# 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, 2019**

**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: 001-38740**

# Vapotherm, Inc.

**(Exact name of Registrant as specified in its Charter)**

| **Delaware** | **46-2259298** |
|---|---|
| **( State or other jurisdiction of incorporation or organization)** | **(I.R.S. Employer Identification No.)** |
| **100 Domain Drive Exeter, NH** | **03833** |
| **(Address of principal executive offices)** | **(Zip Code)** |

**Registrant's telephone number, including area code: (603) 658-0011**

**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, $0.001 per value per share | VAPO | New York Stock Exchange |

**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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on The New York Stock Exchange on June 30, 2019, was $302,970,651.

The number of shares of Registrant's Common Stock outstanding as of February 27, 2020, was 20,875,826.

Portions of the Registrant's Definitive Proxy Statement relating to the Annual Meeting of Shareholders, scheduled to occur on June 23, 2020, are incorporated by reference into Part III of this Report.

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## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical facts contained in this Annual Report on Form 10-K are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements include, but are not limited to, statements concerning:

- estimates regarding the annual total addressable market for our Precision Flow systems, future results of operations, financial position, capital requirements and our needs for additional financing;
- commercial success and market acceptance of our Precision Flow systems, our Oxygen Assist Module, and any future products we may seek to commercialize;
- competitive companies and technologies in our industry;
- our ability to enhance our Hi-VNI Technology, our Oxygen Assist Module, expand our indications and develop and commercialize additional products;
- our business model and strategic plans for our products, technologies and business, including our implementation thereof;
- our ability to accurately forecast customer demand for our products and manage our inventory;
- our ability to expand, manage and maintain our direct sales and marketing organizations in the United States and United Kingdom, and to market and sell our Hi-VNI Technology in markets outside of the United States;
- our ability to hire and retain our senior management and other highly qualified personnel;
- our ability to obtain additional financing in the future;
- our ability to commercialize or obtain regulatory approvals for our products, or the effect of delays in commercializing or obtaining regulatory approvals;
- U.S. Food and Drug Administration or other United States or foreign regulatory actions affecting us or the healthcare industry generally, including healthcare reform measures in the United States and international markets;
- the timing or likelihood of regulatory filings and approvals;
- our ability to establish and maintain intellectual property protection for our Hi-VNI Technology, Precision Flow systems, and our Oxygen Assist Module or avoid claims of infringement;
- the volatility of the trading price of our common stock; and
- our expectations about market trends.

The forward-looking statements in this Annual Report on Form 10-K are only predictions and are based largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Annual Report on Form 10-K and are subject to a number of known and unknown risks, uncertainties and assumptions, including those described in this Annual Report on Form 10-K in Part I, "Item 1A. Risk Factors" and Part II, "Item 7A. Management's Discussion and Analysis of Financial Condition and Results of Operations" and in our other filings with the Securities and Exchange Commission, or SEC. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. Any forward-looking statements made herein speak only as of the date of this Annual Report on Form 10-K, and you should not rely on forward-looking statements as predictions of future events. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

We use "Vapotherm," "Precision Flow," "Hi-VNI", "OAM", and other marks as trademarks in the United States and/or in other countries. This Annual Report on Form 10-K contains references to our trademarks and service marks and to those belonging to other entities. Solely for convenience, trademarks and trade names referred to in this Annual Report on Form 10-K, including logos, artwork and other visual displays, may appear without the ® or ™ symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other entities' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other entity.

Unless otherwise indicated, information contained in this Annual Report on Form 10-K concerning our industry and the markets in which we operate, including our general expectations, market position and market opportunity, is based on our management's estimates and research, as well as industry and general publications and research, surveys and studies conducted by third parties. We believe that the information from these third-party publications, research, surveys and studies included in this Annual Report on Form 10-K is reliable. Management's estimates are derived from publicly available information, their knowledge of our industry and their assumptions based on such information and knowledge, which we believe to be reasonable. This data involves a number of assumptions and limitations which are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in Part I, "Item 1A. Risk Factors." These and other factors could cause our future performance to differ materially from our assumptions and estimates.

Unless the context requires otherwise, references to "Vapotherm," the "Company," "we," "us," and "our," refer to Vapotherm, Inc.

# PART I

# BUSINESS

## Item 1. Business.

### Overview

We are a global medical technology company focused on the development and commercialization of our proprietary Hi-VNI Technology products that are used to treat patients of all ages suffering from respiratory distress. Our Hi-VNI Technology delivers non-invasive ventilatory support by providing heated, humidified and oxygenated air at a high velocity to patients through a comfortable small-bore nasal interface. Our Precision Flow systems, which use Hi-VNI Technology, are clinically validated alternatives to, and address many limitations of, the current standard of care for the treatment of respiratory distress in a hospital setting. As of December 31, 2019, more than 2.1 million patients have been treated with our Precision Flow systems, and we have a global installed base of over 16,000 capital units.

Respiratory distress is caused by a wide range of serious underlying conditions, including pneumonia, chronic obstructive pulmonary disease, or COPD, asthma and heart failure. Patients with respiratory distress have severe difficulty breathing and are unable to sustain sufficient oxygen levels or remove retained carbon dioxide in their lungs and airways. These patients require immediate respiratory support ranging from supplemental oxygen therapy for mild cases to invasive mechanical ventilators for severe cases. Many respiratory distress patients who require ventilatory support are initially treated in the emergency department, or ED, with the goal of stabilizing these patients with a non-invasive ventilation therapy so their underlying condition can be treated. Patients who cannot be adequately stabilized are often transferred to the intensive care unit, or ICU, a high cost and capacity-constrained setting in the hospital. An independent third-party study published in the June 2005 issue of *Critical Care Medicine* determined that the average cost for a typical three day stay in the ICU in the United States was $13,347. This cost increased by an average of 47% to $19,558 when the patient required mechanical ventilation.

The market for the treatment of respiratory distress is large and growing. Based on industry sources, we estimate that there are over 12 million patients who suffer from respiratory distress each year in the United States and select international markets that could benefit from our Hi-VNI Technology that would be eligible for our Precision Flow systems. As a result, we believe the annual total addressable global market for our Precision Flow systems exceeds $1.5 billion. We believe that an aging population and growing prevalence of heart failure and COPD will lead to an increase in the size of our total addressable market in the future.

Our Hi-VNI Technology competes with non-invasive positive pressure ventilation, or NIPPV, the traditional standard of care for respiratory distress. NIPPV uses pressure to drive gas in and out of a patient's lungs. It is typically administered through the fitting of an air-tight mask over the patient's nose and mouth and tightening a strap around the patient's head to secure the mask in place. NIPPV delivered through a mask is associated with increased patient discomfort and anxiety and can cause facial skin ulceration and trauma to the lungs. The mask complicates the care required to support a patient because they cannot talk, eat, drink or take oral medications while wearing the tight-fitting mask, and must time their breaths to be in sync with the bursts of air being forced into their lungs. NIPPV can also be delivered through a tight-fitting mask that only covers the nose or tight-fitting prongs that seal the external opening of each nostril. These alternatives, which usually require a chin strap to limit air leaks by keeping the patient's mouth closed, can also cause skin ulceration around the nose and nostrils. Third-party clinical evidence published in the June 2000, January 2009 and February 2013 issues of *Critical Care Medicine* suggests that delivering NIPPV through a mask that covers both the nose and mouth is generally preferred from an effectiveness perspective over a mask that only covers the nose or nasal prongs, particularly in the acute setting.

NIPPV is typically an escalation therapy, which means that practitioners often start at low pressures and increase as tolerated until the patient stabilizes. Patients treated with NIPPV are often transferred to the ICU because NIPPV typically requires frequent patient monitoring to ensure patient compliance and safety. Clinical evidence published in the November 2007 issue of *Respiratory Care* shows that approximately 30% of patients are intolerant of NIPPV masks, which can cause them to become non-compliant with their treatment for respiratory distress. Patients who cannot tolerate NIPPV are often sedated and potentially intubated in preparation for mechanical ventilation. Intubation involves the insertion of a plastic tube into the trachea to maintain an open airway. Mechanical ventilation is a complex, invasive procedure that is associated with increased costs of care, lengths of stay, incidence of infections, ventilator dependence and mortality.

In contrast to NIPPV, our Hi-VNI Technology delivers heated, humidified and oxygenated air at a high velocity to patients through a comfortable small-bore nasal interface to help reduce the work of breathing. Our Precision Flow systems, which use our Hi-VNI Technology, are clinically validated alternatives to NIPPV, and we believe they also provide the following primary benefits for the patient, the clinician and the hospital:

- meaningful improvement in patient comfort and compliance;
- facilitation of patient admissions to lower intensity, lower cost and less capacity-constrained care settings;
- reduced risk of pressure ventilation related side effects; and
- clinician workflow benefits, including easier administration and reduced patient monitoring.

A compelling body of clinical data supports the efficacy and benefits of Hi-VNI Technology for respiratory distress. In 2018, the U.S. Food and Drug Administration, or FDA, granted our *de novo* request for an expanded indication for the Precision Flow Hi-VNI system, which incorporates our Hi-VNI Technology. The FDA also created a new classification regulation under which this system is currently the only product listed. The expanded indication identified this system as a high velocity nasal insufflation device that augments breathing of spontaneously breathing patients suffering from respiratory distress in a hospital setting. We believe this FDA indication validates our clinical differentiation and compelling value proposition, establishing Hi-VNI Technology as an attractive alternative to NIPPV.

We currently offer four versions of our Precision Flow systems: Precision Flow Hi-VNI, Precision Flow Plus, Precision Flow Classic and Precision Flow Heliox. We also initiated a limited release of our Oxygen Assist Module to certain United Kingdom accounts in February 2020 and we may expand that limited release into certain European accounts during the second quarter of 2020. The Oxygen Assist Module can be used with all versions of our Precision Flow systems except for the Precision Flow Heliox. Our Oxygen Assist Module helps clinicians maintain the pulse oxygen saturation, or SpO2, within the target SpO2 range over a significantly greater proportion of time while requiring significantly fewer manual adjustments to the equipment. Maintenance of the prescribed oxygen saturation range may reduce the health risks associated with dosing too much, or too little, oxygen, such as visual or developmental impairment, and mortality in neonates. We intend to fully launch the Oxygen Assist Module commercially throughout the United Kingdom and Europe by the end of 2020, at which time we believe we will begin generating revenue from the product.

We sell our Precision Flow systems to hospitals through a direct sales organization in the United States and in the United Kingdom and through distributors in other select countries outside of the United States and the United Kingdom. Once fully launched, our Oxygen Assist Module will be sold through a direct sales organization in the United Kingdom and through distributors in other select countries in Europe. In addition, we have clinical educators who are experienced users of Hi-VNI Technology and who focus on our medical education efforts to facilitate adoption and increase utilization. We focus on physicians, respiratory therapists and nurses who work in acute hospital settings, including the ED and adult, pediatric and neonatal ICUs. Our relationship with these clinicians is particularly important, as it enables our products to follow patients through the care continuum. We have sold our Precision Flow systems to over 1,500 hospitals across the United States, where they have been primarily deployed in the ICU setting.

We generate revenue primarily from sales of the disposable products utilized with our proprietary Precision Flow systems. We also generate revenue from the capital units themselves. Our revenue grew from $42.4 million for the year ended December 31, 2018 to $48.1 million for the year ended December 31, 2019. Revenue from single-use disposables represented approximately 67.1% and 72.9% of our total revenue for the years ended December 31, 2018 and December 31, 2019, respectively. During this time, our international revenue also grew, representing 22.1% of our total revenue in 2018 and 24.0% of our total revenue in 2019. For the years ended December 31, 2018 and 2019, we incurred net losses of $42.5 million and $51.1 million, respectively.

We believe our anticipated growth will be driven by the following strengths: disruptive technology supported by a compelling body of clinical and economic evidence; expanded FDA indications for use; new FDA clearances and/or approvals, recurring revenue model with high visibility on our disposables utilization; dedicated respiratory United States and United Kingdom sales forces and experienced international distributors; comprehensive approach to market development with an established clinical team and digital marketing initiatives; robust and growing intellectual property portfolio; and an experienced senior management team and board members with deep industry practice.

Our goal is for our Hi-VNI Technology products to become the standard of care for the treatment of respiratory distress. Our strategy includes: attracting new customers while driving penetration within our existing customer base; continuing to build the preeminent respiratory sales team to facilitate further adoption; increasing awareness of our therapy through social media, digital marketing, and medical education programs; continuing to drive manufacturing cost efficiencies and leveraging our infrastructure to expand margins; leveraging our innovation capabilities to expand our Hi-VNI Technology and Oxygen Assist Module market penetration and opportunity.

**Respiratory Distress Market Overview**

***Overview of Respiratory Distress***

Respiratory distress is caused by a wide range of serious underlying conditions, including pneumonia, COPD, asthma and heart failure. The World Health Organization, or WHO, estimates that COPD and lower respiratory infections (pneumonia) were the third and fourth leading causes of death world-wide, respectively, in 2016. Further, WHO expects total deaths due to COPD to increase 30% in the next 10 years. Patients with respiratory distress have severe difficulty breathing, resulting in an increased respiratory rate and work of breathing. The inability to breathe is one of the most distressing conditions a patient may experience and is almost always associated with anxiety and discomfort. These patients require immediate respiratory support ranging from supplemental oxygen therapy for mild cases to more invasive mechanical ventilators that perform the work of breathing for severe cases. Many respiratory distress patients who require ventilatory support are treated in the ED with the goal of quickly stabilizing these patients with a non-invasive ventilation therapy so that their underlying condition can be treated. Patients who cannot be adequately stabilized are often transferred to the ICU, a high cost and capacity-constrained setting in the hospital. An independent third-party study published in the June 2005 issue of *Critical Care Medicine* determined the average cost for a typical three day stay in the ICU in the United States was $13,347. The cost increased by an average of 47% to $19,558 when the patient required mechanical ventilation.

***Conventional Methods of Treating Respiratory Distress and Their Limitations***

Under normal breathing conditions, approximately 30% of the air that is inhaled fills anatomical dead spaces in the respiratory system such as the nasal cavities, sinuses and mouth. These dead spaces constitute air passages that do not have the ability to enrich the blood with oxygen or rid the blood of carbon dioxide. Upon exhaling, these spaces fill with air from previous breaths and, as a result, this air contains lower levels of oxygen and higher levels of carbon dioxide than normal air. For most patients, this rebreathing of dead space gas does not have adverse effects as their respiratory capacity is sufficient to manage these higher levels of carbon dioxide. However, in patients with respiratory distress, rebreathing dead space gas adds to an already strained respiratory process, further increasing the work of breathing. Patients in respiratory distress often have rapid, shallow breathing, significant anxiety and discomfort.

Conventional non-pharmaceutical therapies used to provide respiratory support include the delivery of oxygen through a standard nasal interface, otherwise known as a cannula, or a non-rebreather mask which is a mask that covers the nose and mouth and is attached to a bag, which in turn is connected to an oxygen source. Patients who require oxygenation can also be treated with conventional heated humidified high flow oxygen devices which deliver breathing gases using large-bore cannulas. However, to our knowledge, none of these devices have been shown to deliver breathing gases at a sufficient velocity to rapidly flush the dead space in the limited time between breaths when respiratory rates are elevated. As such, we do not believe oxygen cannulas, non-rebreather masks, or conventional heated humidified high flow oxygen devices can provide adequate ventilatory support to patients in higher acuity respiratory distress who have elevated carbon dioxide levels.

