Trial and OCS Heart DCD Trial and sales of OCS disposable sets to customers for use in our OCS Liver PROTECT CAP Trial, partially offset by a decrease in sales of our OCS Lung disposable sets. Net revenue from sales of OCS Lung products in the United States decreased from $8.0 million in the fiscal year ended December 28, 2019 to $5.4 million in the fiscal year ended December 31, 2020. The decrease was due to fewer sales of OCS Lung disposable sets as a result of the COVID-19 pandemic, which impacted lung transplants more than other organ transplants due to the nature of the disease, new protocols required for safe lung transplants and the necessary use of ventilators post-transplant. Net revenue from OCS Heart disposable sets sold to customers for use in our OCS Heart EXPAND CAP Trial and OCS Heart DCD Trial increased from $4.7 million in the fiscal year ended December 28, 2019 to $8.6 million in the fiscal year ended December 31, 2020. Net revenue from OCS Liver disposable sets sold to customers for use in our OCS Liver PROTECT Trial increased from $3.5 million in the fiscal year ended December 28, 2019 to $5.2 million in the fiscal year ended December 31, 2020. In addition, the U.S. selling price of OCS disposable sets sold in the fiscal year ended December 31, 2020 was approximately 12% higher than the U.S. selling prices of OCS disposable sets sold in the fiscal year ended December 28, 2019, which accounted for $2.0 million of the overall $3.0 million increase in net revenue in the United States from the fiscal year ended December 28, 2019 to the fiscal year ended December 31, 2020.

Net revenue from customers outside the United States was $6.4 million in the fiscal year ended December 31, 2020 and decreased by $1.0 million compared to the fiscal year ended December 28, 2019. The decrease in net revenue from customers outside the United States was primarily due to the adverse impact of the COVID-19 pandemic on the global economy.

Cost of Revenue, Gross Profit and Gross Margin

Cost of revenue decreased by $0.7 million in the fiscal year ended December 31, 2020 compared to the fiscal year ended December 28, 2019. Gross profit increased by $2.8 million in the fiscal year ended December 31, 2020 compared to the fiscal year ended December 28, 2019. Gross margin was 65% and 59% for the fiscal year ended December 31, 2020 and December 28, 2019, respectively. Gross profit and gross margin increased primarily as a result of a higher average selling price of OCS disposable sets sold in the United States in the fiscal year ended December 31, 2020 relative to the average selling price of OCS disposable sets sold in the fiscal year ended December 28, 2019 and cost reduction and cost containment measures adopted by management to address the challenges of the operating environment caused by the COVID-19 pandemic.

Operating Expenses

Research, Development and Clinical Trials Expenses

	Fiscal Year Ended		
	December 31, 2020	December 28, 2019	Change
	(in thousands)		
Personnel related (including stock-based compensation expense)	$ 7,853	$ 6,322	$ 1,531
Clinical trials costs	4,708	4,326	382
Consulting and third-party testing	1,432	4,108	(2,676)
Laboratory supplies and research materials	2,095	2,254	(159)
Other	2,743	2,860	(117)
Total research, development and clinical trials expenses	$ 18,831	$ 19,870	$ (1,039)

Total research, development and clinical trials expenses decreased by $1.0 million from $19.9 million in the fiscal year ended December 28, 2019 to $18.8 million in the fiscal year ended December 31, 2020. Personnel related costs and clinical trial costs increased by $1.5 million and $0.4 million, respectively, due primarily to additional resources supporting clinical trials and new product development. Consulting and third-party testing, laboratory supplies and research materials costs and other costs decreased by $2.7 million, $0.2 million and $0.1 million, respectively, due primarily to our cost management and cost containment strategies implemented by our management in 2020 to address the challenges of the operating environment caused by the COVID-19 pandemic.

Selling, General and Administrative Expenses

	Fiscal Year Ended		
	December 31, 2020	December 28, 2019	Change
	(in thousands)		
Personnel related (including stock-based compensation expense)	$ 12,292	$ 9,772	$ 2,520
Professional and consultant fees	5,479	6,286	(807)
Tradeshows and conferences	931	2,072	(1,141)
Other	5,486	5,466	20
Total selling, general and administrative expenses	$ 24,188	$ 23,596	$ 592

Total selling, general and administrative expenses increased by $0.6 million from $23.6 million in the fiscal year ended December 28, 2019 to $24.2 million in the fiscal year ended December 31, 2020 due primarily to increases in personnel related costs, as we hired additional resources and engaged consultants to support commercial sales of our OCS Lung product in the United States and to support our operation as a public company. Stock-based compensation expense also increased by $1.3 million due primarily to additional grants to existing employees. These increases were partially offset by professional and consultant fees and tradeshows and conferences decreases of $0.8 million and $1.1 million, respectively, primarily as a result of tradeshows and conferences being canceled or delayed due to the COVID-19 pandemic and cost management and cost containment strategies implemented by our management.

Other Income (Expense)

Interest Expense

Interest expense decreased to $4.0 million for the fiscal year ending December 31, 2020 from $4.4 million for the fiscal year ending December 28, 2019, as a result of lower interest rates.

Change in Fair Value of Preferred Stock Warrant Liability

The change in the fair value of our preferred stock warrant liability in the fiscal year ended December 28, 2019 was due primarily to the changes in the fair value of our preferred stock during that period.

On May 6, 2019, immediately prior to the closing of our IPO, the warrants to purchase preferred stock were converted into warrants to purchase common stock, and the fair value of the warrant liability at that time was reclassified to common stock. As a result, subsequent to the closing of our IPO, we no longer remeasure the fair value of the warrant liability at each reporting date.

Other Income (Expense), Net

Other income (expense), net for the fiscal years ended December 31, 2020 and December 28, 2019 included interest income of $0.7 million and $1.0 million, respectively, resulting from interest earned on invested cash balances, and included $1.0 million of realized and unrealized foreign currency transaction gains and $0.2 million of realized and unrealized foreign currency transaction losses for the fiscal years ended December 31, 2020 and December 28, 2019, respectively. Interest income decreased from fiscal 2019 to fiscal 2020 as a result of lower interest rates on invested balances.

Liquidity and Capital Resources

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

On May 6, 2019, we completed our IPO, pursuant to which we issued and sold 6,543,500 shares of common stock, inclusive of 853,500 shares we sold pursuant to the full exercise of the underwriters' option to purchase additional shares. The aggregate net proceeds received by us from the IPO were $91.4 million, after deducting underwriting discounts and commissions as well as other offering costs of $6.0 million. On May 26, 2020, we completed an underwritten public offering of our common stock, which resulted in the sale of 5,750,000 shares of common stock, inclusive of 750,000 shares we sold pursuant to the full exercise of the underwriters' option to purchase additional shares. The aggregate net proceeds received by us from the offering were $75.1 million, after deducting underwriting discounts and commissions as well as other offering costs of $0.6 million.

As of December 31, 2020, we had cash, cash equivalents, and marketable securities of $125.6 million.

Cash Flows

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

	Fiscal Year Ended	
	December 31, 2020	December 28, 2019
	(in thousands)	
Cash used in operating activities	$ (30,265)	$ (32,286)
Cash used in investing activities	(41,598)	(60,501)
Cash provided by financing activities	75,549	92,723
Effect of exchange rate changes on cash, cash equivalents and restricted cash	803	(85)
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 4,489	$ (149)

Operating Activities

During the fiscal year ended December 31, 2020, operating activities used $30.3 million of cash, primarily resulting from our net loss of $28.7 million and net cash used by changes in our operating assets and liabilities of $5.6 million, partially offset by net non-cash charges of $4.1 million. Net cash used by changes in our operating assets and liabilities for the fiscal year ended December 31, 2020 consisted primarily of a $3.9 million decrease in accounts payable and accrued expenses and other current liabilities, a $1.7 million increase in inventory and a $0.8 million increase in prepaid expenses and other current assets, partially offset by a $0.9 million increase in deferred rent.

During the fiscal year ended December 28, 2019, operating activities used $32.3 million of cash, primarily resulting from our net loss of $33.5 million and net cash used by changes in our operating assets and liabilities of $1.6 million, partially offset by net non-cash charges of $2.9 million. Net cash used by changes in our operating assets and liabilities for the fiscal year ended December 28, 2019 consisted primarily of a $4.1 million increase in inventory and a $3.2 million increase in accounts receivable, partially offset by a $5.9 million increase in accounts payable and accrued expenses and other current liabilities.

Changes in accounts receivable, inventory, accounts payable, and accrued expenses and other current liabilities in each reporting period are generally due to growth in our business, including the growth in sales, expenses and employee headcount.

Investing Activities

During the fiscal year ended December 31, 2020, net cash used in investing activities of $41.6 million consisted of $121.8 million in purchases of marketable securities and $0.5 million in purchases of property and equipment, partially offset by proceeds from sales and maturities of marketable securities of $80.7 million.

During the fiscal year ended December 28, 2019, net cash used by investing activities was $60.5 million, primarily due to the purchases of marketable securities of $82.4 million and purchases of property and equipment of $0.2 million, partially offset by the proceeds from sales and maturities of marketable securities of $22.0 million.

Financing Activities

During the fiscal year ended December 31, 2020, net cash provided by financing activities of $75.5 million consisted primarily of proceeds from the issuance of common stock in our May 2020 public offering of $75.7 million and our employee share ownership plans of $0.6 million, both partially offset by payments of offering costs of $0.7 million.

During the fiscal year ended December 28, 2019, net cash provided by financing activities was $92.7 million, consisting primarily of net proceeds from issuance of common stock in our IPO that closed in May 2019, partially offset by payment of offering costs related to our IPO.