NIPPV, a 35 year old technology, is the traditional standard of care for patients in respiratory distress, including those with elevated carbon dioxide levels. NIPPV uses pressure to drive gas in and out of a patient's lungs. It is typically administered by fitting an air-tight mask over the patient's nose and mouth and tightening a strap around the patient's head to secure the mask in place. NIPPV delivered through a mask is associated with increased patient discomfort and anxiety and can cause facial skin ulceration and trauma to the lungs. The masks complicate the care required to support the patients because they cannot talk, eat, drink or take oral medications while wearing the tight-fitting mask, and must time their breaths to be in sync with the bursts of air being forced into their lungs. NIPPV can also be delivered through a tight-fitting mask that only covers the nose or tight-fitting prongs that seal the external opening of each nostril. These alternatives, which usually require a chin strap to limit air leaks by keeping the patient's mouth closed, can also cause skin ulceration around the nose and nostrils.

Third-party clinical evidence published in the June 2000, January 2009 and February 2013 issues of *Critical Care Medicine*, suggests that delivering NIPPV through a mask that covers both the nose and mouth is generally preferred from an effectiveness perspective over a mask that only covers the nose or nasal prongs, particularly in the acute setting.

Patients treated with NIPPV are often transferred to the ICU because NIPPV typically requires intensive monitoring to ensure patient compliance and safety. Clinical evidence shows that approximately 30% of patients are intolerant of NIPPV masks. Such intolerance is caused by a variety of reasons including: discomfort, claustrophobia and the inability of patients to time their breaths to be in sync with the bursts of air provided by the device.

Patients who cannot tolerate NIPPV are often sedated and potentially intubated as the first step before mechanical ventilation. Intubation involves the insertion of a plastic tube into the trachea to maintain an open airway. Mechanical ventilation is a complex, invasive procedure that is associated with increased costs of care, lengths of stay, incidence of infections, ventilator dependence and mortality.

Patients on mechanical ventilators can become dependent on the ventilator to breathe. As a result, patients who have become ventilator-dependent must be gradually weaned off of the ventilator until the patient is able to breathe on his or her own. Discontinuing mechanical ventilation continues to be one of the most challenging events in ICU management. Approximately 40% of time spent on the mechanical ventilator is dedicated to slowly transitioning patients back to breathing on their own. Reducing the number of patients that require mechanical ventilation would be expected to both decrease the number of patients who require ICU care and shorten their stay in the ICU leading to overall cost savings to the healthcare system and increasing ICU throughput.

**Conventional approaches to respiratory distress and their limitations**


| Product | Description | Limitations |
|---|---|---|
| **Oxygen-Based Therapies** | • Includes standard nasal cannula, non-rebreather masks and conventional heated humidified high flow oxygen devices<br>• Increases oxygen concentration in breathing gas and improves alveolar gas exchange | • Highly passive system<br>• Oxygen delivery only – to our knowledge none of these devices have clinical evidence demonstrating that they adequately treat respiratory distress in patients with elevated carbon dioxide |
| **NIPPV** | • Typically delivered by a tight-fitting mask<br>• Forces gas in and out to augment respiration and improves alveolar gas exchange | • 30% of patients do not tolerate therapy<br>• Requires high intensity of care<br>• Risks of skin breakdown, lung injury and other adverse events |
| **Mechanical Ventilation** | • Delivered by a tube placed down the throat (intubation)<br>• Forces gas in and out of the lungs to augment respiration and improves alveolar gas exchange | • Frequently requires sedation<br>• Increases clinical risk and cost of care<br>• Risk of long-term difficulty weaning patients off ventilation |

***Conventional Method for Titrating FiO2 and its Limitations***

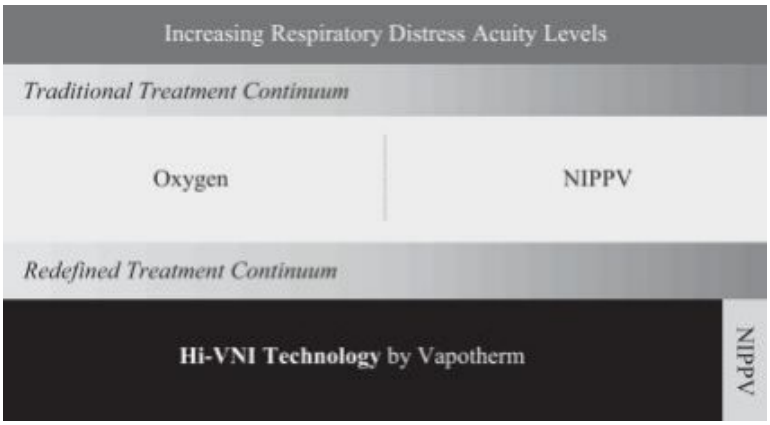
Another challenge faced by clinicians when treating patients experiencing respiratory distress is maintaining SpO2 within a tight target range, particularly neonates, where a range between 90% and 95% is typically desired. Hyperoxia, or too much oxygen, is associated with a higher risk of retinopathy of prematurity and lung damage. Hypoxemia, or too little oxygen, is associated with a higher risk of death and neurodevelopmental impairment. The current standard of care is manual control, whereby clinicians respond to alarms indicating the SpO2 is outside of the target range by manually titrating the fraction of inspired oxygen in the air or FiO2 in the breathing gases being delivered to the patient. A recent third-party study found that while training can improve the effectiveness of manual control, maintaining SpO2 between 90% and 95% in neonates may be achieved less than 50% of the time.

**Our Solutions**

***Overview of Hi-VNI Technology***

Hi-VNI Technology delivers heated, humidified and oxygenated air at a high velocity through a small-bore nasal interface to treat patients of all ages suffering from respiratory distress. Our Precision Flow systems, which use Hi-VNI Technology, can treat nearly all patients in respiratory distress who would not otherwise require mechanical ventilation, regardless of whether they are in need of an oxygen-based therapy or NIPPV. There is a subset of patients who will require NIPPV that we might otherwise have been able to treat, but for their absence of a respiratory drive, or the inability to breathe on their own. These patients include drug overdose patients and patients with advanced neuromuscular disease.

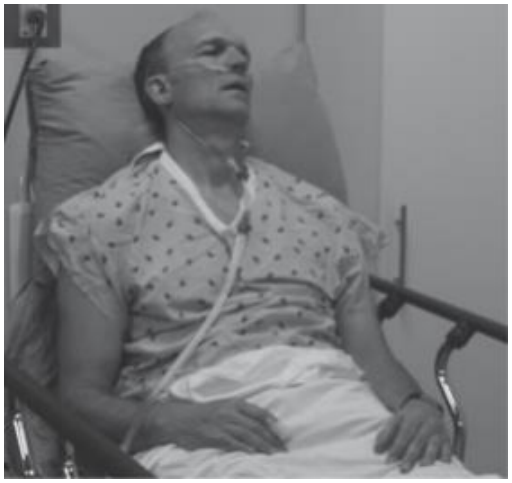
**Patient groups that can be treated with Hi-VNI Technology. These include patients suffering from a wide range of respiratory distress acuity levels, including most of those traditionally treated by NIPPV.**



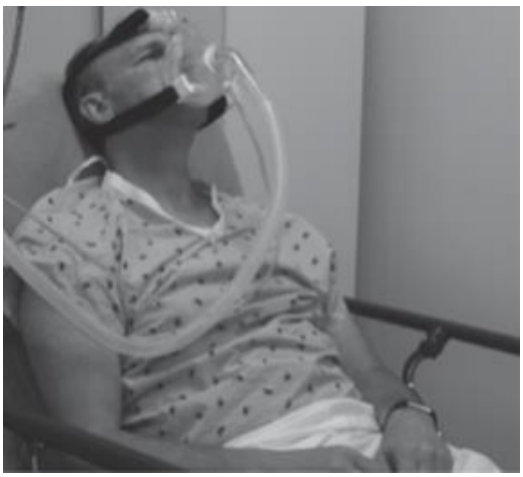

Instead of a mask, Hi-VNI Technology delivers temperature-controlled humidified gas to the patient at a high velocity through a small-bore nasal interface. High velocity nasal insufflation is typically a de-escalation therapy, which means it is appropriate to start at higher flows. Breathing while on Hi-VNI Technology helps patients ventilate and return to their normal breathing pattern. In comparison to NIPPV, we believe that our product improves patient comfort and compliance due to the delivery of breathing gases through a small-bore nasal interface that does not completely cover the patient's nose and mouth. While using our products, patients can eat and drink, talk with their caregivers and loved ones, and in some cases where important to the patient's rehabilitation, remain ambulatory. For parents with infants in the neonatal intensive care unit, or NICU, our products allow more direct skin-to-skin contact between parents and their babies which has been shown to improve

cardiorespiratory and temperature stability, sleep organization and duration of quiet sleep, neurodevelopmental outcomes, breastfeeding and modulation of pain responses in published clinical literature.

**Hi-VNI Technology**



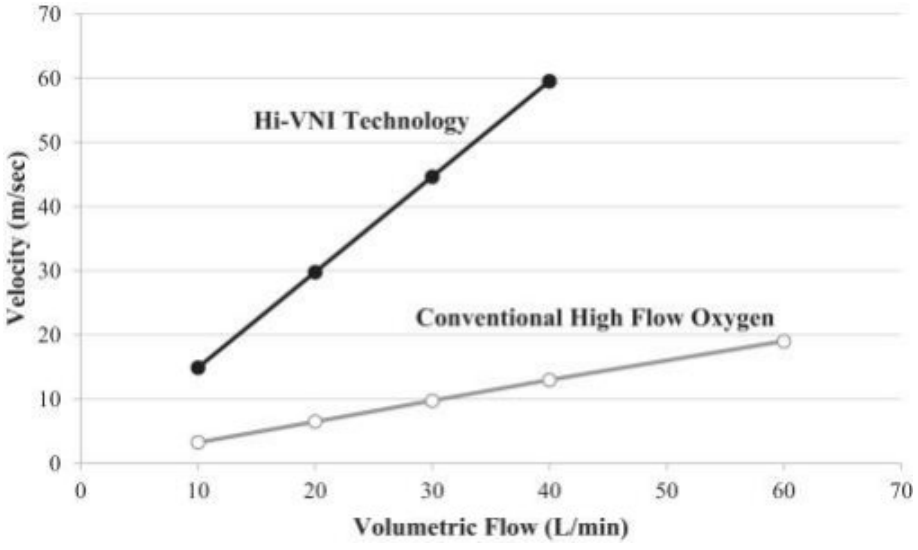
**NIPPV**



***Hi-VNI Technology Mechanism of Action***

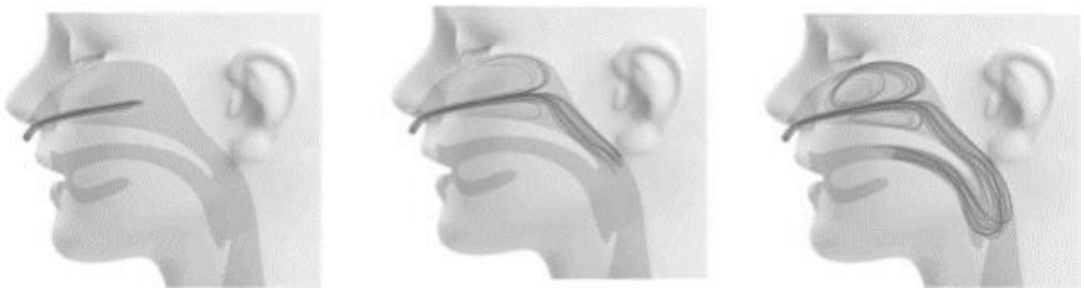
The key to Hi-VNI Technology is the ability to deliver conditioned breathing gases to patients in respiratory distress at a sufficient velocity to flush out the anatomical dead space between breaths when the patient's respiratory rate is elevated. As patients inhale this properly humidified, oxygen rich and carbon dioxide depleted medical gas, the work of breathing is reduced. Similar to the effect seen with water flowing from a garden hose, narrowing of the opening leads to dramatic increases in water velocity and turbulent kinetic energy exiting the hose or, in the case of Hi-VNI Technology, air exiting the cannula. The graph below depicts the calculated flow-velocity relationship for gas moving through different sized cannula openings. The Precision Flow systems' high-velocity delivery of breathing gases through a small-bore adult cannula results in an approximately four-fold increase in velocity as compared to the same flow from the large-bore adult cannula of conventional heated humidified high flow oxygen devices. This increased velocity promotes turbulent flush of the airway, even for patients breathing very rapidly.

**At all air flow rates, Hi-VNI Technology delivers higher velocity air than conventional heated humidified high flow oxygen devices.**



The high velocity breathing gases delivered by Precision Flow systems both actively push the air out of the anatomical dead space through the mouth and nose and also replace air containing carbon dioxide from the lungs with freshly oxygenated air.

**Diagram depicting the ability of high velocity air to displace dead air in the nasal cavities and the back of the throat.**



Increasing the flow rate of untreated air would typically present challenges to the upper airway structures which are responsible for both heating and humidifying the inhaled gas prior to reaching the lungs. The increased air flow has the potential to cause drying and damage to the mucosa, which in turn could lead to complications such as increased infection rates. Breathing gases provided by our Hi-VNI Technology products are temperature controlled and humidified both for patient comfort as well as to protect the integrity of the airway. This is accomplished by a proprietary vapor transfer cartridge, or VTC, containing water-vapor-permeable hollow fibers that provide a high surface area allowing air to become saturated with water vapor at body temperature. The result is a very fine, molecular water vapor that is energetically stable.

An important factor in providing temperature-controlled humidified air to patients is ensuring that the intended temperature and humidity are maintained as the air travels from the device to the patient. Hi-VNI Technology products accomplish this by using a proprietary triple-lumen water-jacketed delivery tube which maintains the air at a constant temperature throughout the length of the delivery tube. This design, coupled with the very fine, molecular water vapor generated by our proprietary VTC, is designed to prevent water from condensing in the delivery tube and to eliminate the risk of having liquid water introduced into the patient's airway. Other conventional humidified high flow oxygen delivery device manufacturers create humidified breathing gases by heating a bulk volume of water to create steam, which is then transferred to patients through electrically heated concentric wires. This results in the breathing gases passing through areas of uneven heating, including areas of excess heat which could be dangerous to the patient as well as cooler areas where condensation, or rainout, occurs. Delivery of liquid water rainout into the nose of the patient is both uncomfortable and potentially harmful. The Precision Flow systems' triple-lumen delivery tube has been shown in a study we sponsored to provide excellent control of rainout of condensation as compared to the humidified breathing gas systems with the heated wire.

The oxygen content of the air and its flow rate can be precisely regulated by Precision Flow systems using a simple, intuitive single-dial interface. Connections to air and oxygen are through standard wall connectors or via standard oxygen and air tanks typically available in hospitals. Precision Flow systems make use of industry-standard, user-replaceable oxygen sensors to measure oxygen concentrations.

***Benefits of Hi-VNI Technology***

We believe our Hi-VNI Technology addresses the key limitations of existing respiratory distress treatment options and provides the following principal benefits to hospitals, patients and providers:

- ***Meaningful improvement in patient comfort and compliance.*** Our proprietary Hi-VNI Technology is an innovative solution that provides non-invasive ventilatory support and enhances patient comfort and compliance when compared to NIPPV. According to a third-party clinical study published in the November 2007 issue of *Respiratory Care*, approximately 30% of patients are intolerant of NIPPV masks. The tight-fitting and difficult to seal masks can cause patient discomfort, anxiety and complicate the care required to support patients. In a Company-sponsored, randomized clinical trial, physicians reported a higher median score for Hi-VNI Technology than NIPPV for patient comfort, ease of use, clinical response and need for monitoring, which we believe is due to properly conditioned medical gases being delivered through a small-bore nasal interface that does not completely cover the patient's nose and mouth. While using our products, patients can eat and drink, talk with their caregivers and loved ones, take oral medications and may remain ambulatory. For parents with infants in the NICU, our product allows more direct skin-to-skin contact between the parents and their babies.