Long-Term Debt

In June 2018, TransMedics entered into the Credit Agreement with OrbiMed, pursuant to which it borrowed $35.0 million.

Borrowings under the Credit Agreement bear interest at an annual rate equal to the LIBOR subject to a minimum of 1.0% and a maximum of 4.0%, plus 8.5%, or the Applicable Margin, subject in the aggregate to a maximum interest rate of 11.5%. In addition, borrowings under the Credit Agreement bear paid-in-kind, or PIK interest, at an annual rate equal to the amount by which LIBOR plus the Applicable Margin exceeds 11.5%, but not to exceed 12.5%. The PIK interest is added to the principal amount of the borrowings outstanding at the end of each quarter until the maturity date of the Credit Agreement in June 2023. Borrowings under the Credit Agreement are repayable in quarterly interest-only payments until the maturity date, at which time all principal and accrued interest is due and payable. At our option, we may prepay outstanding borrowings under the Credit Agreement, subject to a prepayment premium that decreases annually. Our current prepayment premium is 4.5% and will decrease to zero in June 2021. We are also required to make a final payment in an amount equal to 3.0% of the principal amount of any prepayment or repayment, which we are accreting to interest expense over the term of the Credit Agreement using the effective interest method.

All obligations under the Credit Agreement are guaranteed by us and each of our material subsidiaries. All obligations of us and each guarantor are secured by substantially all of our and each guarantor's assets, including their intellectual property, subject to certain exceptions, including a perfected security interest in substantially all tangible and intangible assets of us and each guarantor. Under the Credit Agreement, we have agreed to certain affirmative and negative covenants to which we will remain subject until maturity. The covenants include maintaining a minimum liquidity amount of $3.0 million; the requirement, on an annual basis, to deliver to OrbiMed annual audited financial statements with an unqualified audit opinion from our independent registered public accounting firm; and restrictions on our activities, including limitations on dispositions, mergers or acquisitions; encumbering our intellectual property; incurring indebtedness or liens; paying dividends; making certain investments; and engaging in certain other business transactions. The obligations under the Credit Agreement are subject to acceleration upon the occurrence of specified events of default, including payment default, change in control, bankruptcy, insolvency, certain defaults under other material debt, certain events with respect to governmental approvals (if such events could cause a material adverse change in our business), failure to comply with certain covenants. including the minimum liquidity and unqualified audit opinion covenants, and a material adverse change in our business, operations or other financial condition. As of December 31, 2020, we were in compliance with all of the other covenants under the Credit Agreement.

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

Funding Requirements

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

- the amount of net revenue generated by sales of our OCS Consoles, OCS disposable sets and other products that may be approved in the United States and select non-U.S. markets;
- the costs and expenses of expanding our U.S. and non-U.S. sales and marketing infrastructure and our manufacturing operations;
- the extent to which our OCS products are adopted by the transplant community;
- the ability of our customers to obtain adequate reimbursement from third-party payors for procedures performed using the OCS products;

- the degree of success we experience in commercializing our OCS products for additional indications;
- the costs, timing and outcomes of any future clinical studies and regulatory reviews, including to seek and obtain approvals for new indications for our OCS products;
- the emergence of competing or complementary technologies;
- the number and types of future products we develop and commercialize;
- the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims; and
- the level of our selling, general and administrative expenses.

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

Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of December 31, 2020 and the effects that such obligations are expected to have on our liquidity and cash flows in future periods:

	Payments Due by Period				
	Total	Less Than 1 Year	1 to 3 Years	4 to 5 Years	More Than 5 Years
	(in thousands)				
Operating lease commitments(1)	$ 14,344	$ 1,900	$ 3,945	$ 4,144	$ 4,355
Debt obligations(2)	44,307	3,334	40,973	—	—
Total	$ 58,651	$ 5,234	$ 44,918	$ 4,144	$ 4,355

(1) Amounts in table reflect payments due for our leases of office and laboratory space in Andover, Massachusetts under two operating lease agreements. For more information, see "Note 12. Commitments and Contingencies" to the consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K.

(2) Amounts in table reflect the contractually required principal and interest payments payable under the Credit Agreement, under which borrowings bear interest at a variable rate. For purposes of this table, the interest due under the Credit Agreement was calculated using an assumed interest rate of 9.5% per annum, which was the interest rate in effect as of December 31, 2020. Because such interest rate is below the PIK interest threshold of 11.5%, we did not include PIK in our calculated payments.

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 and therefore, our commitments in the table above will increase by $1.5 million in the next year, $2.0 million in 1-3 years, $2.0 million in years 3-5, and $4.0 million in more than 5 years.

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 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 table above as the amount and timing of such payments are not known.

Inflation Risk

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

Critical Accounting Policies and Significant Judgments and Estimates

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

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

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

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

When a customer order includes an OCS Console, whether sold or loaned, 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. Consequently, we do not recognize any revenue from any component of a customer order that includes an OCS Console, whether sold or loaned, until the OCS Console has arrived at the customer site and the training and equipment set-up have been completed by us. We have concluded that "transfer of control" of an OCS Console occurs only after the console has arrived at the customer site and the training and equipment set-up have been completed by us.

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

When a customer contract contains multiple-performance obligations that include a loan of an OCS Console for the customer's use at the customer site as well as OCS disposable sets that are delivered simultaneously, we allocate the selling price 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, or SSP, of each distinct performance obligation. To date, the amounts allocated to lease deliverables have been insignificant. In determining SSP, we maximize observable inputs and consider a number of data points, including: (1) the pricing of standalone sales (in instances where available), (2) the pricing established by management when setting prices for deliverables that are intended to be sold on a standalone basis, (3) contractually stated prices for deliverables that are intended to be sold on a standalone basis, and (4) other pricing factors, such as the geographical region in which the products are sold and expected discounts based on the customer size and type.

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

Performance Obligations

The primary performance obligations in our customer contracts from which we derive revenue are as follows:

- *OCS Console*—The OCS Console is a medical device that houses and controls the function of the OCS. The performance obligation of the OCS Console includes customer training and equipment set-up. Revenue for each OCS Console is recognized at the point in time at which control is transferred to the customer, which is typically only after the console has arrived at the customer site and the training and equipment set-up have been completed by us because the customer cannot benefit from the OCS Console without the training and equipment set-up having been completed. At that time, we believe control has been transferred to the customer.
- *OCS Perfusion Set*—The OCS Perfusion Set is a single-use disposable set that stores the organ and circulates blood. Revenue for each OCS Perfusion Set is recognized at the point in time at which control is transferred to the customer, which is when title transfers to the customer in connection with delivery. In most of our customer contracts, title to the OCS Perfusion Set transfers when the OCS Perfusion Set arrives at the customer site. In limited instances, title transfers upon shipment by us to the customer.
- *OCS Solutions*—The OCS Solutions are a set of nutrient-enriched solutions to optimize the organ's condition outside the human body. Revenue for each OCS Solution is recognized at the point in time at which control is transferred to the customer, which is when title transfers to the customer in connection with delivery. In most of our customer contracts, title to the OCS Solutions transfers when the OCS Solutions arrive at the customer site. In limited instances, title transfers upon shipment by us to the customer.

Payments Made to Customers

Under our customer contracts that include a customer clinical trial agreement, we receive payments from sales to the customer of its OCS products and also make payments to that customer for reimbursements of clinical trial costs, materials, and for specified clinical documentation related to the customer's 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.

In these cases, we have determined that the payments made to the customer for reimbursement of clinical trial materials and its costs incurred to execute specific clinical trial protocols related to our OCS products do not provide us with a distinct good or service transferred by the customer, and, therefore, we record such payments as a reduction of revenue from the customer in our consolidated statements of operations. Reductions of revenue related to such payments made to customers for reimbursements are recognized when we recognize the revenue for the sale of our OCS disposable sets. For the fiscal years ended December 31, 2020 and December 28, 2019, we recorded as a reduction of revenue $2.7 million and $2.2 million, respectively, of reimbursable clinical trial costs.

In these same cases, we have also determined that payments made to the customer to obtain information related to post-approval studies or existing standard-of-care protocols (i.e., unrelated to our OCS products) do meet the criteria to be classified as a cost because we receive a distinct good or service transferred by the customer separate from the customer's purchase of our OCS products and the price paid represents the fair value of the distinct good or service received by us. As a result, these payments made by us to customers for information related to post-approval studies or standard-of-care protocols are recorded as operating expenses. For the fiscal years ended December 31, 2020 and December 28, 2019, we recorded as operating expenses $1.6 million and $1.2 million, respectively, related to payments made to customers for information related to post-approval studies or existing standard-of-care protocols.

Variable Consideration

Revenue is reported net of any taxes assessed by a governmental authority that are directly imposed on a revenue-producing transaction (e.g., sales, use, and value added taxes). 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.

Revenue from reimbursements of out-of-pocket expenses, including travel, lodging, and meals, is accounted for as variable consideration and is insignificant.

We do not consider shipping to be a performance obligation. We record shipping costs billed to customers as revenue and records the associated costs incurred by us for those items as cost of revenue.

Stock-Based Compensation

We measure stock-based option awards granted to employees, directors and non-employees based on their fair value on the date of the grant using the Black-Scholes option-pricing model. Compensation expense for those awards is recognized over the requisite service which is generally the vesting period of the respective award. Generally, we issue awards with only service-based vesting conditions and record the expense for these awards using the straight-line method. We account for forfeitures as they occur and record compensation cost assuming all option holders will complete the requisite service period. If an award is forfeited, the Company reverses compensation expense previously recognized in the period the award is forfeited.

The Black-Scholes option-pricing model uses as inputs the fair value of our common stock and assumptions we make for the volatility of our common stock, the expected term of our common stock options, the risk-free interest rate for a period that approximates the expected term of our common stock options, and our expected dividend yield.

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.

At the end of each reporting period, we assess whether losses should be accrued on long-term manufacturing purchase commitments in accordance with ASC 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 statements of operations unless they are deemed recoverable through firm sales contacts 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.

Backlog

We define backlog as contractually committed orders for our products for which the associated revenue has not been recognized and the customer has not been invoiced. Amounts that have been invoiced but not yet recognized as revenue are reported as deferred revenue on our consolidated balance sheets and are not included in our calculation of backlog. As of December 31, 2020 and December 28, 2019, we had backlog of $0.5 million. Of the amount of backlog as of December 31, 2020, we expect that substantially all of it will be invoiced to customers within the following 12 months. However, because our customers may cancel, change or reschedule orders without penalty at any time prior to shipment, we have no assurance that we will be able to convert our backlog into shipped orders.

Off-Balance Sheet Arrangements

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

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position, results of operations or cash flows is disclosed in Note 2 to our consolidated financial statements included elsewhere in this 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 our transactions in a variety of foreign currencies. Changes in these rates may have an impact on future cash flow and earnings. We manage these risks through normal operating and financing activities.

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 fiscal year ended December 31, 2020.

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 loss, a separate component of stockholders' equity (deficit) on our consolidated balance sheets. We recorded a foreign currency translation loss of less than $0.1 million during the fiscal year ended December 31, 2020.

For the fiscal year ended December 31, 2020, 18% of our net revenue and 7% 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 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, 2020, we had cash, cash equivalents, and marketable securities of $125.6 million, which consisted of cash, money market funds and short-term investments. Interest income is sensitive to changes in the general level of interest rates; however, due to the nature of these investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our investment portfolio.

In June 2018, we entered into our Credit Agreement with OrbiMed. Borrowings under the Credit Agreement bear interest at a variable rate per annum equal to LIBOR plus 8.5%. As of December 31, 2020 borrowings outstanding under the Credit Agreement totaled $35.0 million and the interest rate applicable to such borrowings was 9.5%. An immediate 10% change in LIBOR would not have a material impact on our debt-related obligations, financial position or results of operations.

Inflation Risk

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

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.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of TransMedics Group, Inc. and its subsidiaries (the "Company") as of December 31, 2020 and December 28, 2019, and the related consolidated statements of operations, of comprehensive loss, of convertible preferred stock and stockholders' equity (deficit) and of cash flows for the years then ended, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and December 28, 2019, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements 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 of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits 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. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts
March 11, 2021

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

TRANSMEDICS GROUP, INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share amounts)

	December 31, 2020	December 28, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 24,581	$ 20,092
Marketable securities	101,061	60,596
Accounts receivable	6,864	6,559
Inventory	11,934	11,216
Prepaid expenses and other current assets	2,326	1,538
Total current assets	146,766	100,001
Property and equipment, net	4,754	4,792
Restricted cash	500	500
Other long-term assets	6	6
Total assets	$ 152,026	$ 105,299
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,206	$ 7,247
Accrued expenses and other current liabilities	10,317	8,332
Deferred revenue	263	166
Current portion of deferred rent	93	370
Total current liabilities	11,879	16,115
Long-term debt, net of discount and current portion	34,657	34,146
Deferred rent, net of current portion	1,599	389
Total liabilities	48,135	50,650
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; 27,175,305 shares and 21,184,524 shares issued and outstanding at December 31, 2020 and December 28, 2019, respectively	502,217	424,134
Accumulated other comprehensive loss	(95)	(2)
Accumulated deficit	(398,231)	(369,483)
Total stockholders' equity	103,891	54,649
Total liabilities and stockholders' equity	$ 152,026	$ 105,299

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)

	Fiscal Year Ended	
	December 31, 2020	December 28, 2019
Net revenue	$ 25,639	$ 23,604
Cost of revenue	9,004	9,741
Gross profit	16,635	13,863
Operating expenses:		
Research, development and clinical trials	18,831	19,870
Selling, general and administrative	24,188	23,596
Total operating expenses	43,019	43,466
Loss from operations	(26,384)	(29,603)
Other income (expense):		
Interest expense	(3,985)	(4,353)
Change in fair value of preferred stock warrant liability	—	(341)
Other income, net	1,653	790
Total other expense, net	(2,332)	(3,904)
Loss before income taxes	(28,716)	(33,507)
Provision for income taxes	(32)	(40)
Net loss	$ (28,748)	$ (33,547)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.16)	$ (2.36)
Weighted average common shares outstanding, basic and diluted	24,702,764	14,204,787

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

TRANSMEDICS GROUP, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)

	Fiscal Year Ended	
	December 31, 2020	December 28, 2019
Net loss	$ (28,748)	$ (33,547)
Other comprehensive income (loss):		
Foreign currency translation adjustment	(49)	45
Unrealized gains (losses) on marketable securities, net of tax of $0	(44)	54
Total other comprehensive income (loss)	(93)	99
Comprehensive loss	$ (28,841)	$ (33,448)

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

TRANSMEDICS GROUP, INC.

CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)

(In thousands, except share amounts)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehen-sive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balances at December 29, 2018	50,404,140	$ 186,519	1,397,493	$ 1	$ 143,794	$ (101)	$ (335,936)	$ (192,242)
Conversion of convertible preferred stock into common stock upon initial public offering	(50,404,140)	(186,519)	13,119,424	186,519	—	—	—	186,519
Conversion of TransMedics' common stock into TransMedics Group's common stock upon corporate reorganization	—	—	—	143,859	(143,859)	—	—	—
Conversion of preferred stock warrants into common stock warrants upon initial public offering	—	—	—	1,239	—	—	—	1,239
Issuance of common stock in initial public offering, net of discounts and issuance costs of $5,966	—	—	6,543,500	91,401	—	—	—	91,401
Issuance of common stock upon the exercise of common stock options	—	—	124,107	194	8	—	—	202
Stock-based compensation expense	—	—	—	797	57	—	—	854
Settlement of accrued financing fees	—	—	—	124	—	—	—	124
Foreign currency translation adjustment	—	—	—	—	—	45	—	45
Unrealized gains on marketable securities	—	—	—	—	—	54	—	54
Net loss	—	—	—	—	—	—	(33,547)	(33,547)
Balances at December 28, 2019	—	—	21,184,524	424,134	—	(2)	(369,483)	54,649
Issuance of common stock upon the exercise of common stock options	—	—	218,084	227	—	—	—	227
Issuance of common stock in connection with employee stock purchase plan	—	—	22,697	357	—	—	—	357
Issuance of common stock in public offering, net of discounts and issuance costs of $585	—	—	5,750,000	75,085	—	—	—	75,085
Stock-based compensation expense	—	—	—	2,414	—	—	—	2,414
Foreign currency translation adjustment	—	—	—	—	—	(49)	—	(49)
Unrealized losses on marketable securities	—	—	—	—	—	(44)	—	(44)
Net loss	—	—	—	—	—	—	(28,748)	(28,748)
Balances at December 31, 2020	—	$ —	27,175,305	$ 502,217	$ —	$ (95)	$ (398,231)	$ 103,891

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

TRANSMEDICS GROUP, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Fiscal Year Ended	
	December 31, 2020	December 28, 2019
Cash flows from operating activities:		
Net loss	$ (28,748)	$ (33,547)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	1,577	1,222
Stock-based compensation expense	2,414	854
Change in fair value of preferred stock warrant liability	—	341
Non-cash interest and end of term accretion expense	511	475
Net amortization (accretion) of premiums (discounts) on marketable securities	634	(205)
Unrealized foreign currency transaction (gains) losses	(1,065)	200
Changes in operating assets and liabilities:		
Accounts receivable	(218)	(3,166)
Inventory	(1,740)	(4,121)
Prepaid expenses and other current assets	(769)	250
Accounts payable	(5,802)	3,443
Accrued expenses and other current liabilities	1,948	2,453
Deferred revenue	60	(136)
Deferred rent	933	(349)
Net cash used in operating activities	(30,265)	(32,286)
Cash flows from investing activities:		
Purchases of property and equipment	(455)	(165)
Purchases of marketable securities	(121,793)	(82,371)
Proceeds from sales and maturities of marketable securities	80,650	22,035
Net cash used in investing activities	(41,598)	(60,501)
Cash flows from financing activities:		
Proceeds from issuance of common stock in public offering, net of underwriting discounts and commissions	75,670	97,367
Payments of public offering and other financing costs	(705)	(4,846)
Proceeds from issuance of common stock upon exercise of stock options	227	202
Proceeds from issuance of common stock in connection with employee stock purchase plan	357	—
Proceeds from Paycheck Protection Program loan	2,249	—
Repayment of Paycheck Protection Program loan	(2,249)	—
Net cash provided by financing activities	75,549	92,723
Effect of exchange rate changes on cash, cash equivalents and restricted cash	803	(85)
Net increase (decrease) in cash, cash equivalents and restricted cash	4,489	(149)
Cash, cash equivalents and restricted cash, beginning of period	20,592	20,741
Cash, cash equivalents and restricted cash, end of period	$ 25,081	$ 20,592
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 3,475	$ 3,877
Supplemental disclosure of non-cash investing and financing activities:		
Conversion of convertible preferred stock to common stock upon initial public offering	$ —	$ 186,519
Transfers of inventory to property and equipment	$ 1,191	$ 2,146
Reclassification of warrant liability to equity upon initial public offering	$ —	$ 1,239
Purchases of property and equipment included in accounts payable	$ —	$ 169
Offering costs included in accounts payable and accrued expenses	$ —	$ 120
Settlement of accrued financing fee	$ —	$ 124
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$ 24,581	$ 20,092
Restricted cash	500	500
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	$ 25,081	$ 20,592

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

1. Nature of the Business and Basis of Presentation

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

On May 6, 2019, the Company completed its initial public offering (the "IPO"), pursuant to which it issued and sold 6,543,500 shares of common stock, inclusive of 853,500 shares sold by the Company pursuant to the full exercise of the underwriters' option to purchase additional shares. The aggregate net proceeds received by the Company from the IPO were $91.4 million, after deducting underwriting discounts and commissions as well as other offering costs of $6.0 million. On May 26, 2020, the Company completed an underwritten public offering of 5,750,000 shares of its common stock, inclusive of 750,000 shares sold by the Company pursuant to the full exercise of the underwriters' option to purchase additional shares. The aggregate net proceeds received by the Company from the offering were approximately $75.1 million, after deducting underwriting discounts and commissions as well as other offering costs of $0.6 million.