- ***Reduced risk of pressure ventilation related side effects.*** In addition to improving overall patient comfort and ability to communicate, we believe our Precision Flow systems address other negative side effects caused by pressure ventilation and tight-fitting masks. These potential side effects include facial skin pressure ulcers, lung injury, claustrophobia, patient anxiety and risk of vomiting and aspiration.
- ***Facilitation of patient admissions to lower intensity, lower cost and less capacity-constrained care settings.*** As we believe our Precision Flow systems are more easily tolerated by patients, the monitoring requirements may be lower, which may increase the likelihood that a patient can be admitted to a general care floor, step-down unit or discharged home from the ED. Patients who are placed on NIPPV in an ED are often admitted to an ICU. In comparison, in a multicenter utilization study we sponsored that included 128 patients with respiratory distress treated in emergency rooms with Hi-VNI Technology, the physicians' perception was that 54% of the patients could be transferred to general care floors as opposed to being admitted to the ICU. An independent third-party study published in the June 2005 issue of *Critical Care Medicine* determined the average cost for a typical three day stay in the ICU in the United States was $13,347. The cost increased by an average of 47% to $19,558 when the patient required mechanical ventilation.
- ***Clinician workflow benefits, including easier administration and reduced patient monitoring.*** As the patient monitoring requirements may be lower than NIPPV, our Precision Flow systems may improve clinician and hospital workflow. Additionally, unlike conventional humidified high flow oxygen delivery devices, our Precision Flow systems can be connected directly to standard nurse call systems found in most hospitals. Connecting to the nurse call systems allows the nursing staff to be immediately alerted to alarms indicating that the patient may not be obtaining optimal therapy. Our Precision Flow Hi-VNI and Precision Flow Plus systems can also be connected to an electronic medical record, or EMR, system to record the delivered flow rate, temperature, and percent oxygen. These accessories help reduce the time clinicians need to spend with a single patient and enable them to have more time to see other patients.

We believe we can replace NIPPV as the standard of care for treating respiratory distress patients who require non-invasive ventilatory support and who are capable of spontaneously breathing. The table below highlights the key advantages of Hi-VNI Technology over NIPPV.

**Advantages of Hi-VNI Technology over NIPPV**

| | |
|---|---|
| **Patients** | • Potential opportunity for reduced patient monitoring<br>• Mask-free<br>• Facilitates ability to eat, drink, talk, participate in care and take oral medications<br>• Enhanced patient comfort<br>• Facilitates skin-to-skin care ("kangaroo care" for infants) |
| **Clinicians** | • Fewer adverse side effects<br>• Improved workflow<br>• Potential opportunity for reduced patient monitoring |
| **Hospitals** | • Potential to reduce ICU admission rate<br>• Improved workflow<br>• Lower capital investment |

***Overview and Benefits of our Oxygen Assist Module***

Our Oxygen Assist Module is a module for use with most versions of our Precision Flow systems, designed to be used with Hi-VNI Technology to help clinicians maintain oxygen levels within a tight SpO2 range. The Oxygen Assist Module adjusts delivered FiO2 in response to SpO2 readings captured by a standard pulse oximetry probe. We initiated a limited release of our Oxygen Assist Module to certain United Kingdom accounts in February 2020 after we received the CE Mark on January 30, 2020, and we may expand that limited release into certain European accounts during the second quarter of 2020.

We believe our Oxygen Assist Module has the potential to address the key limitations of utilizing manual control to maintain oxygen levels, particularly neonates, within a tight SpO2 range, and provides the following principal benefits to hospitals, patients and providers:

- Allows reliable realization of SpO2 target;
- Assists staff in maintaining targeted SpO2 range, including during stress, movement and, with neonates, feeding;
- May allow nurses to spend more time with patients and parents and less time changing settings;
- Allows for further evaluation of consequences of selected SpO2 targeted range, including clinical indications, outcomes, and workflow improvement; and
- Allows for the use of the Precision Flow system to provide respiratory support and its attendant benefits, including facilitation of cuddling and kangaroo care with neonates.

The Oxygen Assist Module is not an SpO2 monitor and does not eliminate the need for separate and independent patient monitoring.

**Our Market Opportunity**

Based on our internal estimates, there are over 12 million patients per year who experience respiratory distress that could benefit from our Hi-VNI Technology. According to U.S. Department of Health & Human Services data, in the United States, there were over four million patients treated for respiratory distress in 2014 and we estimate there are over eight million patients per year treated for respiratory distress in select international markets including, but not limited to, the United Kingdom, Germany, Turkey, Brazil, Mexico and Japan. We believe that our total addressable market for Hi-VNI Technology is $1.5 billion per year.

We calculated our total addressable market for Hi-VNI Technology based on (i) the 12 million patients per year who experience respiratory distress between the United States and select international markets, (ii) our average selling price of the Precision Flow systems capital units and single-use disposables and (iii) a five-year replacement cycle for the capital units. We expect our total addressable market to increase in the future due to an aging population, a growing prevalence of heart failure and COPD. The prevalence of heart failure is expected to grow 46% from 2012 to 2030, while WHO expects the number of deaths from COPD to increase 30% in the next 10 years. Our product supports neonatal and pediatric patients, as well as patients in EDs, ICUs, general care floors and long-term acute care hospitals.

***Hospitals: Emergency Departments***

EDs are the gateway to the hospital in the United States. Over 50% of hospital admissions enter the hospital through the ED. Patients in the ED may not have a clearly defined diagnosis until later in their hospital stay and the goal is to treat the symptoms of respiratory distress, rapidly stabilize patients, and move them out of the ED for treatment of their underlying condition. EDs place value on efficient workflow, minimizing patient wait time, and enabling the best clinical and economic post-ED outcome. Patient satisfaction around ED visits can impact reimbursement rates, hospital ratings, and community reputation and therefore patient choice. Technologies that can address patients' clinical needs without requiring admission to the ICU may be viewed favorably by patients and may help hospitals manage the overall flow of patients. Hi-VNI Technology is currently available in over 500 of the approximately 5,000 EDs in the United States.

***Hospitals: Intensive Care Unit and General Care Floor***

ICUs are often specialized for neonatal, pediatric, medical, and post-surgical patients. However, in all of these ICU areas there are patients requiring respiratory support. The goal of the ICU is to treat acute symptoms and stabilize patients, allowing them to be treated on a less expensive and less capacity-constrained general care floor or step-down unit. Reimbursement for many diagnoses is generally capped by admission diagnosis, so it is in a hospital's best interest to minimize the amount of time a patient spends in the expensive ICU setting, and thus, reduce the cost of care. While some hospitals allow patients on NIPPV support to be treated on a general care floor or step-down unit, most still require the higher intensity ICU environment.

***Hospitals: Neonatal Care Unit***

The neonatal ICU, or NICU, is the location for babies born prematurely or with medical issues that require intensive monitoring and support. Since the lungs develop late in gestation, the most significantly premature babies require extended pulmonary support. NICUs are classified as Level I, Level II or Level III, with Level III NICUs serving as referral centers that care for the sickest and most premature babies. Clinical outcome is paramount in NICUs, and significant emphasis is also placed on decreasing length of stay and overall patient and family satisfaction.

The traditional mode of NIPPV respiratory support in the NICU is nasal continuous positive airway pressure, or nCPAP. nCPAP is an effective tool for treating respiratory distress but carries an increased risk of pressure ulcers, formation of air pockets outside of the lungs and gastric distention. nCPAP typically requires a mask and large bore tubes that blocks the face of the patient and severely limits the ability of parents to hold or bond with their child. The American Academy of Pediatrics recommends that Level II NICUs only provide assisted ventilation on an interim basis until the infant's condition either soon improves or the infant can be transferred to a higher-level facility better suited to handling increasingly complex cases, in part due to the availability of pediatric medical subspecialists, pediatric surgical respiratory support, and physiologic monitoring equipment. This can result in newborn babies spending their entire hospitalization far away from home, increasing the cost to the medical system and creating economic and emotional challenges to patients and families. Hi-VNI Technology is currently available in over 400 of the approximately 1,100 NICUs in the United States.

***Long-Term Acute Care Hospitals***

Long-term acute care hospitals, or LTACHs, serve patients with complex needs requiring longer hospital stays and highly specialized care. LTACHs are designed for patients who need intense, extended care for more than 25 days. Many patients admitted to LTACHs arrive directly from the ICU of traditional hospitals and require ventilator support. Similar to the ICU setting, reimbursement in LTACHs and in the acute space in general is capped by admission diagnosis. As LTACHs are focused on maintaining or lowering their overall costs per treated patient, a therapeutic approach that could keep patients from going on mechanical ventilation or that could allow patients to be weaned off mechanical ventilation more quickly and efficiently may be viewed favorably by LTACH administrators in charge of managing the business. Hi-VNI Technology is currently available in over 190 of the approximately 400 LTACHs in the United States.

**Our Product Portfolio**

***Precision Flow Systems Family***

We currently offer four versions of our Precision Flow systems: Precision Flow Hi-VNI, Precision Flow Plus, Precision Flow Classic and Precision Flow Heliox. Our Precision Flow systems include a capital unit, a single-use disposable and a nasal interface. The capital unit contains all the electronic components and the input gas controls that enable the delivery of breathing gas at a precise level of oxygenation at flow rates, controlled by the operator, ranging from 1 to 40 liters per minute. All of our Precision Flow versions are integrated systems that provide precise user control of temperature, air flow and percentage oxygen through a simple one-button interface. Setup time, including warm-up time, for all of our Precision Flow versions is less than five minutes and alarms are incorporated into the system to alert the operator to disruption of respiratory support. All four versions are also mounted on a roll stand pole for easy transfer, use and visualization of the displayed settings. All four versions are easy to set up and require little support to operate beyond changing sterile inhalation water bags as needed.

The Precision Flow Hi-VNI system was fully launched in February 2019. When compared to the Precision Flow Plus, which was launched in April 2017 and today is currently sold in the United States and a limited number of international markets, the Precision Flow Hi-VNI system includes incremental hardware and software updates to improve the reliability and ease of manufacture and to comply with the Electromagnetic Compatibility or EMC 4th Edition requirements for medical devices. The primary change was to limit the maximum temperature to 39 degrees Celsius. As with the Precision Flow Plus, the Precision Flow Hi-VNI system offers connectivity to a hospital's nurse call system to alert the staff to disruption of the patient's respiratory support and/or to most hospitals' EMR systems to record the user selected and current delivered flow rate, temperature, percent oxygen, and the status of the supply gas connections and water supply as well as any fault codes. Similar to both the Precision Flow Plus and the Precision Flow Classic, which preceded the Precision Flow Plus, the Precision Flow Hi-VNI system includes Hi-VNI Technology.

The Precision Flow Heliox also includes the same Hi-VNI Technology as the other Precision Flow versions and is also able to precisely deliver heliox gas. As with the Precision Flow Classic, the Precision Flow Heliox does not offer connectivity to a hospital's nurse call system or EMR system.

The single-use, disposable component of our Precision Flow systems has two parts: (1) the disposable patient circuit, or DPC, which includes all of the components that generate the temperature-controlled humidified breathing gas, including the VTC and (2) the triple-lumen delivery tube which ensures the heated, humidified gas is delivered from the DPC to the patient at constant temperature and humidification level. We also sell a series of small-bore nasal interfaces and adapters. The interfaces we offer come in a variety of sizes, ranging from premature infants to adults, allowing clinicians to select an interface that blocks less than half of the external opening of each nostril, thereby maximizing the technology's ability to flush the anatomical dead space.

**Components of the Precision Flow Plus System**

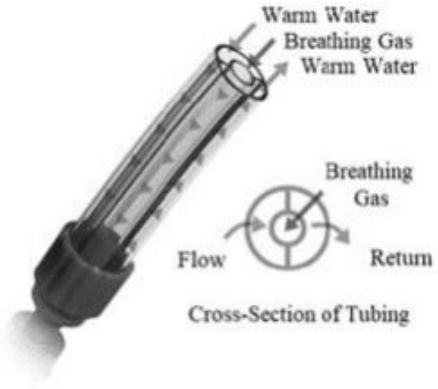
**Capital Unit**

**Disposable Patient Circuit**

**Disposable Patient Circuit Components**

**Vapor Transfer Cartridge**

**Delivery Tube**




***Companion Products and Enhancements***

We have launched companion products that facilitate clinical use and enable rapidly growing market acceptance and expansion. These products include (i) the Vapotherm Transfer Unit 2.0, which allows patients to be transferred between care areas within the hospital or ambulate while on therapy, (ii) the Q50 compressor, which provides a compact, relatively low noise, low cost source of compressed air necessary to run the Precision Flow systems in areas of the hospital without access to compressed air outlets built into the wall, (iii) the aerosol aeroneb adaptor, which is designed to facilitate delivery of ultrasonic aerosolized medication, and (iv) a tracheostomy adaptor that simplifies the connection of the Precision Flow systems to a tracheostomy collar used to wean patients off mechanical ventilation. Specialized capital units and disposable products also enable the delivery of specialized nitric oxide and heliox breathing gases. In January 2020, we also fully launched in the United States a new lightweight ProSoft cannula that is designed to provide gentle contact with the skin and an aerosol disposable patient circuit that is designed to streamline the provision of intermittent and continuous aerosol nebulization by limiting condensate management.

In addition, we have product enhancement projects ongoing at any point in time. These enhancements incorporate customer feedback with the goal of improving the patient and caregiver experience.

***Market Expanding Products***

We initiated a limited release of our Oxygen Assist Module to certain United Kingdom accounts in February 2020 and we may expand that limited release into certain European accounts in the second quarter of 2020. We intend to fully launch the Oxygen Assist Module commercially throughout the United Kingdom and Europe by the end of 2020, at which time we believe we will begin generating revenue from the product. The Oxygen Assist Module helps clinicians maintain oxygen levels within a target range by simplifying and automating adjustments to the Precision Flow systems' delivery of oxygenated breathing gases based on feedback provided by oxygen levels in the patients. Additionally, we are continuing to engage with the FDA on the possibility of obtaining approval for an Investigational Device Exemption, or IDE, neonatal clinical study of our Oxygen Assist Module in the United States.

We are also working on developing our next generation Hi-VNI Technology product, which is designed to provide high velocity nasal insufflation using a portable device, removing the requirement for access to built-in wall air outlets. Removing the requirement to be tethered to built-in wall air outlets will enable the next generation Hi-VNI Technology product to provide high velocity nasal insufflation to patients in other areas of the hospitals, LTACHs and SNFs. We believe that the next generation Hi-VNI Technology product may have the potential to be adopted in the future for applications in ambulance transport and in the homes of patients requiring non-invasive ventilatory support. On October 10, 2019 we received 510(k) clearance from the FDA on the first iteration of our next generation Hi-VNI Technology product. We currently anticipate the first patient use of this product by the end of 2020.

**Clinical Results and Studies and Economic Data**

We have a compelling body of clinical studies and economic data that supports the use of the Precision Flow Classic, which uses Hi-VNI Technology, for treating respiratory distress and providing non-invasive ventilatory support. Maintaining an ongoing cadence of clinical study and economic data publications is an important component of our strategy, including both Vapotherm-sponsored research and providing grants for investigator-initiated research.