Prior to 2020, the Company's fiscal year ended on the last Saturday in December, and the Company reported fiscal years using a 52/53-week convention. Under this convention, certain fiscal years contained 53 weeks. Each fiscal year was typically composed of four 13-week fiscal quarters, but in years with 53 weeks, the fourth quarter was a 14-week period. The fiscal year ended December 28, 2019 included 52 weeks. In February 2020, the Company changed the end of its fiscal year end from the last Saturday in December to December 31. As a result of this change, the Company's current fiscal year ended on December 31, 2020 and its fiscal quarters end on March 31, June 30 and September 30.

The accompanying consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the ordinary course of business. The Company has incurred recurring losses since inception, including net losses attributable to the Company of $28.7 million for the fiscal year ended December 31, 2020 and $33.5 million for the fiscal year ended December 28, 2019. As of December 31, 2020, the Company had an accumulated deficit of $398.2 million. The Company expects to continue to generate operating losses in the foreseeable future.

The Company believes that its existing cash, cash equivalents, and marketable securities of $125.6 million as of December 31, 2020 will be sufficient to fund operations, capital expenditures, and debt service payments for at least the next twelve months following the filing of this Annual Report on Form 10-K. The Company may need to seek additional funding through equity financings, debt financings or strategic alliances. The Company may not be able to obtain financing on acceptable terms, or at all, and the terms of any financing may adversely affect the holdings or the rights of the Company's shareholders. If the Company is unable to obtain funding, the Company will be required to delay, reduce or eliminate some or all of its research and development programs, product expansion or commercialization efforts, or the Company may be unable to continue operations.

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

The impact of the COVID-19 pandemic has been and will likely continue to be extensive in many aspects of society, which has resulted in and will likely continue to result in significant disruptions to the global economy, as well as businesses and capital markets around the world. Impacts to the Company's business as a result of COVID-19 include the temporary disruption of transplant procedures at many of the organ transplant centers that purchase OCS products; disruptions to the Company's manufacturing operations and supply chain caused by facility closures, reductions in operating hours, staggered shifts and other social distancing efforts; labor shortages; decreased productivity and unavailability of materials or components; restrictions on or delays of the Company's clinical trials and studies; delays of reviews and approvals by the Food and Drug Administration ("FDA") and other health authorities; limitations on its employees' and customers' ability to travel, and delays in product installations, trainings or shipments to and from affected countries and within the United States. In response to the pandemic, healthcare providers have, and may need to further, reallocate resources, such as physicians, staff, hospital beds and intensive care unit facilities, and these actions significantly delay the provision of other medical care such as organ transplantation and reduce the number of transplant procedures that are performed, which negatively impacts the Company's revenue and clinical trial activities. The Company's sales and clinical adoption team has been and may continue to be restricted in visiting many transplant centers in person. The Company plans to maintain these or similar restrictions until it believes employees can fully resume such activities in accordance with federal, state and local requirements. In addition, the Company had temporarily reduced the manufacturing and distribution of its OCS products at its facility in Andover, Massachusetts. Starting in May 2020, the Company resumed manufacturing and distribution operations to pre-COVID levels. While the Company maintains an inventory of finished products and raw materials used in its OCS products, a prolonged pandemic could lead to shortages in the raw materials necessary to manufacture its products. The COVID-19 pandemic also has impacted operations at the FDA and other health authorities, resulting in delays of reviews and approvals, including with respect to the Company's OCS Heart Pre-Market Approval ("PMA") application, and may affect other potential PMA applications.

While the COVID-19 pandemic did not significantly impact the Company's business or results of operations during the first quarter of 2020, OCS product sales have been negatively impacted by the COVID-19 pandemic since the second quarter of 2020 and the Company anticipates a negative impact to OCS product sales in 2021. The extent of the future impact on the Company's operations and financial condition will depend on the length and severity of the pandemic, its consequences, and containment and vaccination efforts. While the FDA approved emergency use authorization of vaccines in December 2020, it is expected to take several months for widespread vaccinations to occur and it is not yet known how vaccination efforts will impact the COVID-19 pandemic.

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

Risk of Concentrations of Credit, Significant Customers and Significant Suppliers

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

Significant customers are those that accounted for 10% or more of the Company's total revenue or accounts receivable. For the fiscal year ended December 31, 2020, two customers represented 14% and 10% of net revenue, respectively. For the fiscal year ended December 28, 2019, no customer accounted for 10% or more of net revenue. As of December 31, 2020, one customer accounted for 30% of accounts receivable. As of December 28, 2019, no customer accounted for 10% or more of accounts receivable.

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

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, 2020 and December 28, 2019, 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, 2020 and December 28, 2019. The Company's cash, cash equivalents and restricted cash was $25.1 million and $20.6 million for the years ended December 31, 2020 and December 28, 2019, respectively.

Accounts Receivable

Accounts receivable are presented net of a provision for doubtful accounts, which is an estimate of amounts that may not be collectible. The Company performs ongoing credit evaluations of its customers and, if necessary, provides an allowance for doubtful accounts and expected losses. The Company writes off accounts receivable against the allowance when it determines a balance is uncollectible and no longer actively pursues collection of the receivable. As of December 31, 2020 and December 28, 2019, the Company had no allowance for doubtful accounts. During the fiscal years ended December 31, 2020 and December 28, 2019, the Company did not record any provisions for doubtful accounts and did not write off any accounts receivable balances.

Property and Equipment

Property 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
Manufacturing equipment	5 years
OCS Consoles loaned to customers	5 years
Computer equipment and software	3 years
Laboratory equipment	3 years
Office and trade show equipment	5 years
Leasehold improvements	Shorter of term of lease or 15 years

Costs incurred for OCS Consoles are recorded as inventory unless and until the Company determines that an OCS Console will be loaned to a customer for its use. When an OCS Console is loaned to a customer, the Company reclassifies the cost of the OCS Console from inventory to property and equipment and begins to depreciate the loaned OCS Console over its estimated life. Related depreciation expense for the loaned OCS Console is classified as a cost of revenue. If an OCS Console is returned to the Company, it will continue to be classified as property and equipment and depreciated over its remaining useful life. The Company retains title to all OCS Consoles loaned to customers.

Other than for 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 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 and equipment. 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 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. The Company did not record any impairment losses on long-lived assets during the fiscal years ended December 31, 2020 and December 28, 2019.

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, upon general release, are amortized based upon the pattern in which economic benefits related to such assets are realized. 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 fiscal years ended December 31, 2020 and December 28, 2019.

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 Accounting Standards Codification ("ASC") 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 statements of operations unless they are deemed recoverable through firm sales contacts 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 fiscal year ended December 31, 2020.

Deferred Rent

The Company's lease agreements include payment escalations, rent holidays and other lease incentives, which are accrued or deferred as appropriate such that rent expense for each lease is recognized on a straight-line basis over the respective lease term. Adjustments for such items, consisting primarily of payment escalations, are recorded as deferred rent and amortized over the respective lease terms.

Fair Value Measurements

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

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

The Company's cash equivalents and marketable securities are carried at fair value, determined according to the fair value hierarchy described above (see Note 3). The carrying values of the Company's accounts receivable, accounts payable and accrued expenses approximate their fair values due to the short-term nature of these assets and liabilities. The carrying value of the Company's long-term debt approximates its fair value (a level 2 measurement) at each balance sheet date due to its variable interest rate, which approximates a market interest rate.

Marketable Securities

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

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

Segment Information

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

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, 2020 and December 28, 2019, the warranty accrual was less than $0.1 million.

Revenue Recognition

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

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

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

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

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

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

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

Performance Obligations

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

- *OCS Console* — The OCS Console is a medical device that houses and controls the function of the OCS. The performance obligation of the OCS Console includes customer training and equipment set-up. Revenue for each OCS Console is recognized at the point in time at which control is transferred to the customer, which is typically only after the console has arrived at the customer site and the training and equipment set-up have been completed by the Company because the customer cannot benefit from the OCS Console without the training and equipment set-up having been completed. At that time, the Company believes that the customer has the significant risks and rewards of ownership.
- *OCS Perfusion Set* — The OCS Perfusion Set is a single-use disposable set that stores the organ and circulates blood. Revenue for each OCS Perfusion Set is recognized at the point in time at which control is transferred to the customer, which is when title transfers to the customer in connection with delivery. In most of the Company's customer arrangements, title to the OCS Perfusion Set transfers when the OCS Perfusion Set arrives at the customer site. In limited instances, title transfers upon shipment to the customer by the Company.
- *OCS Solutions* — The OCS Solutions are a set of nutrient-enriched solutions to optimize the organ's condition outside the human body. Revenue for each OCS Solution is recognized at the point in time at which control is transferred to the customer, which is when title transfers to the customer in connection with delivery. In most of the Company's customer arrangements, title to the OCS Solutions transfers when the OCS Solutions arrive at the customer site. In limited instances, title transfers upon shipment to the customer by the Company.

Payments Made to Customers

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

The Company has determined that the payments made to the customer for reimbursement of clinical trial materials and customer's costs incurred to execute specific clinical trial protocols related to the Company's OCS products do not provide the Company with a distinct good or service transferred by the customer, and therefore such payments are recorded as a reduction of revenue from the customer in the Company's consolidated statements of operations. Reductions of revenue related to such payments made to customers for reimbursements are recognized when the Company recognizes the revenue for the sale of its OCS disposable sets. The Company recorded the reimbursable clinical costs as a reduction of revenue of $2.7 million and $2.2 million for the fiscal years ended December 31, 2020 and December 28, 2019, respectively, as presented below in disaggregated revenue.

The Company has also determined that payments made to customers to obtain information related to post-approval studies or existing standard-of-care protocols (i.e., unrelated to the Company's OCS products) do meet the criteria to be classified as a cost because the Company receives a distinct good or service transferred by the customer separate from the customer's purchase of the Company's OCS products and the consideration paid represents the fair value of the distinct good or service received by the Company. As a result, these payments made to the customers for information related to post-approval studies or standard-of-care protocols are recorded as operating expenses. The Company recorded payments made to customers related to post-approval studies and for documentation related to existing standard-of-care protocols of $1.6 million and $1.2 million for the fiscal years ended December 31, 2020 and December 28, 2019, respectively, as operating expenses.

Variable Consideration

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

Revenue from reimbursements of out-of-pocket expenses, including travel, lodging, and meals, is accounted for as variable consideration and is insignificant.

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

Contract Assets and Liabilities

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

Contract assets arise from unbilled amounts in customer arrangements when revenue recognized exceeds the amount billed to the customer and the Company's right to payment is not just subject to the passage of time. The Company had no contract assets as of December 31, 2020 and December 28, 2019.

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

The Company generally satisfies performance obligations within one year of the contract inception date. As of December 31, 2020, the Company's wholly- or partially unsatisfied performance obligations totaled $0.8 million and are expected to be completed within the next year.

Disaggregated Revenue

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

	Fiscal Year Ended	
	December 31, 2020	December 28, 2019
Gross revenue from sales to customers	$ 28,356	$ 25,844
Less: Clinical trial payments reducing revenue	2,717	2,240
Total net revenue	$ 25,639	$ 23,604

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

	Fiscal Year Ended	
	December 31, 2020	December 28, 2019
Net revenue by OCS product:		
OCS Lung net revenue	$ 6,194	$ 8,664
OCS Heart net revenue	14,196	11,442
OCS Liver net revenue	5,249	3,498
Total net revenue	$ 25,639	$ 23,604

	Fiscal Year Ended	
	December 31, 2020	December 28, 2019
Net revenue by country (1):		
United States	$ 19,239	$ 16,253
All other countries	6,400	7,351
Total net revenue	$ 25,639	$ 23,604

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

Other Revenue Considerations

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

Distributors

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

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

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

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 bonuses, stock-based compensation, employee benefits, 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 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 loss, a separate component of stockholders' equity (deficit).

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 and $(0.2) million for the fiscal years ended December 31, 2020 and December 28, 2019, respectively.

Stock-Based Compensation

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

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

Comprehensive Loss and Accumulated Other Comprehensive Loss

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

Accumulated other comprehensive gains (losses) on the consolidated balance sheets consists primarily of foreign currency translation adjustments. Accumulated other comprehensive loss attributable to unrealized losses on marketable securities has not been significant.

Net Income (Loss) per Share

Prior to closing of the IPO, the Company followed the two-class method when computing net income (loss) per share, as TransMedics had issued shares that met the definition of participating securities. The two-class method determines net income (loss) per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed. The outstanding convertible preferred stock contractually entitled the holders of such shares to participate in dividends but did not contractually require the holders of such shares to participate in losses of the Company. Accordingly, in periods in which the Company reported a net loss, such losses were not allocated to such participating securities, and as a result, basic and diluted net loss per share were the same.

Subsequent to the closing of its IPO, the Company only has one class of shares outstanding and basic net income (loss) per common share is computed by dividing the net income (loss) by the weighted average number of shares of common stock outstanding for the period. Diluted net income (loss) per common share is computed by dividing net income (loss) by the weighted average number of shares of common stock outstanding for the period, including potential dilutive common shares assuming the dilutive effect of outstanding stock awards. For periods in which the Company reports a net loss, diluted net loss per common share is the same as basic net loss per common share, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive. The Company reported a net loss attributable to common stockholders for each of the fiscal years ended December 31, 2020 and December 28, 2019.

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

	As of	
	December 31, 2020	December 28, 2019
Warrants to purchase common stock	64,440	64,440
Options to purchase common stock	2,261,234	1,952,300
Employee stock purchase plan	14,951	—
	2,340,625	2,016,740

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 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 Issued Accounting Pronouncements

The Company qualifies as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 and has elected not to "opt out" of the extended transition related to complying with new or revised accounting standards, which means that when a standard is issued or revised and it has different application dates for public and nonpublic companies, the Company will adopt the new or revised standard at the time nonpublic companies adopt the new or revised standard and will do so until such time that the Company either (i) irrevocably elects to "opt out" of such extended transition period or (ii) no longer qualifies as an emerging growth company.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* ("ASU 2016-02"), which sets out the principles for the recognition, measurement, presentation, and disclosure of leases for both parties to a contract (i.e., lessees and lessors). The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or less may be accounted for similar to existing guidance for operating leases today. For public entities, the guidance has been effective for annual reporting periods beginning after December 15, 2018 and for interim periods within those fiscal years. ASU 2016-02 initially required adoption using a modified retrospective approach, under which all years presented in the financial statements would be prepared under the revised guidance. In July 2018, the FASB issued ASU No. 2018-11, *Leases (Topic 842)*, which added an optional transition method under which financial statements may be prepared under the revised guidance for the year of adoption, but not for prior years. Under the latter method, entities will recognize a cumulative catch-up adjustment to the opening balance of retained earnings in the period of adoption. In November 2019, the FASB issued ASU No. 2019-10, which deferred the effective date for nonpublic entities to annual reporting periods beginning after December 15, 2020, and interim periods within fiscal years beginning after December 15, 2021. In June 2020, the FASB issued ASU No. 2020-05, which grants a one-year effective-date delay for nonpublic entities to annual reporting periods beginning after December 15, 2021 and to interim periods within fiscal years beginning after December 15, 2022. The Company is currently planning to adopt this guidance on January 1, 2022 in accordance with the nonpublic company requirements and is evaluating the method of adoption and the impact that the adoption of ASU 2016-02 will have on its consolidated financial statements.

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

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

3. Marketable Securities and Fair Value Measurements

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

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

	December 28, 2019			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Treasury securities (due within one year)	$ 23,318	$ 17	$ —	$ 23,335
U.S. government agency bonds (due within one year)	37,224	39	(2)	37,261
	$ 60,542	$ 56	$ (2)	$ 60,596

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

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

	Fair Value Measurements at December 28, 2019 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 11,760	$ —	$ —	$ 11,760
Marketable securities:				
U.S. Treasury securities	—	23,335	—	23,335
U.S. government agency bonds	—	37,261	—	37,261
	$ 11,760	$ 60,596	$ —	$ 72,356

Money market funds were valued by the Company based on quoted market prices, which represent a Level 1 measurement within the fair value hierarchy. U.S. Treasury securities and U.S. government agency bonds were valued by the Company using quoted prices in active markets for similar securities, which represent a Level 2 measurement within the fair value hierarchy. During the fiscal years ended December 31, 2020 and December 28, 2019, there were no transfers between Level 1, Level 2 and Level 3.

4. Inventory

Inventory consisted of the following (in thousands):

	December 31, 2020	December 28, 2019
Raw materials	$ 6,770	$ 4,881
Work-in-process	1,102	903
Finished goods	4,062	5,432
	$ 11,934	$ 11,216

During the fiscal years ended December 31, 2020 and December 28, 2019, the Company made non-cash transfers of OCS Consoles from inventory to property and equipment (OCS Consoles loaned to customers) of $1.2 million and $2.1 million, respectively.

5. Property and Equipment, Net

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

	December 31, 2020	December 28, 2019
Manufacturing equipment	$ 1,725	$ 1,408
OCS Consoles loaned to customers	7,196	6,005
Computer equipment and software	1,338	1,273
Laboratory equipment	617	524
Office and trade show equipment	177	177
Leasehold improvements	1,319	1,319
Construction-in-progress	409	433
	12,781	11,139
Less: Accumulated depreciation and amortization	(8,027)	(6,347)
	$ 4,754	$ 4,792

During the fiscal years ended December 31, 2020 and December 28, 2019, total depreciation and amortization expense was $1.6 million and $1.2 million, respectively. Of those amounts, $1.3 million and $1.0 million, respectively, was recorded as expense in cost of revenue related to the depreciation of OCS Consoles loaned to customers. The Company retains title to OCS Consoles loaned to customers.

Construction-in-progress recorded as of December 31, 2020 and December 28, 2019 was primarily related to the in-process construction of manufacturing equipment.