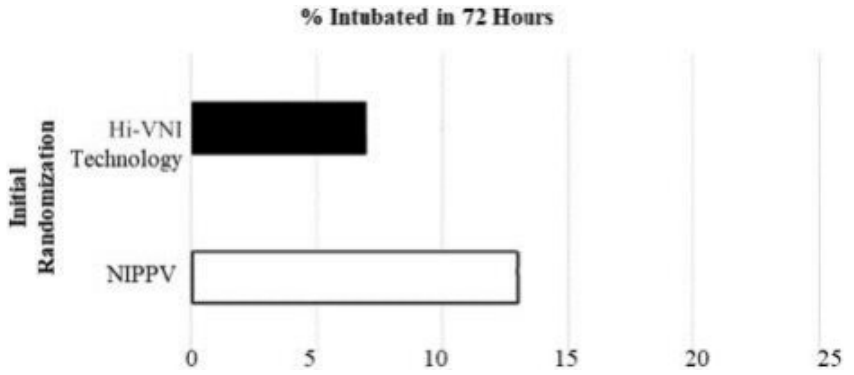
***Hi-VNI Technology Compared to NIPPV***

A significant body of clinical studies across multiple patient populations has validated Hi-VNI Technology as a safe and effective alternative to NIPPV. In the adult population, we sponsored a 204 patient (100 NIPPV patients and 104 Hi-VNI Technology patients), multisite randomized controlled trial in the ED, which was published in the July 2018 issue of *Annals of Emergency Medicine*. Patients in respiratory distress were recruited with the need for non-invasive ventilatory support in the ED. Of the patients who were enrolled in the study, 65 were suffering from hypercapnia, the inability to efficiently clear carbon dioxide from the respiratory system. The primary outcome measure was respiratory failure requiring intubation, the insertion of a plastic tube into the trachea to maintain an open airway for mechanical ventilation, within 72 hours of initiation or clinical decision to cross-over to the alternative therapy. This study concluded that high velocity nasal insufflation delivered with Hi-VNI Technology is non-inferior to NIPPV in preventing patients from being intubated and receiving mechanical ventilation.

Patients were recruited with the need for non-invasive ventilatory support and followed for 72 hours. The primary outcome measure was respiratory failure requiring intubation within 72 hours of initiation or clinical decision to cross-over to the alternative therapy. The outcome showed Hi-VNI Technology was non-inferior to NIPPV. The following chart conveys the rates of failure resulting in intubation for those randomized to Hi-VNI Technology and NIPPV. There was no statistically significant difference between the two.

**Rate of intubation in a 204-patient, multicenter randomized clinical trial of ED patients with respiratory distress.**

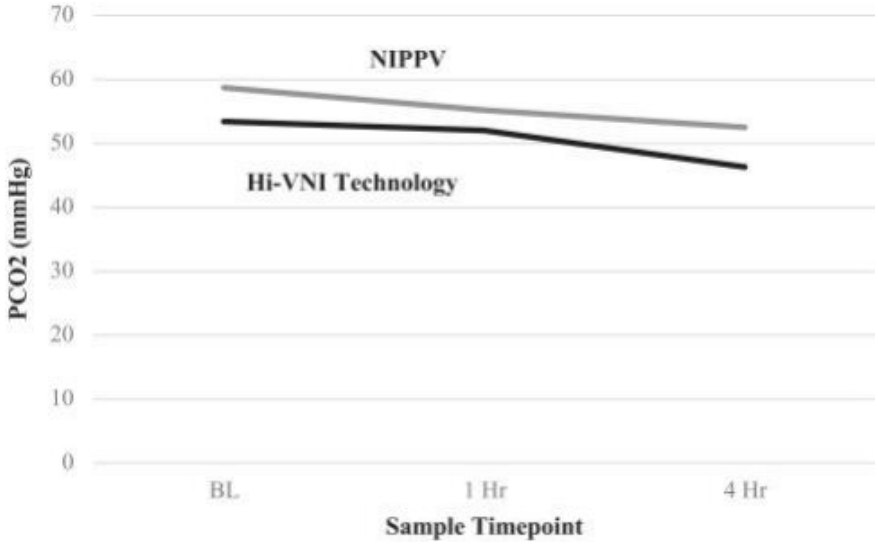
**Rate of Intubation**




Secondary outcomes included monitoring of vital signs, oxygen and carbon dioxide in the blood, and patient reports of their perception of shortness of breath were monitored during the first four hours of therapy, and Hi-VNI Technology performed as well as NIPPV during this period. The important measure of the effect of the therapy on providing ventilatory support is blood carbon dioxide and how that changes over time. Elevated blood carbon dioxide levels will generally decline over time when a patient receives adequate ventilatory support. Use of both Hi-VNI Technology and NIPPV led to similar decreases in carbon dioxide levels within the blood.

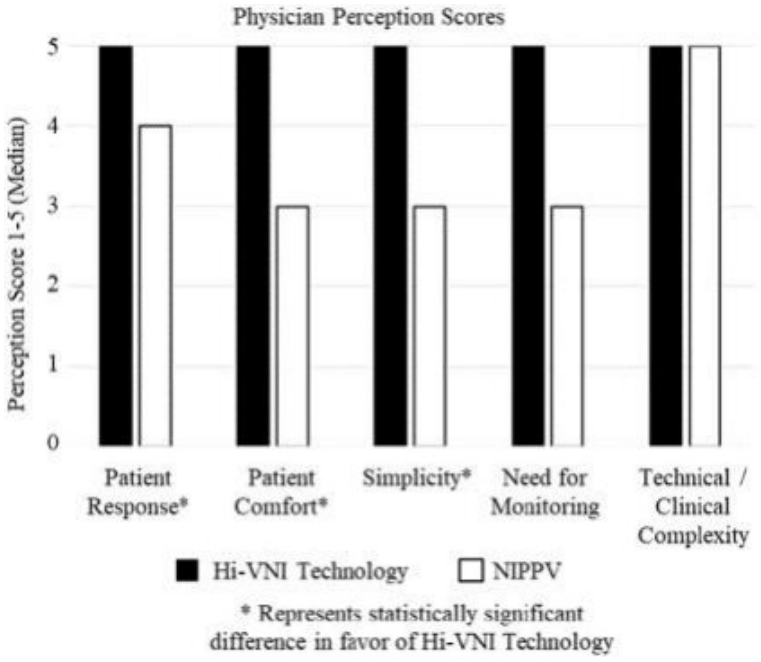
The chart below demonstrates the changes observed in blood gas values for both Hi-VNI Technology and NIPPV therapy. Both begin at baseline with elevated carbon dioxide values, and both drop at a similar rate over time, at one hour and four hours of therapy.

**Blood carbon dioxide levels over time**




The clinicians involved in the trial were asked for their perception of the various therapies. The clinicians reported a higher median score for Hi-VNI Technology than NIPPV for patient comfort, ease of use, clinical response and need for monitoring. The clinicians reported the same median score for Hi-VNI Technology and NIPPV for technical/clinical complexity. The authors also concluded that patients treated with Hi-VNI Technology can more easily communicate, receive oral medications, and eat without interruption of therapy, which are limitations of NIPPV.

**Median clinicians' perception of Hi-VNI Technology to NIPPV on a scale of 1 to 5 where 5 represents the best score**




In February 2018, the *NEJM Journal Watch*, which reviews and summarizes medical research studies across 12 specialties, concluded after reviewing our Company-sponsored ED study described above that Hi-VNI Technology is easier to set up than NIPPV. Further, the *NEJM Journal Watch* noted that Hi-VNI Technology has the potential to replace NIPPV in EDs, ICUs and ambulances.

Subgroup analyses of these data have been performed and were presented from the podiums at the American Thoracic Society congress and the Society for Academic Emergency Medicine in 2018. 65 patients among the 204 in this study were diagnosed with significant hypercapnia and specifically evaluated. The ability of Hi-VNI Technology to adequately provide ventilatory support is particularly important in this population. This subgroup analysis showed that 6% of the Hi-VNI Technology patients and 16% of the NIPPV patients required intubation within the first 72 hours of care after admission, with comparable ability to reduce carbon dioxide levels over time. They concluded that Hi-VNI Technology provided ventilatory support similar to NIPPV in patients presenting with hypercapnic respiratory distress. Another sub-group analysis was performed on patients from the study presenting with acute decompensated heart failure. This analysis of 42 patients from the primary ED study demonstrated comparable results between Hi-VNI Technology and NIPPV. The results from this subgroup analysis suggest that physicians may use Hi-VNI Technology when NIPPV fails or is not tolerated by patients in the ED.

Hi-VNI Technology was also observed in a third-party study published in the May 2013 issue of the *Journal of Pediatrics* to have similar efficacy when compared to nCPAP in a randomized controlled trial of premature infants who were receiving non-invasive ventilatory support after being removed from intubation, or extubation. nCPAP is the standard non-invasive therapy for management of respiratory distress in neonates in the NICU. nCPAP is administered using a tight-fitting nasal plugging cannula and delivers pressure to the lungs. It is efficacious, but it is also associated with trauma to the face of the baby, pressure and volume-related complications to the chest, and limitation of access to both parents and caregivers to maintain close contact with the newborns. Hi-VNI Technology produced similar rates of extubation failure as the standard of care nCPAP, and significantly reduced nasal trauma.

Additionally, Hi-VNI Technology was observed in a third-party study published in the May 2016 issue of *JAMA Pediatrics* to be non-inferior to NIPPV as a primary respiratory support therapy in a randomized controlled clinical trial of premature newborn infants with respiratory distress syndrome. In this trial, 316 infants were randomized to Hi-VNI Technology or NIPPV. The primary outcome of the trial was the number of patients who required intubation and mechanical ventilation within 72 hours, and there was no significant difference seen between Hi-VNI Technology and NIPPV. No significant differences in other measures such as the length of time on respiratory therapy, infection rates or other prematurity-associated complications such as bronchopulmonary dysplasia, a disease in newborns caused by destruction of lung tissue, were reported.

The results from an independent clinical trial of Hi-VNI Technology versus NIPPV in 76 preterm infants published in the May 2015 issue of *Pediatric Pulmonology* similarly suggest that Hi-VNI Technology is non-inferior to NIPPV. These trials support the use of Hi-VNI Technology as an alternative to nCPAP and NIPPV for primary and post-extubation support of neonates in respiratory distress.

***Economic Cost Savings Data***

An independent third-party study published in the June 2005 issue of *Critical Care Medicine* determined the average cost for a typical three day stay in the ICU in the United States is $13,347. The cost increased by an average of 47% to $19,558 when the patient required mechanical ventilation. Treatment of patients with Hi-VNI Technology can impact admission and placement of patients due to the lower complexity of Hi-VNI Technology as compared to NIPPV. This is dependent on the individual sites, which often require admission to the high cost and resource-constrained ICUs if NIPPV is initiated on the patient. In a multicenter utilization study, we sponsored published in the Winter 2015 issue of *Respiratory Therapy* including 128 patients with respiratory distress treated in emergency rooms with Hi-VNI Technology, treating physicians perceived that 54% of patients could be admitted to the general care floor, as opposed to the ICU. This finding is exemplified by a single-patient case study report from Athens Regional Medical Center. In this report, a patient with end-stage COPD who was well-known to that facility had recently been discharged from the hospital following a three day stay in the ICU where the patient was intubated and mechanically ventilated. Upon a subsequent arrival in the ED with severe difficulty breathing, this patient was treated using Hi-VNI Technology and within 44 minutes her respiratory rate had decreased from 36 to 20 breaths per minute. Blood measurements later confirmed a normalization of pH, reduction in carbon dioxide, and maintenance of oxygenated levels of hemoglobin. The patient was kept overnight and discharged the following day. We believe the less intensive nature of the Hi-VNI Technology permitted the physician to direct the patient to the general care floor, rather than the ICU, in this situation resulting in a savings of an estimated $3,750 for this hospital (estimated $4,500 cost for a three day stay in the ICU versus an estimated $750 cost for a one day stay on the general care floor).

Additionally, patients who are intolerant of NIPPV devices are often sedated and potentially intubated and escalated to mechanical ventilation, an invasive procedure that often results in increased care costs, increased lengths of stay, ventilator dependence, and increased morbidity and mortality. Because patients who are placed on Hi-VNI Technology are no more likely to fail to intubation than NIPPV patients and Hi-VNI Technology may be more easily tolerated, its utilization has the ability to reduce the number of NIPPV intolerant patients who otherwise would have been intubated. Therefore, in addition to increased patient benefits due to potentially avoiding intubation for patients who are intolerant of the masks associated with NIPPV, there may be substantial savings to the healthcare system for each patient that can be successfully treated with Hi-VNI Technology.

Studies have shown that reducing the duration of mechanical ventilation days is an important element in reducing the potential for ventilator-associated consequences, including pneumonia, a life-threatening complication associated with mechanical ventilation. One role LTACHs play is to help wean patients from their dependence on mechanical ventilation. Gaylord Hospital, a LTACH, presented at the 2017 National Association of Long Term Hospital conference that their adoption of Hi-VNI Technology helped them achieve an average reduction of four days of mechanical ventilation per patient, yielding an annual average cost savings for that facility of $394,000 between 2012 and 2015.

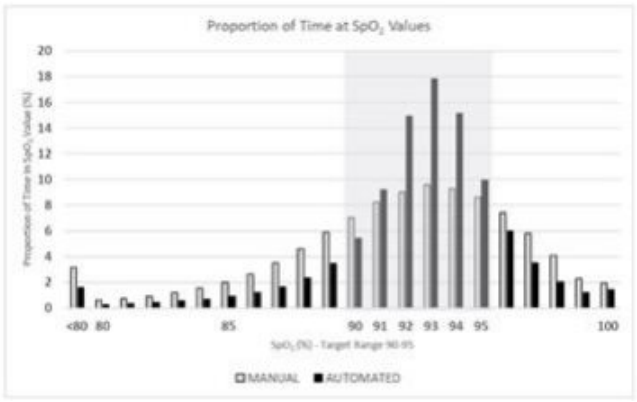
***Oxygen Assist Module Prototype Study***

Our Oxygen Assist Module helps clinicians maintain oxygen levels within a target range by simplifying and automating adjustments to most versions of our Precision Flow systems' delivery of oxygenated breathing gases. The adjustments are based on the module's continuous readings of a patient's oxygen from a standard pulse oximetry probe. In November 2018, the *Archives of Disease in Childhood: Fetal & Neonatal edition* published the results of our sponsored prospective, two-center, order-randomized cross-over study performed at two NICUs in the United Kingdom, designed to evaluate the performance of a prototype of our Oxygen Assist Module technology as a module to our Precision Flow Plus system. The Oxygen Assist Module is referred to in the study as the IntellO2.

The target $SpO_2$ range set in this study was 90-95% in preterm babies being supported by Hi-VNI Technology. Babies were randomized to receive 24 hours of either manual control or automatic control using the Oxygen Assist Module. After the first 24 hours, the babies were crossed over to the alternative therapy for another 24 hours. The primary outcome measure was percent of time spent within the target $SpO_2$range. Secondary outcomes included the overall proportion and durations of $SpO_2$ within specified hyperoxemic and hypoxemic ranges, and the characteristics of the times within and outside $SpO_2$ target range. Data were analyzed from 30 preterm infants with median gestation at birth of 26 (24–27) weeks, age during the study of 29 (18–53) days and study weight 1080 (959–1443) g.

When using the Oxygen Assist Module, clinician performance in maintaining $SpO_2$ within the target $SpO_2$ range was significantly greater proportion of the time than during manual control alone, while at the same time requiring significantly fewer manual adjustments to the equipment. The median target $SpO_2$ range was achieved 80% of the time on automated (Oxygen Assist Module) control compared with 49% under manual control. In addition to the greater proportion of time in the target range, there were also fewer episodes of transient severe hypoxemia (defined as $SpO_2$ below 80% lasting at least 60 seconds) under automated control compared with manual control. There were no differences in the number of episodes per hour of $SpO_2$ above 98% between the study arms, but the average episode duration and the total percentage of time spent above the $SpO_2$ target range was significantly lower under Oxygen Assist Module automated control as compared to manual control.

The chart below depicts a composite SpO2 histogram of all patient data (n=30) with paired bars as automated control (white) and manual control (black). The frequency of SpO2 values denotes the proportion of total time (%) spent at each SpO2, with aggregated SpO2 values <80%. The target SpO2 range for babies receiving oxygen (90%–95%) is illustrated in the blue outlines. The chart is based on graphic found in the aforementioned November 2018 edition of the *Archives of Disease in Childhood: Fetal & Neonatal edition*.




**Sales and Marketing**

As of December 31, 2019, our sales organization consisted of approximately 100 full time employees serving our U.S. market and 57 sales territories. We also have 10 full time employees serving our U.K. market and 6 sales territories. Additionally, we have 11 individuals serving select additional international markets. In 2019, 76.0% of our revenue was derived in the United States and 24.0% was derived outside the United States. No single customer accounted for more than 10% of our revenue.