6. Accrued Expenses and Other Current Liabilities

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

	December 31, 2020	December 28, 2019
Accrued research, development and clinical trial expenses	$ 4,426	$ 3,144
Accrued payroll and related expenses	4,030	3,604
Accrued financing fees	—	120
Accrued professional fees	344	537
Accrued other	1,517	927
	$ 10,317	$ 8,332

7. Long-Term Debt

As of December 31, 2020 and December 28, 2019, long-term debt consisted of the following (in thousands):

	December 31, 2020	December 28, 2019
Principal amount of long-term debt	$ 35,000	$ 35,000
Less: Current portion of long-term debt	—	—
Long-term debt, net of current portion	35,000	35,000
Debt discount, net of accretion	(834)	(1,139)
Accrued end-of-term payments	491	285
Long-term debt, net of discount and current portion	$ 34,657	$ 34,146

In June 2018, the Company entered into a credit agreement (the "Credit Agreement") with OrbiMed Royalty Opportunities II, LP ("OrbiMed") pursuant to which OrbiMed made certain term loans available to the Company. The Credit Agreement provides for aggregate maximum borrowings of up to $65.0 million, consisting of (i) $35.0 million upon entering into the Credit Agreement, which was borrowed by the Company in June 2018, and (ii) potential additional borrowings of up to $30.0 million that could have become available upon the Company's achievement of specified revenue thresholds and a regulatory milestone by determinable dates. The Company did not achieve these revenue thresholds and regulatory milestones by such dates, and therefore OrbiMed's commitment to fund any additional borrowing was terminated.

Borrowings under the Credit Agreement bear interest at an annual rate equal to the London Interbank Offered Rate ("LIBOR"), subject to a minimum of 1.0% and a maximum of 4.0%, plus 8.5% (the "Applicable Margin"), subject in the aggregate to a maximum interest rate of 11.5%. In addition, borrowings under the Credit Agreement bear paid-in-kind ("PIK") interest at an annual rate equal to the amount by which LIBOR plus the Applicable Margin exceeds 11.5%, but not to exceed 12.5%. The PIK interest is added to the principal amount of the borrowings outstanding at the end of each quarter until the maturity date of the Credit Agreement in June 2023. Borrowings under the Credit Agreement are repayable in quarterly interest-only payments until the maturity date, at which time all principal and accrued interest is due and payable. At its option, the Company may prepay outstanding borrowings under the Credit Agreement, subject to a prepayment premium that decreases annually. The current prepayment premium is 4.5% and will decrease to zero in June 2021. The Company is also required to make a final payment in an amount equal to 3.0% of the principal amount of any prepayment or repayment. The final payment and debt discount amounts are being accreted to interest expense over the term of the Credit Agreement using the effective interest method.

In connection with entering into the Credit Agreement, the Company paid OrbiMed an upfront fee of $0.9 million and paid other costs to OrbiMed and third parties of $0.7 million, both of which were recorded by the Company as a debt discount. The debt discount is reflected as a reduction of the carrying value of long-term debt on the Company's consolidated balance sheet and is being accreted to interest expense over the term of the Credit Agreement using the effective interest method.

All obligations under the Credit Agreement are guaranteed by the Company and each of its material subsidiaries. All obligations of the Company and each guarantor are secured by substantially all of the Company's and each guarantor's assets, including their intellectual property, subject to certain exceptions, including a perfected security interest in substantially all tangible and intangible assets of the Company and each guarantor. Under the Credit Agreement, the Company has agreed to certain affirmative and negative covenants to which it will remain subject until maturity. The financial covenants include maintaining a minimum liquidity amount of $3.0 million; the requirement, on an annual basis, to deliver to OrbiMed annual audited financial statements with an unqualified audit opinion from the Company's independent registered public accounting firm; and restrictions on the Company's activities, including limitations on dispositions, mergers or acquisitions; encumbering its intellectual property; incurring indebtedness or liens; paying dividends; making certain investments; and engaging in certain other business transactions. As of December 31, 2020, the Company was in compliance with the financial covenants under the Credit Agreement.

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

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

The Company assessed all terms and features of the 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 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, 2020 and December 28, 2019, the interest rate applicable to borrowings under the Credit Agreement was 9.5% and 10.6%, respectively. During the fiscal years ended December 31, 2020 and December 28, 2019, the weighted average effective interest rate on outstanding borrowings under the Credit Agreement was approximately 11.2% and 12.4%, respectively.

Paycheck Protection Program Loan

On April 20, 2020, TransMedics issued a Promissory Note to Bank of America, NA, pursuant to which it received loan proceeds of $2.2 million (the "Loan") provided under the Paycheck Protection Program established under the Coronavirus Aid, Relief, and Economic Security Act and guaranteed by the U.S. Small Business Administration (the "Paycheck Protection Program"). However, based on updated guidance related to this program, the Company decided to repay the full amount of the Loan, and repaid the Loan on May 1, 2020. The Loan was unsecured, was scheduled to mature on April 20, 2022, had a fixed interest rate of 1.0% per annum and was subject to the standard terms and conditions applicable to loans administered under the Paycheck Protection Program.

8. Convertible Preferred Stock and Warrants

Convertible Preferred Stock

TransMedics, Inc. issued Series A-1 convertible preferred stock (the "Series A-1 Preferred Stock"), Series B convertible preferred stock (the "Series B Preferred Stock"), Series B-1 convertible preferred stock (the "Series B-1 Preferred Stock"), Series C convertible preferred stock (the "Series C Preferred Stock"), Series D convertible preferred stock (the "Series D Preferred Stock"), Series E convertible preferred stock (the "Series E Preferred Stock") and Series F convertible preferred stock (the "Series F Preferred Stock"). The Series A-1 Preferred Stock, Series B Preferred Stock, Series B-1 Preferred Stock, Series C Preferred Stock, Series D Preferred Stock, Series E Preferred Stock and Series F Preferred Stock are collectively referred to as the "Preferred Stock".

Immediately prior to the closing of the IPO on May 6, 2019, all of the outstanding shares of convertible preferred stock of TransMedics were converted into an aggregate of 13,119,424 shares of common stock of TransMedics Group.

Warrants

TransMedics had outstanding warrants to purchase shares of Series D Preferred Stock and Series F Preferred Stock as of December 29, 2018. The Company classified all of its preferred stock warrants as a liability on its consolidated balance sheets because the warrants were freestanding financial instruments that could require TransMedics to transfer assets upon exercise. The liability associated with each of these warrants was initially recorded at fair value upon the issuance date of each warrant and subsequently remeasured to fair value at each reporting date.

Immediately prior to the closing of the IPO on May 6, 2019, all of the outstanding preferred stock warrants of TransMedics were converted into warrants to purchase an aggregate of 64,440 shares of which warrants to purchase 50,000 shares of common stock at an exercise price of $8.75 per share expire on November 7, 2022 and warrants to purchase 14,440 shares of common stock at an exercise price of $17.47 per share have an expiration date of May 6, 2024. Upon conversion, the fair value of the warrant liability at that time was reclassified to common stock. As a result, subsequent to the closing of the Company's IPO, the Company no longer remeasures the fair value of the warrant liability at each reporting date.

9. Equity

On May 6, 2019, the Company filed a restated certificate of incorporation in the State of Massachusetts, which, among other things, restated the number of shares of all classes of stock that the Company has authority to issue to 175,000,000 shares, consisting of (i) 25,000,000 shares of preferred stock, no par value per share, and (ii) 150,000,000 shares of common stock, no par value per share. 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. The shares of preferred stock currently undesignated. 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, voting exclusively and as a separate class, are entitled to elect two directors of the Company. 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, 2020, no dividends had been declared or paid.

10. Stock-Based Compensation

2019 Stock Incentive Plan and Option Grants

On April 15, 2019, TransMedics Group's board of directors adopted and its sole stockholder approved the 2019 Stock Incentive Plan (the "2019 Plan"), which became effective on that same date. The 2019 Plan provides for the grant of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock, restricted stock units, unrestricted stock, unrestricted stock units, and other stock-based awards to employees, directors, and consultants of the Company and its subsidiaries. The number of shares of common stock of TransMedics Group initially available for issuance under the 2019 Plan was 3,428,571 shares, plus the number of shares underlying awards under the previously outstanding 2014 Stock Incentive Plan (the "2014 Plan"), not to exceed 1,595,189 shares, that expire or are terminated, surrendered, or cancelled without the delivery of shares, are forfeited to or repurchased by TransMedics Group or otherwise become available again for grant. Since the effectiveness of the Company's 2019 Plan in April 2019, no future awards will be made under the 2014 Plan.

Shares withheld in payment of the exercise or purchase price of an award or in satisfaction of tax withholding requirements, and the shares covered by a stock appreciation right for which any portion is settled in stock, will reduce the number of shares available for issuance under the 2019 Plan. In addition, the number of shares available for issuance under the 2019 Plan (i) will not be increased by any shares delivered under the 2019 Plan that are subsequently repurchased using proceeds directly attributable to stock option exercises and (ii) will not be reduced by any awards that are settled in cash or that expire, become unexercisable, terminate or are forfeited to or repurchased by TransMedics Group without the issuance of stock under the 2019 Plan. As of December 31, 2020, 2,447,687 shares of common stock were available for issuance under the 2019 Plan.

During the fiscal year ended December 31, 2020, the Company granted options to its employees and a director with service-based vesting for the purchase of an aggregate of 603,336 shares of common stock with a weighted average grant-date fair value of $7.91 per share.

2019 Employee Stock Purchase Plan

On April 15, 2019, TransMedics Group's board of directors adopted and its sole stockholder approved the 2019 Employee Stock Purchase Plan (the "2019 ESPP"), which became effective that same date. A total of 371,142 shares of common stock of TransMedics Group are reserved for issuance under the 2019 ESPP as of December 31, 2020. As of December 31, 2020, 22,697 shares have been issued under the 2019 ESPP and 348,445 shares remained available for issuance.

Stock Option Valuation

The fair value of stock option grants is estimated using the Black-Scholes option-pricing model. Prior to the IPO, the Company was a private company and lacks company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. 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:

	Fiscal Year Ended	
	December 31, 2020	December 28, 2019
Risk-free interest rate	0.91%	2.29%
Expected term (in years)	5.97	6.02
Expected volatility	54%	52%
Expected dividend yield	0%	0%

The following table summarizes the Company's option activity since December 28, 2019:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 28, 2019	1,952,300	$ 5.31	5.87	$ 26,415
Granted	603,336	15.69		
Exercised	(217,965)	1.04		
Forfeited	(65,566)	10.01		
Expired	(10,871)	43.96		
Outstanding as of December 31, 2020	2,261,234	$ 8.17	6.22	$ 26,671
Vested and expected to vest as of December 31, 2020	2,261,234	$ 8.17	6.22	$ 26,671
Options exercisable as of December 31, 2020	1,425,910	$ 4.26	4.73	$ 22,363

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 fiscal years ended December 31, 2020 and December 28, 2019, was $2.9 million and $2.3 million, respectively.

The weighted average grant-date fair value of stock options granted during the fiscal years ended December 31, 2020 and December 28, 2019 was $7.91 per share and $8.55 per share, respectively.

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

Stock-Based Compensation

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

	Fiscal Year Ended	
	December 31, 2020	December 28, 2019
Cost of revenue	$ 27	$ 17
Research, development and clinical trials expenses	396	104
Selling, general and administrative expenses	1,991	733
	$ 2,414	$ 854

As of December 31, 2020, total unrecognized compensation cost related to unvested share-based awards was $5.9 million, which is expected to be recognized over a weighted average period of 2.5 years.

11. Income Taxes

Tax Provision Components

During the fiscal years ended December 31, 2020 and December 28, 2019, the Company recorded no income tax benefits for the net operating losses incurred or for the research and development tax credits generated in each year in the United States, due to the uncertainty regarding the realizability of these respective deferred tax assets. The Company generated income in the Netherlands for the fiscal years ended December 31, 2020 and December 28, 2019 and, accordingly, recorded a foreign income tax provision of less than $ 0.1 million for each of the fiscal years ended December 31, 2020 and December 28, 2019.

Income Before Taxes

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

	Fiscal Year Ended	
	December 31, 2020	December 28, 2019
United States	$ (28,803)	$ (33,668)
Foreign	87	161
	$ (28,716)	$ (33,507)

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate is as follows:

	Fiscal Year Ended	
	December 31, 2020	December 28, 2019
Federal statutory income tax rate	(21.0)%	(21.0)%
State taxes, net of federal benefit	(5.7)%	(6.2)%
Federal and state research and development tax credits	(3.6)%	(2.8)%
Nondeductible items	(0.2)%	0.2%
Deferred tax effect of change in state blended rate	7.8%	0.0%
Return to provision	1.7%	0.0%
Other	0.0%	0.9%
Change in deferred tax asset valuation allowance	20.9%	29.0%
Effective income tax rate	(0.1)%	0.1%

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

	December 31, 2020	December 28, 2019
Deferred tax assets:		
Net operating loss carryforwards	$ 81,390	$ 74,206
Capitalized research and development expense	6,136	8,505
Research and development tax credit carryforwards	11,541	10,745
Accrued expenses	1,390	1,309
Stock-based compensation expense	791	243
Deferred rent	79	157
Other	132	—
Total deferred tax assets	101,459	95,165
Deferred tax liabilities:		
Other	(218)	(141)
Unrealized gain (loss)	(212)	—
Total deferred tax liabilities	(430)	(141)
Valuation allowance	(101,029)	(95,024)
Net deferred tax assets	$ —	$ —

As of December 31, 2020, the Company had U.S. federal and state net operating loss carryforwards of $322.0 million and $252.7 million, respectively, which may be available to offset future taxable income and begin to expire in 2021 and 2030, respectively. The Company's federal net operating losses include $108.0 million, which can be carried forward indefinitely. As of December 31, 2020, the Company also had U.S. federal and state research and development tax credit carryforwards of $7.6 million and $5.0 million, respectively, which may be available to offset future tax liabilities and begin to expire in 2021 and 2024, respectively. As of December 31, 2020, 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 a substantial annual 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 or that could occur in the future. 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. The Company has not conducted a study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception due to the significant complexity and cost associated with such a study. If the Company has experienced a change of control, as defined by Section 382, at any time since inception, utilization of the net operating loss carryforwards or research and development tax credit carryforwards would be subject to an annual limitation under Section 382, which is determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the net operating loss carryforwards or research and development tax credit carryforwards before utilization. Further, until a study is completed by the Company and any limitation is known, no amounts are being presented as an uncertain tax position.

As required by Accounting Standard Codification 740, management of the Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets, which are comprised principally of net operating loss carryforwards. Management has determined that it is more likely than not that the Company will not recognize the benefits of federal and state deferred tax assets and, as a result, a valuation allowance of approximately $101.0 million has been recorded. During 2020, the Company recorded a net increase to its valuation allowance in the amount of $6.0 million primarily attributable to the current year operating loss and research credit generation for which the Company cannot provide a tax benefit.

The Company had no unrecognized tax benefits or related interest and penalties accrued for the fiscal years ended December 31, 2020 and December 28, 2019. The Company's policy is to record any interest or penalties related to income taxes as part of the income tax provision.

The Company generated research credits for the tax years ending after December 31, 2001, but has not conducted a study to document qualified activities. This study may result in an adjustment to the Company's research and development carryforwards; however, until a study is completed and any adjustment is known, no amounts are being presented as an unrecognized tax benefit for the year ended December 31, 2020. A full valuation allowance has been provided against the Company's research and development credits and, if an adjustment is required, this adjustment would be offset by an adjustment to the deferred tax asset established for the research credit carryforward and the valuation allowance.

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 from fiscal year 2017 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.

Changes in the valuation allowance for deferred tax assets during the fiscal years ended December 31, 2020 and December 28, 2019 related primarily to the increase in net operating loss carryforwards and research and development tax credit carryforwards in 2020 and 2019, and were as follows (in thousands):

	Fiscal Year Ended	
	December 31, 2020	December 28, 2019
Valuation allowance as of beginning of year	$ (95,024)	$ (85,316)
Decreases recorded as benefit to income tax provision	—	—
Increases recorded to income tax provision	(6,005)	(9,708)
Valuation allowance as of end of year	$ (101,029)	$ (95,024)

As of December 31, 2020 and December 28, 2019, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts had been recognized in the Company’s consolidated statements of operations.

12. Commitments and Contingencies

Operating Leases

The Company leases its office, laboratory and manufacturing space under two noncancelable operating leases that expire in December 2027. On January 9, 2020, the Company amended each of the lease agreements for its corporate headquarters (the “Amendment”) to lease an additional 39,744 square feet for general office use and an additional 11,735 square feet for operational use (the “Extension Premises”). The Amendment also extended each of the existing lease terms from December 2021 to December 2026, with an option to extend for one additional period of five years. Under the Amendment, the landlord will contribute up to $3.4 million towards the Company’s leasehold improvements. The Amendment provides for annual base rent for the premises of approximately $1.9 million for the first year of the lease. Thereafter, the annual base rent will increase at an average of 2.5% each year until the end of the term. The Company is also obligated to pay the landlord certain costs, taxes, and operating expenses, subject to certain exclusions. On June 2, 2020, the Company further amended each of the lease agreements (the “Second Amendment”). The changes provided by the Second Amendment include (i) extending each of the existing lease terms for an additional year through December 31, 2027, (ii) delaying to October 23, 2020 the commencement of the Company’s occupation of the Extension Premises, and (iii) extending to December 23, 2021 the Company’s ability to utilize the contribution from the landlord toward the Company’s work on improvements of the premises. The Second Amendment provides for annual base rent of approximately $2.0 million for the additional lease year and postponed the Company’s obligation to pay rent for the Extension Premises until October 23, 2020.

The Company’s lease agreements, as amended, include payment escalations, rent holidays and other lease incentives, which are accrued or deferred as appropriate such that rent expense for each lease is recognized on a straight-line basis over the respective lease terms, recording deferred rent for rent expense incurred but not yet paid. The Company recorded rent expense of $1.8 million and $1.2 million in the fiscal years ended December 31, 2020 and December 28, 2019, respectively. Costs incurred by the Company for tenant improvements but not yet reimbursed by the landlord are presented on the accompanying consolidated balance sheets as a tenant receivable within prepaid expenses and other current assets. As of December 31, 2020, the Company did not have a tenant receivable.

Future minimum lease payments under operating leases as of December 31, 2020 are as follows (in thousands):

Year Ending:		
December 31, 2021	$	1,900
December 31, 2022		1,948
December 31, 2023		1,997
December 31, 2024		2,047
December 31, 2025		2,098
Thereafter		4,354
	$	14,344

License Agreement with the Department of Veterans Affairs

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

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

The Company paid the VA royalties of $0.3 million during each of the fiscal years ended December 31, 2020 and December 28, 2019. The Company also accrued VA royalties of $0.1 million as of December 31, 2020.

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

401(k) Savings Plan

The Company has a defined-contribution savings plan under Section 401(k) of the Internal Revenue Code. This plan covers substantially all employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. Company contributions to the plan may be made at the discretion of the board of directors. For the fiscal years ended December 31, 2020 and December 28, 2019, the Company had not made any contributions to the plan.