***Commercial Activities within the United States***

We work to grow the sales of our disposable products by increasing the installed base of our Precision Flow systems. We utilize a direct sales organization in the United States that leverages numerous call points within the hospital, including physicians, respiratory therapists and nurses. Our sales team is focused on building relationships with clinicians across care settings, including EDs and adult, pediatric and neonatal ICUs, enabling our products to follow patients through the care continuum. We offer different options to our hospital customers for acquiring Precision Flow capital units, ranging from the purchase of the Precision Flow capital units with payment in full at the time of purchase, to financed purchases of the Precision Flow capital units, to bundled discounts involving the placement of Precision Flow capital units for use by the customer at no upfront charge in connection with the customer's ongoing purchase of disposable products.

We have structured our sales and clinical support team with specialized roles to sell our Precision Flow systems and single-use disposables, while delivering customer support and medical education on an ongoing basis. Our field sales representatives are responsible for identifying key customer prospects, educating them on the value of our Hi-VNI Technology, gaining their commitment for acquiring our capital units and introducing our clinical educators.

Our clinical educators enhance the experience for customers and help facilitate adoption. We established a medical education department that develops and delivers physician-to-physician, Company-sponsored education events, and sponsors continuing medical education programs focused on addressing respiratory distress.

Our customer service and technical support team is responsible for addressing maintenance, repairs and general product and technical questions to help ensure uninterrupted patient treatments. We also use an inbound digital marketing campaign to drive leads and accelerate sales. We leverage the internet, social media, and email channels to increase brand awareness and educate customers. Data and analytics drive our decision making and help us hone our messaging and strategies. Educated and interested potential customers convert to sales prospects on our website and all leads integrate with our CRM system.

***Commercial Activities Outside of the United States***

We conduct our international business in the United Kingdom through a direct sales organization operated by our wholly owned subsidiary, Solus Medical Limited ("Solus Medical"). We conduct our remaining international business through a distributor model, partnering with 37 distributors in 42 countries around the world. We focus our efforts on our most established and fastest growing markets, including the United Kingdom, Germany, Brazil, Mexico, Turkey, and Japan. We have directly employed or retained through professional employment organizations 11 individuals to support our distributors in several of these key markets. Additionally, in the United Kingdom, our subsidiary Solus Medical now has 10 full time commercial employees. As in the United States, our direct sales team in the United Kingdom and our distributors around the world work to grow the sales of our disposable products by increasing the installed base of our Precision Flow Systems. Our direct sales team in the United Kingdom and our distributors around the world work to offer different options to our customers for acquiring Precision Flow capital units as appropriate on a country by country basis, ranging from the purchase of the Precision Flow capital units with payment in full at the time of purchase, to financed purchases of the Precision Flow capital units, to bundled discounts involving the placement of Precision Flow capital units for use by the customer at no upfront charge in connection with the customer's ongoing purchase of disposable products. We leverage our digital marketing platform abroad to educate our international clinicians, focusing primarily in the United Kingdom. We continue to evaluate market opportunities outside of the United States for business expansion.

**Reimbursement**

Payment for patient care in the United States is generally made by third-party payors, including private insurers and government healthcare programs. The reimbursement from third-party payors for patients that require Hi-VNI Technology is typically intended to cover the overall cost of treatment, including the cost of our devices used during the procedure as well as the overhead cost associated with the facility where the procedure is performed. We do not directly bill any third-party payors and receive payment from the hospital or providers for our devices.

Reimbursement for hospital services, including the cost of our devices, during an inpatient stay generally is made to the healthcare provider under a prospective payment system that is determined by a classification system known as Diagnosis Related Groups, or DRGs. A DRG is a statistical system of classifying any inpatient stay into groups for the purposes of payment using a number of factors including, among other things, the principal diagnosis, major procedures, discharge status, patient age and complicating secondary diagnoses. DRGs are used in both acute and chronic care settings and employed by both private insurers and government payors. Rather than paying the hospital or provider for what it spent caring for a patient, payors pay a fixed amount based on the patient's DRG. Similar reimbursement methodologies that bundle the cost of our devices into a provider's payment also exist for services provided to patients in the ED and out-patient settings.

**Research and Development**

As of December 31, 2019, our research and development team consisted of 16 individuals, including mechanical, electrical, software, biomedical, and plastic engineers. For the years ended December 31, 2018 and 2019, we incurred research and development expenses of $8.8 million and $13.4 million, respectively.

Maintaining a strong cadence of new product introductions is an integral part of our strategy. We initiated a limited release of our Oxygen Assist Module to certain United Kingdom accounts in February 2020 and we may expand that limited release into certain European accounts in the second quarter of 2020. We previously entered into an agreement with a third party for a perpetual, exclusive, world-wide license to certain intellectual property related to the Oxygen Assist Module for the delivery of non-invasive ventilatory support. Pursuant to the agreement, we will pay a royalty starting on the date of the first commercial sale of the Oxygen Assist Module, which we anticipate to occur by the end of 2020, and continuing for a ten year term from the first commercial sale equal to 10% of the first $3.0 million of Oxygen Assist Module revenue, 5% of the next $6.0 million of Oxygen Assist Module revenue, and 2% of any additional Oxygen Assist Module revenue until the end of the ten year term. We also license the pulse oximetry technology utilized with the Oxygen Assist Module from other manufacturers.

Our pipeline of new products also includes our next generation Hi-VNI Technology. On October 10, 2019, we received 510(k) clearance from the FDA on the first iteration of our next generation Hi-VNI Technology product. We currently anticipate the first patient use of this product by the end of 2020.

In addition, we have sought and continue to seek to expand the FDA-cleared indications for Hi-VNI Technology. For instance, on April 10, 2018, the FDA granted our *de novo* request for an expanded indication to use with the Precision Flow Hi-VNI system, which incorporates Hi-VNI Technology. The expanded indication for use builds on the existing indication for delivering heated, humidified and oxygenated breathing gases by recognizing a mechanism of action, high velocity nasal insufflation, as well as adding an intended use, to augment breathing in spontaneously breathing patients suffering from respiratory distress in a hospital setting. Further, the expanded indication states this system does not provide the total ventilatory requirements for patients. The FDA also created a new classification regulation under which this system is currently the only product. The indications of our product are similar to NIPPV, but the therapy has a different mechanism of action, using velocity instead of pressure to provide ventilatory support for patients in respiratory distress.

**Competition**

The medical device industry is subject to rapid change from the introduction of new products and technologies and other activities of industry participants. We compete as a clinically validated alternative to NIPPV for treatment of patients who are suffering from respiratory distress.

As our product is capable of treating respiratory distress, including those suffering from low oxygen levels, as well as those who have historically required NIPPV because they were unable to flush retained carbon dioxide from their respiratory system, we consider our primary competition to be NIPPV manufacturers, including Philips Respironics. We also compete on a secondary basis with manufacturers of conventional heated humidified high flow oxygen delivery products, such as Fisher & Paykel Healthcare.

We believe that the primary competitive factors in the respiratory distress market are:

- product efficacy and ability to prevent intubation;
- product safety, reliability and durability;
- product ease of use and patient comfort;
- quality and volume of clinical evidence;
- product support and service;
- pricing and revenue strategies;
- technological innovation;
- effective marketing to and education of clinicians;
- sales force experience and access; and
- Company, product and brand recognition.

Other companies that offer treatments for respiratory distress against which we compete are larger businesses that have greater resources than we do. NIPPV is an established proven therapy and is currently better known to physicians, nurses and respiratory therapists, and it is currently considered the standard of care for treating patients with respiratory distress. However, we believe clinician awareness of Hi-VNI Technology is increasing.

**Intellectual Property**

As of December 31, 2019, we held more than 100 issued patents and more than 50 patent applications, totaling an active patent portfolio of over 150 filings granted or pending. These filings can be organized into four main categories representing our patent portfolio: Precision Flow, next generation system filings, Flow Rest, and various accessory technologies. In the United States, we hold ten issued patents for the Precision Flow family, six for the Flow Rest family (a legacy device), eight for the accessories (including the Oxygen Assist Module), and three for our next generation technology. The Precision Flow patents are expected to expire between March 2024 and March 2033, the Flow Rest patents are expected to expire between November 2026 and January 2033, and the accessories patents are expected to expire between December 2031 and August 2038. Additionally, we have six pending U.S. patent applications directed to our next generation technologies, three pending U.S. patent applications directed at our Precision Flow systems technology, two pending U.S. patent application directed to our Flow Rest technology and thirteen pending U.S. patent applications directed to accessories for the aforementioned technologies (including the Oxygen Assist Module). We maintain a strategic international patent portfolio primarily in the European Union, Australia, Japan and China. Since 2016, we have maintained and executed on deliberate innovation areas designed to sustain the continued growth of our patent portfolio to protect our proprietary technology from competitor use.

As of December 31, 2019, we have at least 11 trademark registrations with the U.S. Patent and Trademark Office, at least 2 trademarks applications pending with the U.S. Patent and Trademark Office, at least 14 trademarks with common law rights, and a wide range of international protection of its trademarks with a focus of increasing brand awareness and market penetration globally.

**Manufacturing and Supply**

We manage all aspects of product supply through our operations team based in Exeter, New Hampshire. We manufacture certain components of our Precision Flow systems in-house, but primarily rely on third-party suppliers to manufacture the majority of our Precision Flow systems' components. Outsourcing manufacturing reduces our need for capital investment and provides expertise and the capacity necessary to meet demand for our Precision Flow systems. We assess, qualify and select our suppliers with a view towards ensuring that our Precision Flow systems and their components are safe and effective, adhere to all applicable regulations, are of the highest quality, and meet our supply needs. Our quality assurance process monitors and maintains supplier performance through qualification and periodic supplier reviews and audits against the requirements of the FDA, the International Organization for Standardization and our own policies and procedures.

Certain components used in our Precision Flow systems are supplied by single source suppliers. Our suppliers manufacture the components they produce for us and test our components and devices to our specifications. We intend to maintain sufficient levels of inventory to enable us to continue our operations while we obtain another supplier if one or more of our single source suppliers were to encounter a delay in supply or end supply.

**Government Regulation**

Our 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 EEA. 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, efficacy, labeling, packaging, storage, installation, servicing, recordkeeping, premarket clearance or approval, import, export, 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 EEA governing clinical trials and the 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 process varies 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 FDA clearance of a 510(k) premarket notification, granting of a *de novo* request, or approval of an application for premarket approval, or PMA. 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 of 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. 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 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.

Our currently marketed nasal interfaces and VTU are classified as Class I medical devices, and our Precision Flow systems, including the single-use disposables and the Q50 Compressor are classified as Class II medical devices subject to 510(k) clearance.

***The 510(k) Process***

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, and for which a PMA is not required, a device that has been reclassified from Class III to Class II or Class I, or another commercially available device that was cleared through the 510(k) process. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data is sometimes required to support substantial equivalence.

After a 510(k) premarket notification is submitted, the FDA determines whether to accept it for substantive review. If it lacks necessary information for substantive review, the FDA will refuse to accept the 510(k) notification. If it is accepted for filing, the FDA begins a substantive review. By statute, the FDA is required to complete its review of a 510(k) notification within 90 days of receiving the 510(k) notification. As a practical matter, clearance often takes longer, and clearance is never assured. Although many 510(k) premarket notifications are cleared without clinical data, the FDA may require further information, including clinical data, to make a determination regarding substantial equivalence, which may significantly prolong the review process.

If the FDA agrees that the device is substantially equivalent to a predicate device currently on the market, it will grant 510(k) clearance to commercially market the device. If the FDA determines that the device is "not substantially equivalent" to a previously cleared device, the device is automatically designated under the FDCA as a Class III device. The device sponsor must then fulfill more rigorous PMA requirements, or can request a risk-based classification determination for the device in accordance with the *de novo* process, which is a route to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device.

After a device receives 510(k) marketing clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, will require a new 510(k) marketing clearance or, depending on the modification, a *de novo* grant or PMA approval. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k) (or a PMA) in the first instance, but the FDA can review any such decision and disagree with a manufacturer's determination. Many minor modifications today are accomplished by a manufacturer documenting the change in an internal letter-to-file. The FDA can review these letters to file during an inspection. If the FDA disagrees with a manufacturer's determination, the FDA can require the manufacturer to cease marketing and/or request the recall of the modified device until 510(k) clearance, *de novo* grant or PMA approval is obtained. In these circumstances, we may be subject to significant regulatory fines or penalties.

***De Novo Classification***

Medical device types that the FDA has not previously classified as Class I, II or III are automatically classified under the FDCA into Class III regardless of the level of risk they pose. The Food and Drug Administration Modernization Act of 1997 established a route to market for low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the "Request for Evaluation of Automatic Class III Designation," or the *de novo* classification procedure. This procedure allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA application. Prior to the enactment of the Food and Drug Administration Safety and Innovation Act of 2012, or FDASIA, a medical device could be eligible for *de novo* classification only if the manufacturer first submitted a 510(k) premarket notification and received a determination from the FDA that the device was not substantially equivalent to a legally marketed predicate device. FDASIA streamlined the *de novo* classification pathway by permitting manufacturers to request *de novo* classification directly without first submitting a 510(k) premarket notification to the FDA and receiving a not substantially equivalent determination. Under FDASIA, the FDA is required to classify the device within 120 days following receipt of the *de novo* application. If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. In addition, the FDA may reject the request if it identifies a legally marketed predicate device that would be appropriate for a 510(k) notification, determines that the device is not low to moderate risk, or that general controls would be inadequate to control the risks and special controls cannot be developed. After a device receives *de novo* classification, any modification that could significantly affect its safety or efficacy, or that would constitute a major change or modification in its intended use, will require a new 510(k) clearance or, depending on the modification, another *de novo* petition or even PMA approval.

***Clinical Trials***

Clinical trials are almost always required to support a PMA and are sometimes required to support a 510(k) submission. All clinical investigations of investigational devices to determine safety and effectiveness must be conducted in accordance with the FDA's IDE regulations which 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. 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 allowed to go into effect by the FDA and the study approved by the reviewing IRB(s), human clinical trials may begin at a specific number of investigational sites with a specific number of subjects as set forth in the study protocol. 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 review 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 or warrant the continuation of clinical trials. An IDE supplement must be submitted to, and allowed to go into effect 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, 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.

***Post-market Regulation***

After a device is cleared or approved for marketing, numerous and extensive regulatory requirements may continue to apply. These include but are not limited to:

- annual and updated establishment registration and device listing with the FDA;
- QSR requirements, which require manufacturers to follow stringent design, testing, control, documentation, complaint handling and other quality assurance procedures during all aspects of the design and manufacturing process;
- advertising and promotion requirements;
- restrictions on sale, distribution or use of a device;
- labeling and marketing regulations, which require that promotion is truthful, not misleading, and provides 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;
- the federal Physician Sunshine Act and various state and foreign laws on reporting remunerative relationships with health care customers;
- the federal Anti-Kickback Statute (and similar state laws) prohibiting, among other things, soliciting, receiving, offering or providing remuneration intended to induce the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as Medicare or Medicaid. A person or entity does not have to have actual knowledge of this statute or specific intent to violate it to have committed a violation;

- the federal False Claims Act (and similar state laws) prohibiting, among other things, knowingly presenting, or causing to be presented, claims for payment or approval to the federal government that are false or fraudulent, knowingly making a false statement material to an obligation to pay or transmit money or property to the federal government or knowingly concealing, or knowingly and improperly avoiding or decreasing, an obligation to pay or transmit money to the federal government. The government may assert that a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the false claims statute;
- clearance or approval of product modifications to legally marketed devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use;
- medical device reporting regulations, which require that a manufacturer report to the FDA if 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 there is a reasonable probability that the use of the device would cause a serious, adverse health consequence 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.