Indemnification Agreements

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

The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not currently aware of any indemnification claims and had not accrued any liabilities related to such obligations in its consolidated financial statements as of December 31, 2020 and December 28, 2019.

Unconditional Purchase Commitment

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

Legal Proceedings

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

13. Segment Reporting and Geographic Data

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

Net revenue by OCS product is summarized as follows (in thousands):

	Fiscal Year Ended	
	December 31, 2020	December 28, 2019
Net revenue by OCS product:		
OCS Lung net revenue	$ 6,194	$ 8,664
OCS Heart net revenue	14,196	11,442
OCS Liver net revenue	5,249	3,498
Total net revenue	$ 25,639	$ 23,604

Financial data by geographical area is summarized as follows (in thousands):

	Fiscal Year Ended	
	December 31, 2020	December 28, 2019
Net revenue by country (1):		
United States	$ 19,239	$ 16,253
All other countries	6,400	7,351
Total net revenue	$ 25,639	$ 23,604

	December 31, 2020	December 28, 2019
Long-lived assets by country[2]:		
United States	$ 4,114	$ 4,007
All other countries	640	785
Total long-lived assets	$ 4,754	$ 4,792

(1) Net revenue by country is categorized based on the location of the end customer.
(2) The Company's only long-lived assets consist of property and equipment, net of depreciation, which are categorized based on their location of domicile.

14. 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 $0.3 million and $0.2 million in total compensation in the fiscal years ended December 31, 2020 and December 28, 2019, respectively, for her services as an employee.

15. Selected Quarterly Results of Operations Data (Unaudited)

The selected quarterly statements of operations data have been prepared on the same basis as the audited consolidated financial statements and include all adjustments necessary to present fairly, in all material respects, the information set forth therein on a consistent basis. The Company's operating results may fluctuate due to a variety of factors. Because the timing of organ transplant procedures is generally unpredictable, the Company has not experienced seasonality in its business from quarter to quarter and does not expect to do so in the foreseeable future. The results of historical periods are not necessarily indicative of the results to be expected for a full year or any future period. The following table sets forth the selected quarterly statements of operations data for each of the eight most recent fiscal quarters in the period ended December 31, 2020 (in thousands, except per share amounts):

	Fiscal Three Months Ended							
	Dec. 31 2020	Sept. 30, 2020	June 30, 2020	March 31, 2020	Dec. 28, 2019	Sept. 28, 2019	June 29, 2019	Mar. 30, 2019
Net revenue	$ 7,627	$ 7,091	$ 3,391	$ 7,530	$ 6,057	$ 7,205	$ 5,666	$ 4,676
Gross profit	4,828	5,038	1,909	4,860	3,741	4,216	3,333	2,573
Loss from operations	(5,896)	(4,610)	(7,861)	(8,017)	(8,694)	(7,242)	(7,705)	(5,962)
Net loss	$ (6,311)	$ (5,088)	$ (8,497)	$ (8,852)	$ (9,177)	$ (8,280)	$ (9,195)	$ (6,895)
Net loss per share (basic and diluted)	$ (0.23)	$ (0.19)	$ (0.36)	$ (0.42)	$ (0.43)	$ (0.39)	$ (0.70)	$ (4.86)

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 and accounting officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2020. 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, 2020, our President and Chief Executive Officer and our Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Internal Control Over Financial Reporting

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 Rule 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 included in such controls may deteriorate.

Our management conducted an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2020 based on the criteria set forth 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, 2020, our internal control over financial reporting was effective.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm due to a transition period established by the JOBS Act for "emerging growth companies."

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three months ended December 31, 2020 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None

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 2021 Annual Meeting of Stockholders and is incorporated herein by reference.

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 2021 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 2021 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 2021 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 2021 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 90 through 119 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	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.4 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 22, 2019)
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	Warrant Agreement to Purchase Preferred Stock, dated as of November 7, 2012, between the Registrant and Hercules Technology Growth Capital, Inc. (incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019).
4.3	Warrant Agreement to Purchase Preferred Stock, dated as of September 11, 2015, between the Registrant and Hercules Technology Growth Capital, Inc. (incorporated by reference to Exhibit 4.3 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)
4.4	Warrant Agreement to Purchase Preferred Stock, dated as of August 4, 2016, between the Registrant and Hercules Technology Growth Capital, Inc. (incorporated by reference to Exhibit 4.4 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)
4.5	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)
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#	2019 Stock Incentive Plan (incorporated by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 22, 2019)
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#	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)
10.13#	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)
10.14#	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)
10.15#	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)
10.16#	Executive Retention Agreement, dated as of March 23, 2015, by and among the Registrant and Stephen Gordon (incorporated by reference to Exhibit 10.16 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)
10.17	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)
10.18	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)
10.19	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)

10.20	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)
10.21	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)
10.22	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)
10.23	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)
10.24	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)
10.25	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)
10.26	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)
10.27	Credit Agreement, dated as of June 22, 2018, by and between the Registrant and OrbiMed Royalty Opportunities II, LP (incorporated by reference to Exhibit 10.26 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)
10.28	Pledge and Security Agreement, dated as of June 22, 2018, by and between the Registrant and OrbiMed Royalty Opportunities II, LP (incorporated by reference to Exhibit 10.27 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)
10.29	Guarantee, dated as of June 22, 2018, made by TransMedics B.V. in favor of OrbiMed Royalty Opportunities II, LP (incorporated by reference to Exhibit 10.28 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)
10.30	Supplement to Guarantee, dated as of May 6, 2019, by TransMedics Group, Inc. in favor of OrbiMed Royalty Opportunities II, LP. (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 1, 2019)
10.31	Supplement to Pledge and Security Agreement, dated as of May 6, 2019, by TransMedics Group, Inc. in favor of OrbiMed Royalty Opportunities II, LP. (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K (File No. 001-38891) filed with the SEC on May 1, 2019)
10.32	Third Waiver to Credit Agreement, dated as of March 29, 2019, by and among TransMedics, Inc., TransMedics B.V. and Orbimed Royalty Opportunities II, LP (incorporated by reference to Exhibit 10.35 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 22, 2019)
10.33+	License Agreement dated as of August 27, 2002 by and between the Registrant and The Department of Veterans Affairs (incorporated by reference to Exhibit 10.31 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)
10.34+	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)
10.35+	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)

10.36	Board Observer Agreement dated as of April 5, 2019 by and among the Registrant, Abrams Capital Partners I, L.P., Abrams Capital Partners II, L.P., Grant Hollow International, L.P., Riva Capital Partners III, L.P. and Whitecrest Partners, LP (incorporated by reference to Exhibit 10.34 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019)
10.37+	Amendment to Executive Retention Agreement, be and between TransMedics, Inc. and Stephen Gordon, dated April 10, 2020 (incorporated by reference to the Registrant's Current Report on Form 8-K (File No. 001-38891) filed with the SEC on April 13, 2020).
10.38	Promissory Note, dated April 20, 2020 ((incorporated by reference to the Registrant's Current Report on Form 8-K (File No. 001-38891) filed with the SEC on April 24, 2020).
10.39	Second Amendment to Credit Agreement, dated as of April 23, 2020, by and among TransMedics, Inc., TransMedics Croup, Inc., TransMedics, B.V. and Orbimed Royalty Opportunities II, L.P. (incorporated by reference to the Registrant's Current Report on Form 8-K (File No. 001-38891) filed with the SEC on April 24, 2020).
10.40	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 the Registrant's Quarterly Report on Form 10-Q (File No. 001-38891) filed with the SEC on August 7, 2020).
21.1	List of Subsidiaries (incorporated by reference to Exhibit 21.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-230736) filed with the SEC on April 5, 2019).
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.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed 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

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**.**

Company Name

Date: March 11, 2021

By: /s/ Stephen Gordon

Stephen Gordon
Chief Financial Officer, Treasurer and Secretary

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	March 11, 2021
/s/ Stephen Gordon **Stephen Gordon**	Chief Financial Officer, Treasurer and Secretary	March 11, 2021
/s/ James R. Tobin **James R. Tobin**	Chairman of the Board of Directors	March 11, 2021
/s/ Edward M. Basile **Edward M. Basile**	Director	March 11, 2021
/s/ Thomas J. Gunderson **Thomas J. Gunderson**	Director	March 11, 2021
/s/ Edwin M. Kania, Jr. **Edwin M. Kania, Jr.**	Director	March 11, 2021
/s/ David Weill, M.D. **David Weill, M.D.**	Director	March 11, 2021
/s/ Merilee Raines **Merilee Raines**	Director	March 11, 2021

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-238052) and Form S-8 (No. 333-231243) of TransMedics Group, Inc. of our report dated March 11, 2021 relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts
March 11, 2021

Exhibit 31.1

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

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

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

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

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

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

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 11, 2021

By: /s/ Waleed H. Hassanein

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

Exhibit 31.2

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

I, Stephen Gordon, certify that:

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

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

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

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

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

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

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 11, 2021

By: /s/ Stephen Gordon

Stephen Gordon
Chief Financial Officer, Treasurer and Secretary

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of TransMedics Group, Inc. (the "Company") for the year ended December 31, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Waleed Hassanein, M.D., President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

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

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

Date: March 11, 2021

By: /s/ Waleed H. Hassanein

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

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of TransMedics Group, Inc. (the "Company") for the year ended December 31, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Stephen Gordon, Chief Financial Officer, Treasurer and Secretary of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

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

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

Date: March 11, 2021

By: /s/ Stephen Gordon

Stephen Gordon
Chief Financial Officer, Treasurer and Secretary