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 510(k) marketing clearance or PMA approvals of new products or modified products;
- withdrawing 510(k) clearances or PMA approvals that have already been granted;
- refusal to grant export or import approvals for our products; or
- criminal prosecution.

***Regulation of Medical Devices in the EEA***

There is currently no premarket government review of medical devices in the EEA (which is comprised of the 28 Member States of the European Union plus Norway, Liechtenstein and Iceland). However, all medical devices placed on the market in the EEA must meet the relevant essential requirements laid down in Annex I of Directive 93/42/EEC concerning medical devices, or the Medical Devices Directive. 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 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 which relate to sterility or metrology), a conformity assessment procedure requires the intervention of a Notified Body. Notified bodies are often separate entities and are authorized or licensed to perform such assessments by government authorities. The notified body would typically 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 EEA. Once the product has been placed on the market in the EEA, the manufacturer must comply with requirements for reporting incidents and field safety corrective actions associated with the medical device.

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 EEA member states. Clinical trials for medical devices usually require the approval of an ethics review board 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.

On April 5, 2017, the European Parliament passed the Medical Devices Regulation (Regulation 2017/745), which repeals and replaces the EU Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the EEA member States, the 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 Medical Devices Regulation, 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 Medical Devices Regulation will take effect on May 26, 2020. Once applicable, the new regulations will 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.

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;
- 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; and
- necessity of testing performed in country by distributors for licensees.

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

***Regulation of Medical Devices in China***

Depending on the product risk level, each imported medical device commercially marketed and distributed in China requires a notification to or a registration with China's National Medical Products Administration ("NMPA", formerly known as CFDA). Under the current Chinese Medical Device Regulation (State Council Order. #680, effective since 2017), medical devices are classified into one of three classes—Class I, Class II or Class III. Class I includes devices with lowest risks to patients, whose safety and effectiveness can be assured by general risk control mechanisms. Class I devices can be marketed in China through a notification to the NMPA. Class II includes devices with medium risks to patients and are under special control of the NMPA. Class III devices are those with high risks to patients, such as life-sustaining, life-supporting or implantable devices, and are under the most stringent regulatory control. Both Class II and Class III devices require a registration with the NMPA.

We plan to initiate a product registration process in China for our Precision Flow systems, VTU and nasal interfaces in 2020. Our Precision Flow systems, VTU and nasal interfaces, which provide ventilatory support to neonatal and pediatric patients, as well as patients in EDs, ICUs, general care floors and LTACHs, are likely to be classified as Class II or Class III device in China, subject to the NMPA's classification designation.

Before registering an imported Class II or Class III medical device with the NMPA, manufacturers are required to prepare the Product Technical Requirements (PTRs) that consist of performance specifications and testing methods specific to their products and in compliance with applicable Chinese device standards. Manufacturers must engage a NMPA-accredited laboratory to conduct an in-country type testing against the PTRs and applicable Chinese device standards. A type testing process typically takes 3-6 months or longer. Under the current medical device regulations, imported medical devices must first be approved for marketing in their country of origin. Manufacturers are obligated to provide the appropriate documents (e.g. CE Mark, 510(k) letter, approved Premarket Approval Application) showing that the device has been approved for marketing in a country where the manufacturer is incorporated or the manufacturing site resides.

All of imported Class II and III devices are required to conduct local clinical trials in China unless (i) they are exempted from clinical trials under the Clinical Trial Exemption List published by the NMPA from time to time or (ii) manufacturers can demonstrate "substantial equivalence" to a predicate device currently on the market. Clinical trials for some particular high risk devices are mandatory and need approval from the NMPA in advance. Clinical trials for other devices require a pre-notification to the NMPA. All registration trials must be approved by and conducted under the oversight of an Institutional Review Board, or Ethics Committee. Local clinical trials in China typically take 6-12 months or longer.

The NMPA, after receiving an application for registration, will review the application dossier and notify the applicant whether the application for registration is approved. The NMPA may require applicants to submit supplemental information (including clinical data and technical data) during its review. Applicants will be given 1 year to prepare and submit the required information. The NMPA's average process time for regulatory approval is 10-18 months for Class II devices and 12-24 months for Class III devices. Subject to specifics of a product, an approval process could take longer, and clearance is never guaranteed. The approval process could be as short as 6-10 months if the products are eligible for fast track or priority review. Fast track or priority review is usually granted by the NMPA to devices that are innovative, address urgent unmet clinical needs, or have significant clinical value.

After a device is approved by the NMPA for marketing, numerous and extensive regulatory requirements will apply post marketing authorization. These include but are not limited to:

- Completion of any post-approval studies that may be required by the NMPA upon its conditional approval; Renewal of the registration with the NMPA every 5 years since the initial registration;
- GMP compliance requirements, which require foreign manufacturers to follow stringent design, testing, control, documentation, complaint handling and other quality assurance procedures during all stages of the manufacturing process;
- Labeling, advertising and promotion requirements, which require that claims are truthful, non-misleading, and substantiated. Instructions for use should be clear to guide correct use of the products, and manufacturers are prohibited from unapproved or "off-label" uses;
- Medical device adverse event monitoring, reporting and re-evaluation obligations, which require a manufacturer to report to the NMPA if a device it markets may have caused or contributed to death or serious injury, would be likely to cause or contribute to death or serious injury, if malfunction were to recur; and
- Medical device recall obligations, which require that manufacturers to report to the NMPA any field corrections and product removals that are undertaken to reduce an unreasonable risk to health posed by the device or to remediate a violation of any applicable Chinese device standards, PTRs, or any applicable regulatory requirements that may present an unreasonable risk; the NMPA also has the authority to order a manufacturer to recall its product.

We will be subject to regular or unnoticed inspections and market surveillance by the NMPA and its local counterparts to determine continuous compliance with regulatory requirements. If the NMPA determines that we fail to comply with applicable regulatory requirements, it can take a variety of enforcement actions, which may result in any of the following sanctions:

- warning letters, corrective actions, fines;
- recalls, detention or seizure of our products, confiscation of illegal revenues;
- import alerts and bans;
- refusing to accept any future applications within a specific period of time;
- withdrawing any NMPA approvals that have already been granted; and
- Debarment of responsible persons from engaging in medical device-related business activities within a specific period of time.

The Chinese government is in the process of amending the current Medical Device Regulation, which is believed to be close to the final shape. The most recent draft amendment to the Medical Device Regulation echoes various regulatory reform initiatives unveiled by the NMPA in recent years with an aim to create a regulatory system that is conducive to device innovation. It reinforces post-approval compliance obligations and expects medical device marketing authorization holders to take primary responsibility for pre- and post-approval compliance. It significantly increases penalties for all kinds of illegal actions, and introduces a dual penalty system, subjecting both companies and individual responsible persons to sanctions. This legislative development may result in the acceleration or delay of certain regulatory clearance or approval for our products in China.

***Pricing, Contracting and Reimbursement***

We believe our products are priced consistent with their value. In order to obtain or maintain business in the competitive respiratory therapy market, however, we have historically had to offer various discounts directly to purchasers or indirectly to purchasers through group purchasing organizations ("GPOs") or integrated delivery networks ("IDNs"). We have recently expanded the use of product discount offerings related to placed capital arrangements for our Precision Flow systems. Such bundled discount offerings involve the placement of capital equipment for use by the customer at no upfront charge in connection with the customer's ongoing purchase of disposable products. In addition, consistent with an increasing emphasis in the medical device and broader healthcare industry on payment based on value (so-called value-based pricing), we may enter into contracts with customers that guarantee performance of our Precision Flow systems by refunding costs of disposables (or providing replacement disposables) used on patients if treatment does not achieve specific patient outcomes. In response to pressure from competition or customers, we may have to offer enhanced discounts or enter into additional value-based contracting arrangements, which may adversely affect our revenue.

Coverage and adequate reimbursement of our products (or services provided using our products) is critical to the success of our business. Sales of our products will depend, in part, on the extent to which our products (or services provided using our products) will be covered and adequately reimbursed by third-party payors, such as government-sponsored health programs and private health plans.

Our products are used in providing services and are often reimbursed by third-party payors as part of a global payment that covers all costs associated with providing that service. Healthcare providers that use our products may therefore be responsible for costs incurred in providing the service that exceed reimbursement. If our products are priced higher than competitor products, including products used to provide alternative treatments, and we are unable to demonstrate that our products are nonetheless cost-effective, we may encounter obstacles in obtaining or maintaining business.

Third-party payors are increasingly reducing reimbursements for clinical products and services. Within the United States and abroad, the containment of healthcare costs has become a priority of federal and state governments. Limits on reimbursement available from governmental or private third-party payors may reduce the demand for, or negatively affect the price of those products, and could significantly harm our business, results of operations, financial condition and cash flows.

***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 and state laws 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 and abuse.

U.S. federal health care fraud and abuse laws generally apply to our activities because our products are covered under federal healthcare programs such as Medicare and Medicaid or, in some instances, private insurance. The principal U.S. federal health care 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 health care program; (2) the False Claims Act, which prohibits the submission of false or otherwise improper claims for payment to a federally-funded health care program, including claims resulting from a violation of the Anti-Kickback Statute; and (3) health care fraud statutes that prohibit false statements and improper claims to any third- party payer. There are also similar state anti-kickback and false claims laws that apply to activities involving state-funded Medicaid and other health care programs as well as private third-party payors.

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 health care 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 meals to healthcare practitioners, could implicate the Anti-Kickback Statute and are not 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 health care 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 health care 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 health care goods and services could adversely affect our reputation, business, financial condition and cash flows.

To help ensure compliance with healthcare laws and regulations applicable to us, we have implemented a comprehensive compliance program based on the HHS Office of Inspector General's Seven Fundamental Elements of an Effective Compliance Program. We adhere to, and the compliance program incorporates, standards consistent with voluntary compliance code standards adopted by the medical device industry to promote compliance with the federal Anti-Kickback Statute. Despite our compliance program, we cannot be certain that we have always operated in full compliance with all applicable healthcare 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 EEA Member State legislation governing the advertising and promotion of medical devices. These laws may limit or restrict the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare professionals.

***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.

Within the United States, our operations may be affected by the Health Insurance Portability and Accountability Act of 1996 as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, collectively, HIPAA, which impose obligations on certain "covered entities" (healthcare providers, health plans and healthcare clearinghouses) and certain of their "business associate" contractors with respect to safeguarding the privacy, security and transmission of individually identifiable health information. Although we believe that we currently are neither a "covered entity" nor a "business associate" under the legislation, 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 because HIPAA affects the ability of these entities to disclose patient health information to us. Various states also have laws that regulate the privacy and security of personal information and so may affect our business operations. Most notably, in 2018, California passed into law the California Consumer Privacy Act (CCPA), which took effect on January 1, 2020 and imposed many requirements on businesses that process the personal information of California residents. Many of the CCPA's requirements are similar to those found in the European Union's General Data Protection Regulation (2016/679), or GDPR, including requiring businesses to provide notice to data subjects regarding the information collected about them and how such information is used and shared, and providing data subjects the right to request access to such personal information. The CCPA contains significant penalties for companies that violate its requirements. It also provides California residents a private right of action, including the ability to seek statutory damages, in the event of a data breach involving their data. In addition to California, many states have laws that impose fines on entities that experience a data breach involving certain types of personal data or that permit consumers to bring private actions against parties that experience a breach involving their data.

***European Data Privacy and Data Security***

In the European Union, we may be subject to laws relating to our collection, control, processing and other use of personal data (i.e. data relating to an identified or identifiable individual) because we process personal data of our employees, customers, vendors and other third parties based in the European Union in relation to the operation of our business.

In the European Union, the data privacy regime applicable to us includes the GDPR and the E-Privacy Directive 2002/58/EC ("EPD"). We depend on a number of third parties to provide our services, a number of which process personal data on our behalf and are therefore considered our processors under the GDPR. With each such provider we enter into contractual arrangements to ensure that they only process personal data according to our instructions, and that they have sufficient technical and organizational measures in place to safeguard the data. Where we transfer personal data outside the EEA, we do so in compliance with the relevant data export requirements. We take our data protection obligations seriously as any improper disclosure, particularly with regard to our customers' sensitive personal data, could negatively impact our business and/or our reputation.

***GDPR***

The GDPR became applicable on May 25, 2018 and replaced the previous data protection regime which consisted of separate laws issued by each EU Member State, based on the EU Data Protection Directive. Unlike the Directive (which needed to be transposed at a national level), the GDPR is directly applicable in each EU Member State, resulting in a more uniform application of data privacy laws across the European Union. However, the GDPR does allow each Member State to implement laws which supplement the GDPR, causing some variation between EU Member States (for example, in connection

with processing employee personal data and processing personal data for scientific purposes). The GDPR also provides that EU Member States may separately 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. We need to ensure compliance with the supplemental laws in each jurisdiction where we operate, either through having an establishment or through offering goods or services to, or monitoring the behavior of, data subjects located in such jurisdiction.

The GDPR imposes accountability obligations requiring controllers and processors to maintain a record of their data processing and policies. It requires us, as a controller of personal data, to be transparent and to disclose to data subjects (being the individuals to whom the personal data relates), in a concise, intelligible and easily accessible form, how their personal information is used by us. It also imposes limitations on our retention of information, introduces requirements to pseudonymize (i.e., key-code) data, introduces mandatory data breach notification requirements and sets certain standards for controllers to demonstrate that they have obtained valid consent for certain data processing activities.

The requirements also state that personal data may only be collected for specified, explicit and legitimate purposes which have a legal basis set out in the GDPR and may only be processed in a manner consistent with those purposes. Personal data must also be adequate, relevant, and not excessive in relation to the purposes for which it is collected and protected using appropriate technical and organizational measures. In addition, personal data must not be transferred outside of the EEA unless certain steps are taken to ensure an adequate level of protection. The GDPR also requires that the data not be kept for longer than necessary to achieve the purposes for which it was collected. To the extent that we process, control or otherwise use sensitive data relating to individuals (for example, patients' health or medical information, race or ethnicity), more stringent rules 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, an additional legal permission is required, such as explicit consent of the data subject to the processing.

Fines for non-compliance with the GDPR have the potential to be significant—the greater of EUR 20 million or 4% of our global annual revenue in the previous financial year.

***EPD***

The requirements laid down by the EPD have been transposed into the national laws of each EEA Member State since 2003. The requirements are particularly relevant when we send electronic direct marketing to individuals in the EEA or when we use cookies or similar technologies on our websites with respect to individuals located in the EEA and will usually require us to obtain consent from such recipients to carry out these activities. Although all EEA Member State national laws stem from the EPD, the laws differ by jurisdiction, sometimes significantly. We need to ensure compliance with the laws in each jurisdiction where we operate.

The European Union is in the process of replacing the EPD with an E-Privacy Regulation which, unlike the EPD which needed to be transposed into the national law of EEA Member States, will be directly applicable in each EEA Member State. The text of the new Regulation has not yet been finalized nor has an implementation date been set. We will continue to monitor the progress of the new Regulation and make necessary modifications to our practices as and when required.

***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. 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.

For example, the Patient Protection an Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the Healthcare Reform Act, substantially changed the way in which healthcare is financed by both governmental and private insurers and affected medical device manufacturers significantly. The Healthcare Reform Act also provides incentives to programs that increase the federal government's comparative effectiveness research and 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. Additionally, the Healthcare Reform Act provided additional federal funding to state Medicaid programs that expanded eligibility for Medicaid programs and required individuals to obtain health insurance or pay a tax penalty.

There have been administrative, judicial and Congressional challenges to certain aspects of the Healthcare Reform Act, and we expect additional challenges and amendments in the future.

With respect to Congressional action, tax legislation enacted at the end of 2017 removed penalties for not complying with the individual mandate to carry health insurance effective in 2019. The Trump Administration has also taken executive actions to undermine or delay implementation of the Healthcare Reform Act. In January 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the Healthcare Reform Act to waive, defer, grant exemptions from, or delay the implementation of any provision of the Healthcare Reform Act that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. In December 2018, a federal district court found the Healthcare Reform Act unconstitutional in its entirety because, once Congress repealed the individual mandate provision, there was no longer a basis to rely on Congressional taxing authority to support enactment of the law. In December 2019, a federal appeals court agreed that the individual mandate provision was unconstitutional, but remanded the case back to the district court to assess more carefully whether any provisions of the Healthcare Reform Act were severable and could survive. Pending action by the district court and resolution of any appeals, which could take some time, the Healthcare Reform Act is still operational in all respects. 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 the services provided using our products) or additional pricing pressure. Future healthcare legislation could also have a significant impact on our business. Due to the uncertainties regarding the outcome of future healthcare reform initiatives and their enactment and implementation, however, we cannot predict which, if any, of the future reform proposals will be adopted or the effect such adoption may have on us.

In addition, other legislative changes have been proposed and adopted since the Healthcare Reform Act was enacted. For example, the Budget Control Act of 2011, among other things, included reductions to Medicare 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 2029 unless additional Congressional action is taken.

***Laws Relating to Foreign Trade***

We are subject to various federal and foreign laws that govern our international business practices. These laws include the U.S. Foreign Corrupt Practices Act, or FCPA, which prohibits U.S. companies and their representatives from paying, offering to pay, promising, or authorizing the payment of anything of value to any foreign government official, government staff member, political party, or political candidate for the purposes of obtaining or retaining business, or to otherwise obtain favorable treatment or influence a person working in an official capacity. In many countries, the health care professionals we regularly interact with may meet the FCPA's definition of a foreign government official. Additionally, interactions with or on the part of our vendors or other agents may also implicate the FCPA. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect their transactions and to devise and maintain an adequate system of internal accounting controls. Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents unique challenges in the medical device industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials.

Our international operations could also be subject to compliance with national laws of other countries, such as the United Kingdom Bribery Act of 2010, or the U.K. Bribery Act. The U.K. Bribery Act applies to any company "carrying on business" in the United Kingdom, irrespective of where the offending conduct occurs. The U.K. Bribery Act applies to bribery activities both in the public and private sector and prohibits the provision of an "advantage" intended to induce or reward "improper performance" of the recipient's function. The failure by a company to prevent third parties from providing a bribe on its behalf could also constitute an offense. Penalties under the U.K. Bribery Act include potentially unlimited fines for companies and criminal sanctions for corporate officers under certain circumstances.

There are also trade laws within the United States and in other regions that regulate the sale, purchase, import, export, re-export, transfer and shipment of goods, currency, products, materials, services and technology. Violations of these laws can lead to serious consequences, including substantial fines.

***Other Regulations***

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future.

**Facilities**

Our principal office is located at 100 Domain Drive, Exeter, New Hampshire 03833, where we lease approximately 84,140 square feet of office, manufacturing, research & development and warehouse space. We lease this space under a lease that terminates on January 28, 2025. We intend to lease additional space as we add employees, and we believe that suitable additional or substitute space will be available as needed to accommodate any such expansion of our operations. Solus Medical leases approximately 453 square meters of office and warehouse space at 2 Dryden Loan, Bilston Glen Industrial Estate, Loanhead, United Kingdom. We lease this space under a lease that terminates on February 15, 2022.

**Segment Information**

We globally manage our business within one reporting segment. Segment information is consistent with how management reviews our business, makes investing and resource allocation decisions and assesses our operating performance.

**Seasonality**

Historically, we have experienced seasonality in our first and fourth quarters, and we expect this trend to continue. We have experienced and may in the future experience higher sales in the fourth quarter as a result of increased sales from hospitals nearing their fiscal year-end that have not fully utilized the funds allocated to purchases of our Precision Flow systems. In the first quarter of each year we have experienced and may in the future experience higher sales in direct correlation with the number of patients presenting with respiratory distress due to the severity of the flu season, especially in the Northern Hemisphere.

**Information about our Executive Officers**

The following table sets forth the name, age, and position of each of our executive officers as of March 4, 2020.

| Name | Age | Title |
|---|---|---|
| Joseph Army | 56 | President, Chief Executive Officer, and Director |
| John Landry | 47 | Vice President, Chief Financial Officer, Secretary and Treasurer |
| David Blouin | 43 | Vice President, United States Sales |
| Gregoire Ramade | 50 | Vice President, International Sales and Worldwide Marketing |

***Joseph Army*** has served as President, Chief Executive Officer and as a member of our board of directors since June 2012. Prior to joining Vapotherm, Mr. Army served as President and Chief Executive Officer of Salient Surgical Technologies, Inc. (formerly TissueLink Medical, Inc.), or Salient, since 2007. He first joined Salient in 1999 as Chief Financial Officer and Vice President of Finance. Prior to his time at Salient, he held various positions including Vice President of Finance and Supply Chain Operations for Westaim Biomedical from 1998 to 1999 and strategy consultant for Coopers & Lybrand LLP from 1991 to 1997. Mr. Army holds an MBA in finance from The Wharton School and a BA in history from the University of Rhode Island. He is certified in production and inventory management and is a certified public accountant (inactive status).

***John Landry*** has served as Vice President and Chief Financial Officer, Secretary and Treasurer since August 2012. Prior to joining Vapotherm, he held a number of leadership roles at Salient from 2004 to 2011, including VP Accounting & Controller and VP Global Business Development. Mr. Landry also served as Director of International Marketing at Medtronic Advanced Energy from 2011 to 2012, which acquired Salient in August 2011. Prior to his time at Salient, he served in various financial leadership roles at Bottomline Technologies from 2000 to 2004, Hussey Seating Company from 1997 to 2000 and Coopers & Lybrand LLP from 1994 to 1997. Mr. Landry graduated summa cum laude from Bentley College with a BS in Accountancy and is a certified public accountant (inactive status).

***David Blouin*** joined Vapotherm in January 2018 as Vice President, U.S. Sales. Prior to Vapotherm, Mr. Blouin served as Area Vice President at Medtronic from August 2011 to January 2018. Before he joined Medtronic, Mr. Blouin worked at Salient from May 2006 to August 2011 where he was promoted to multiple sales and leadership roles. Mr. Blouin is a graduate of Purdue University where he earned his degree in Technology & Organizational Leadership.

***Gregoire Ramade*** joined Vapotherm in May 2016 as Vice President, International. Before joining Vapotherm, Mr. Ramade worked at Becton Dickinson Medical-Pharmaceutical Systems as Vice President of Global Marketing and Business Development from January 2013 to May 2016. He also held the positions of Senior Marketing Director Home Healthcare Solution at Philips Healthcare from 2010 to 2012, Marketing Director EMEA at Philips Respironics from 2005 to 2009 and Product Manager of Consumable Masks and Accessories at Philips Respironics from 2004 to 2005. Mr. Ramade holds a bachelor's degree in International Business with a minor in Economics from the American University of Paris and an MBA in International Business and Marketing from the Ecole Nationale des Ponts et Chausses School of International Management.

**Employees**

As of December 31, 2019, we had approximately 284 employees and contractors, consisting of approximately 279 full-time employees and contractors and approximately five part-time contractors. Of these employees, 17 are in our wholly owned subsidiary, Solus Medical. None of our domestic employees is subject to a collective bargaining agreement or represented by a trade or labor union. As of December 31, 2019, three of our international team members were subject to a collective bargaining agreement, including one direct employee and two individuals retained through professional employment organizations. We believe our relationship with our employees to be good.

**Corporate Information**

We were originally incorporated in Maryland in 1999 and in 2013 we reincorporated in Delaware. Our principal executive offices are located at 100 Domain Drive, Exeter, NH 03833. Our telephone number is (603) 658-0011.

**Available Information**

We file annual, quarterly and current reports, proxy statements and other information with the SEC. Our SEC filings are available to the public over the Internet at the SEC's website at *http://www.sec.gov*. Our SEC filings are also available under the Investor Relations section of our website at *www.vapotherm.com*. Our website and the information contained on or connected to that site are not incorporated into this Annual Report on Form 10-K.

**Item 1A. Risk Factors.**

*Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below together with all of the other information contained in this Annual Report on Form 10-K, including our financial statements and related notes herein, before deciding to invest in our common stock. If any of the events or developments described below were to occur, 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.*

**Risks Related to Our Business**

***We have incurred losses in the past and may be unable to achieve or sustain profitability in the future.***

We have incurred net losses since our inception. We incurred net losses of $42.5 million and $51.1 million for the years ended December 31, 2018 and 2019, respectively. As a result of ongoing losses, as of December 31, 2019, we had an accumulated deficit of $265.4 million. We expect to continue to incur significant product development, regulatory, sales and marketing and other expenses. The net losses we incur may fluctuate significantly from quarter to quarter.

Since 2008, our revenue has been derived, and we expect it to continue to be derived, primarily from sales of our Precision Flow systems and associated disposable products. Because of their recent commercial introduction, our Precision Flow Hi-VNI and Precision Flow Plus systems have limited product and brand recognition. The same is true of our Oxygen Assist Module, for which we initiated a limited release to certain United Kingdom accounts in February 2020 and intend to fully launch commercially throughout the United Kingdom and Europe by the end of 2020. In addition, demand for our Precision Flow systems and Oxygen Assist Module may decline or may not increase as quickly as we expect. Our ability to generate revenue from sales of our Precision Flow systems, its associated disposable products, and our Oxygen Assist Module or from any products we may develop in the future, may not be sufficient to enable us to transition to profitability and generate positive cash flows.

We expect that our operating expenses will continue to increase as we continue to expand our sales and marketing organization, develop, enhance and commercialize new products and incur additional operational costs associated with being a public company. As a result, we expect to continue to incur operating losses for the foreseeable future and may never achieve profitability. Furthermore, even if we do achieve profitability, we may not be able to sustain or increase profitability on an ongoing basis. If we do not achieve or sustain profitability, it will be more difficult for us to finance our business and accomplish our strategic objectives, either of which would have a material adverse effect on our business, financial condition and results of operations and cause the market price of our common stock to decline. In addition, failure of our Precision Flow systems or, in the future, our Oxygen Assist Module, to significantly penetrate existing or new markets would negatively affect our business, financial condition and results of operations.

***Our revenue is primarily generated from sales of the disposable products utilized with our Precision Flow systems, and we are therefore highly dependent on growing the installed base of the system for our success.***

We began selling our Precision Flow Hi-VNI system and our Precision Flow Plus systems in the United States and in select international markets in 2018 and 2017, respectively. Sales of our Precision Flow Plus and Precision Flow Classic systems and associated disposable products accounted for substantially all of our revenue for the years ended December 31, 2018 and 2019. We expect that sales of our Precision Flow systems, including our Precision Flow Hi-VNI system, and associated disposable products will continue to account for the majority of our revenue going forward. Our ability to execute our growth strategy and become profitable will therefore depend upon the adoption by clinicians and customers, among others, of our Precision Flow systems to treat respiratory distress. Some clinicians may not adopt our Precision Flow systems because they have prior history with or a preference for other treatment options that are more established, such as NIPPV, or may be reluctant to alter their practice patterns and undergo the training required to enable them to treat patients with our Precision Flow systems. Some customers may decide to not purchase our Precision Flow systems if, among other potential reasons, they believe our pricing is too high or that alternative devices to manage respiratory therapy are either more clinically efficacious or cost effective than our product. For example, our Precision Flow systems are significantly more expensive than conventional heated humidified oxygen delivery devices.

***If clinicians are not willing to change current practices to adopt our Precision Flow systems to treat respiratory distress and our Oxygen Assist Module to help clinicians maintain oxygen levels within a targeted range, our Precision Flow systems and our Oxygen Assist Module may fail to gain increased market acceptance, and our business will be adversely affected.***

Our primary strategy to grow our revenue is to drive an increase in the adoption of our Precision Flow systems to treat spontaneously breathing patients of all ages suffering from respiratory distress in the hospital setting and our Oxygen Assist Module to help clinicians maintain oxygen levels within a targeted range. While the number of clinicians adopting our Precision Flow systems has increased in recent years, there is a significant subset of clinicians who have not yet adopted our Precision Flow systems, and may never choose to adopt our Precision Flow systems for a number of reasons, including:

- our inability to convince key opinion leaders to provide recommendations regarding our Precision Flow systems, or to convince physicians, nurses, and respiratory therapists that our Precision Flow systems are attractive alternatives to other treatment options;
- our inability to convince current customers to purchase additional equipment;
- perceived inadequacy of evidence supporting clinical benefits or cost-effectiveness of our Precision Flow systems over existing alternatives;
- liability risks generally associated with the use of new products and procedures;
- the training required to use new products;
- inadequate product quality; and
- perceived high cost.

Few clinicians have adopted our Oxygen Assist Module for use with our Precision Flow systems, in part because we only initiated a limited release of our Oxygen Assist Module to certain United Kingdom accounts in February 2020. Clinicians may choose not to adopt our Oxygen Assist Module for similar reasons that clinicians may not adopt our Precision Flow systems.

Clinicians, including physicians and other medical professionals such as nurses and respiratory therapists, historically utilize NIPPV to treat patients in respiratory distress and manual control to maintain oxygen levels within a targeted range. We believe that educating clinicians about the clinical and economic merits and patient benefits of our Hi-VNI Technology as a viable alternative treatment for respiratory distress and our Oxygen Assist Module to help clinicians maintain oxygen levels within a targeted range are key elements for increasing the adoption of our Precision Flow systems and Oxygen Assist Module. If additional clinicians do not adopt, or existing customers cease using our Precision Flow systems or Oxygen Assist Module for any reason, including those listed above, our ability to execute our growth strategy will be impaired, and our business may be adversely affected.

***We may be unable to generate sufficient revenue from the commercialization of our products to achieve and sustain profitability.***

At present, we rely solely on the commercialization of our products to generate revenue, and we expect to generate substantially all of our revenue in the foreseeable future from sales of these products, primarily our Precision Flow systems and associated disposable products. We will need to generate significant additional revenue to achieve and sustain profitability, and even if we achieve profitability, we cannot be sure that we will remain profitable for any period of time. Our failure to achieve or maintain profitability could negatively impact the value of our common stock. In order to successfully commercialize our products, we will need to continue to expand our marketing efforts to develop new relationships and expand existing relationships with customers, to obtain authorization to market our products in additional countries, to achieve and maintain compliance with all applicable regulatory requirements and to develop and commercialize our products with new features or for additional indications, as well as acquire or develop and commercialize new products. If we fail to successfully commercialize our products, we may never receive a return on the substantial investments we have made in product development, sales and marketing, regulatory compliance, manufacturing and quality assurance, as well as further investments we intend to make, which may cause us to fail to generate revenue and gain economies of scale from such investments.

In addition, potential customers may decide not to purchase our products, or our customers may decide to cancel orders due to changes in available care offerings, adverse clinical outcomes, inadequate reimbursement or productivity credits for procedures using our products, complications with manufacturing or the utilization of technology developed by other parties, all of which are circumstances outside of our control.

Further, demand for our products may not increase as quickly as we predict, and we may be unable to increase our revenue to the level that we currently expect. Even if we succeed in increasing adoption of our products by physicians, hospitals and other healthcare providers, maintaining and creating relationships with our existing and new customers and developing and commercializing new features or indications for these systems, we may be unable to generate sufficient revenue to achieve or sustain profitability.

***Our long-term growth depends on our ability to compete effectively in the respiratory market by commercializing our products currently in development as well as developing and commercializing additional new products through our research and development efforts.***

Given the competitiveness of our industry, our future business prospects depend in part on our ability to develop and commercialize new products and product candidates and new applications for products that offer improved performance and cost-effectiveness. New technologies, techniques or products could emerge from competitors that might offer better combinations of price and performance than our products. It is important that we anticipate changes in technology and market demand, as well as physician, hospital and healthcare provider preferences and practices, in order to successfully commercialize new technologies to meet our prospective customers' needs on a timely and cost-effective basis.

We might be unable to successfully commercialize our marketed products or obtain authorization to market new products. The success of any new product offering or enhancement to an existing product will depend on numerous factors, including our ability to:

- properly identify and anticipate clinician and patient needs;
- identify, retain, and manage third-party design and development firms where appropriate to accelerate development;
- develop and introduce new products or product enhancements in a timely manner;
- adequately protect our intellectual property and avoid infringing upon the intellectual property rights of third parties;
- obtain and retain third-party licenses required for the development, commercialization, and/or utilization of new products;
- demonstrate the safety and efficacy of new products;
- obtain the necessary regulatory authorizations to market new products or product enhancements; and
- deliver products at a price point that is both profitable and acceptable to the market.

If we do not develop and obtain regulatory authorization to market new products or product enhancements in time to meet market demand, or if there is insufficient demand for these products or enhancements, our results of operations will suffer. Our internal research and development efforts and our outsourced third-party design and development initiatives may require a substantial investment of time and resources before we are adequately able to determine the commercial viability of a new product, technology, material or other innovation. In addition, even if we are able to develop enhancements or new generations of our products successfully, these enhancements or new generations of products may not produce sales in excess of the costs of development and they may be quickly rendered obsolete by changing customer preferences or the introduction by our competitors of products embodying new technologies or features.

Additionally, we must carefully manage our introduction of new products. If potential customers believe such products will offer enhanced features or be sold for a more attractive price, they may delay purchases until such products are available. We may also have excess or obsolete inventory as we transition to new products, and we have limited experience in managing product transitions.

***We may need to raise additional capital to fund our existing commercial operations, develop and commercialize new products and expand our operations.***

Based on our current business plan, we believe our current cash, borrowing capacity under our credit facilities and cash receipts from sales of our products will be sufficient to meet our anticipated cash requirements for at least the next 12 months. If our available cash balances, borrowing capacity, cash receipts and anticipated cash flow from operations are insufficient to satisfy our liquidity requirements, including because of lower demand for our products as a result of the risks described in this Annual Report on Form 10-K, we may, among other things, seek to sell common or preferred equity, convertible debt securities, or enter into new or amend existing credit facilities.

Additionally, we may consider raising additional capital in the future to expand our business, to pursue strategic investments, to take advantage of financing opportunities or for other reasons, including to:

- increase our sales and marketing efforts to increase market adoption of our products and address competitive developments;
- provide for supply and inventory costs associated with plans to accommodate potential increases in demand for our products;
- fund development and marketing efforts of any future products or additional features to then-current products;
- acquire, license or invest in new technologies;
- acquire or invest in complementary businesses or assets; and
- finance capital expenditures and general and administrative expenses.

Our present and future funding requirements will depend on many factors, including:

- our ability to achieve and sustain revenue growth and improve gross margins;
- the cost of expanding our operations and offerings, including our sales and marketing efforts;
- our rate of progress in, and cost of the sales and marketing activities associated with, establishing adoption of our products;
- the cost of research and development activities;
- the effect of competing technological and market developments;
- costs related to international expansion; and
- the potential cost of and delays in product development as a result of any regulatory oversight applicable to our products.

Additional capital may not be available at such times or in amounts as needed by us. Even if capital is available, it might be available only on unfavorable terms. Any additional equity or convertible debt financing into which we enter could be dilutive to our existing stockholders. Any future debt financing into which we enter will be senior in bankruptcy to our common stock and may impose covenants upon us that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our stock, make certain investments and engage in certain merger, consolidation or asset sale transactions. Any debt financing or additional equity that we raise may contain terms that are not favorable to our stockholders or us. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or our products or grant licenses on terms that are not favorable to us. If access to sufficient capital is not available as and when needed, our business will be materially impaired and we may be required to cease operations, curtail one or more product development or commercialization programs, or we may be required to significantly reduce expenses, sell assets, seek a merger or joint venture partner, file for protection from creditors or liquidate all our assets.

***We face intense international, national, regional and local competition and, if we are unable to compete successfully with such competition, our revenue, market share and financial results could be adversely affected.***

The medical device industry generally and the respiratory market specifically, are characterized by intense competition and evolving industry standards. We compete with a number of manufacturers of non-invasive ventilation products for the treatment of respiratory distress, and on a secondary basis, with conventional heated humidified high flow oxygen devices that facilitate high flow oxygen delivery for hypoxemic patients, and to a far lesser extent, providers of other respiratory support solutions to enhance oxygen delivery such as non-rebreather masks and oxygen cannulas.

Our most significant NIPPV manufacturing competitor is Philips Respironics. Conventional heated humidified high flow oxygen device manufacturers, such as Fisher & Paykel Healthcare, are also potential competitors. In addition, some NIPPV and ventilator companies, including Philips Respironics, offer high flow oxygen delivery options on their NIPPV and mechanical ventilator systems. We expect that the market will become increasingly competitive in the future. Manufacturing companies compete for sales to providers primarily on the basis of product features, service and price.

Some of our competitors are large, well-capitalized companies with greater resources than we have and more products and longer history in the respiratory market. Other competitors are smaller companies who have or in the future may benefit from a strategic investment or acquisition by one of our larger competitors. As a consequence, these competitors are able to spend more aggressively on product development, marketing, sales and other product initiatives than we can. Some of these competitors have:

- significantly greater name recognition;
- established relationships with healthcare professionals and customers including group purchasing organizations and integrated delivery networks;
- established distribution networks;
- additional lines of products, and the ability to offer rebates or bundle products to offer higher discounts or other incentives to gain a competitive advantage;
- greater history in conducting research and development, manufacturing, marketing and obtaining regulatory approval for respiratory support products; and
- greater financial and human resources for product development, sales and marketing, patent litigation and customer financing.

Our competitors have significant development and clinical resources and can rapidly follow any innovations we bring to the marketplace. For example, our competitors could seek to obtain 510(k) clearance for expanded labeling of their products using our current or future Hi-VNI Technology products as predicate devices. Even if our technology and business strategy is more effective than the technology and business strategy of our competitors, current or potential customers might accept competitor products and services in lieu of purchasing our products. We anticipate that we will face increased competition in the future as existing companies and competitors develop new or improved products and business strategies and as new companies enter the market with new technologies and business strategies. We may not be able to compete effectively against these organizations. Increased competition in the future could adversely affect our revenue, market share and financial results.

***If the quality of our products does not meet the expectations of our customers or their patients, then our brand and reputation could suffer, and our business could be adversely impacted.***

In the course of conducting our business, we must adequately address quality issues that may arise with our products, as well as defects in third-party components included in our products. Although we have established internal procedures to minimize risks that may arise from quality issues, we may be unable to eliminate or mitigate occurrences of these issues and associated liabilities.

Additionally, if our products are involved in an instance of patient harm, even if it is through misuse of our products, it could result in an interruption of business and damage to our reputation.

***We may seek to grow our business through acquisitions or investments in new or complementary businesses, products or technologies, through the licensing of products or technologies from third parties or other strategic alliances. The failure to effectively manage acquisitions, investments, licenses or other strategic alliances, or the failure to integrate them with our existing business, could have a material adverse effect on our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense.***

Our success depends on our ability to continually enhance and broaden our product offerings in response to changing customer demands, competitive pressures, technologies and market pressures. Accordingly, from time to time we may consider opportunities to acquire, make investments in or license other technologies, products and businesses that may enhance our capabilities, complement our current products or expand the breadth of our markets or customer base. For example, on February 28, 2019, we acquired our former distributor in the United Kingdom, Solus Medical, providing us with a U.K.-based wholly owned subsidiary and direct sales organization. Potential and completed acquisitions, strategic investments, licenses and other alliances involve numerous risks, including:

- delays or other difficulty assimilating or integrating acquired or licensed technologies, products or business operations;
- failure of the target entity to satisfy post-closing obligations;
- issues maintaining uniform standards, procedures, controls and policies;
- unanticipated costs associated with acquisitions or strategic alliances, including the assumption of unknown or contingent liabilities and the incurrence of debt or future write-offs of intangible assets or goodwill;

- unanticipated problems or liabilities with the businesses or products acquired;
- diversion of management's attention from our core business and disruption of ongoing operations;
- adverse effects on existing business relationships with suppliers and customers;
- risks associated with entering new markets in which we have limited or no experience;
- potential losses related to investments in other companies;
- loss of existing third-party license agreements or the ability to enter into new third-party license agreements for any reason, including without limitation a difference or change in one party's strategic direction ;
- potential loss of key employees of acquired businesses; and
- increased legal and accounting compliance costs.

We do not know if we will be able to identify acquisitions or strategic relationships we deem suitable, whether we will be able to successfully complete any such transactions on favorable terms, or at all, or whether we will be able to successfully integrate any acquired business, product or technology into our business or retain any key personnel, suppliers or distributors. Our ability to successfully grow through strategic transactions depends upon our ability to identify, negotiate, complete and integrate suitable target businesses, technologies or products and, as necessary, to obtain any necessary financing. These efforts could be expensive and time-consuming and may disrupt our ongoing business and prevent management from focusing on our operations.

Additionally, we have and may seek to make additional foreign acquisitions, investments or strategic alliances which involve other unique risks, including those related to integration of operations across different cultures, languages and legal and regulatory environments, currency risks and the particular economic, political and regulatory risks associated with specific countries.

To finance any acquisitions, investments or strategic alliances, we may choose to issue shares of our common stock as consideration, which could dilute the ownership of our stockholders. Additional funds may not be available on terms that are favorable to us, or at all. If the price of our common stock is low or volatile, we may be unable to consummate any acquisitions, investments or strategic alliances using our stock as consideration.

***We have limited experience in directly marketing and selling our products, and if we are unable to successfully expand our sales infrastructure and adequately address our customers' needs, it could negatively impact sales and market acceptance of our products and we may never generate sufficient revenue to achieve or sustain profitability.***

We have limited experience in directly marketing and selling our products in the United States. We transitioned to a direct sales organization in the United States on January 1, 2015, at which time our domestic sales organization consisted of approximately 10 sales and clinical personnel. As of December 31, 2019, our domestic sales organization has grown to approximately 100 representatives, consisting of both sales and clinical personnel. In parallel, we have grown the size of our marketing department and launched a digital marketing campaign in March 2017. Our operating results are dependent upon our sales and marketing efforts. If we fail to adequately promote and market our products, our sales could significantly decrease.

We have limited experience directly marketing and selling our products in the United Kingdom, where we acquired our former distributor, Solus Medical Limited, on February 28, 2019, and we have no experience directly marketing and selling our products in other international countries. As in the United States, our operating results in the United Kingdom and other international countries are dependent upon our sales and marketing efforts in those countries, and if we fail to adequately promote and market our products, our sales in those countries could significantly decrease.

In addition, our future sales will largely depend on our ability to increase our sales and marketing efforts to adequately address our customers' needs. We believe it is necessary to utilize a sales force that incorporates a specialized group consisting of former respiratory therapists who have experience with our products to support our customers' needs. Competition for sales representatives and marketing employees is intense and we may be unable to attract and retain sufficient personnel to maintain an effective sales and marketing force. If we are unable to adequately address our customers' needs, it could negatively impact sales and market acceptance of our products, and we may not generate sufficient revenue to achieve or sustain profitability.

As we launch new products and increase our marketing efforts with respect to our Precision Flow systems and our Oxygen Assist Module, we have and potentially will continue to need to expand and restructure our marketing and sales networks, as well as modify and improve our sales program offerings, such as our provision of bundled discounts involving the placement of Precision Flow capital units for use by the customer at no upfront charge in connection with the customer's ongoing purchase of disposable products. If the percentage of customers who acquire our technology in this manner increases relative to the percentage of customers who purchase our Precision Flow capital units through an upfront or financed payment, the percentage of our revenue derived from Precision Flow capital units may decrease. Our future success will depend largely on our ability to continue to hire, train, retain and motivate skilled sales representatives and clinical educators, and ensuring our sales program offerings satisfy the needs of our customers. New hires require training and take time to achieve full productivity. If we fail to train new hires adequately, if we experience high turnover in our sales force in the future, or if our sales program offerings do not satisfy the needs of our customers, new hires may not become as productive as may be necessary to maintain or increase our sales. In addition, since we have a limited history with a direct sales organization, we may not be as effective or efficient in utilizing our sales representatives as other companies with longer histories utilizing a direct sales organization. As a result, we may be required to restructure our sales organization, which would be costly, may divert attention from management, and lead to both planned and unplanned turnover. If we are unable to expand our sales and marketing capabilities and our educational initiatives domestically and internationally, we may be unable to effectively commercialize our products.

***We conduct a range of nonclinical, as well as clinical trials, comparative effectiveness, economic and other studies of our products. Unfavorable results from these trials or studies or from similar trials or studies conducted by others may negatively affect the use or adoption of our products by physicians and hospitals, which could have a negative impact on the market acceptance of these products and their profitability.***

We expect to continue to expand our marketing programs in the United States and internationally, and to fund research and development activities, including additional investment in sponsored and investigator initiated clinical and nonclinical trials and studies. The purpose of these nonclinical and clinical trials and studies is to obtain clinical efficacy, economic, and comparative effectiveness information about our products in an effort to generate comprehensive clinical and real-world outcome and cost effectiveness data in order to obtain product approval and drive further penetration in the markets we serve. In the event that these trials and studies, or similar trials and studies conducted by others, yield unfavorable results, those results could negatively affect the use or adoption of our products by physicians, hospitals and payors, thereby compromising market acceptance and profitability.

***Except for in the United Kingdom, we rely on a network of third-party distributors to market and distribute our products internationally, and if we are unable to maintain and expand this network, we may be unable to generate anticipated sales.***

Except for in the United Kingdom where we now have a direct sales organization after the acquisition of our former distributor, Solus Medical, on February 28, 2019, we rely on our network of third-party distributors to market and distribute our products internationally and, to a lesser extent, in the United States. Internationally, we sell our products through a network of 37 independent distributors. Through these distributors, we sell our products in 42 countries outside of the United States, and we expect a significant amount of our revenue to come from international sales for the foreseeable future. In the past, we have experienced issues collecting payments from certain of our independent distributors and we may again experience such issues in the future. In the United States, a limited number of our customers purchase the disposable components of our Precision Flow systems through independent distributors who are able to better satisfy their just in time inventory requirements.

We face significant challenges and risks in managing our geographically dispersed distribution network and retaining the companies who make up that network. Broadly, if we fail to comply with export control laws or successfully develop our relationships with international distributors, our sales could fail to grow or could decline, and our ability to grow our business could be adversely affected. We also cannot control the efforts and resources our third-party distributors will devote to marketing our products. Our distributors may be unable or unwilling to successfully market and sell our products and may not devote sufficient time and resources to support the marketing and selling efforts that enable the products to develop, achieve or sustain market acceptance in their respective jurisdictions. Additionally, in some international jurisdictions, we rely on our distributors to manage the regulatory process, while complying with all applicable rules and regulations, and we are dependent on their ability to do so effectively. If we are unable to attract or retain additional international distributors, our international revenue may not grow.

If any of our international distributors were to cease to do business with us, or if we are not able to successfully integrate Solus Medical into our operations, our sales could be adversely affected. Some of our distributors have historically accounted for a material portion of our sales volume. If any such agency or distributor were to have its business operations impacted as a result of a third-party acquisition or cease to sell and market our products altogether, our sales could be adversely affected. In addition, if a dispute arises with a distributor or a distributor is terminated by us or goes out of business, it may take time to locate an alternative distributor or to begin selling directly into that market, to seek appropriate regulatory approvals or to train new personnel to market our products, and our ability to sell those systems in the region formerly serviced by such terminated distributor could be harmed. Any of our distributors could become insolvent or otherwise become unable to pay amounts owed to us when due. Any of these factors could reduce our revenue from affected markets, increase our costs in those markets or damage our reputation. If a distributor were to depart and be retained by one of our competitors, we may be unable to prevent them from helping competitors solicit business from our existing customers, which could further adversely affect our sales.

In any situation in which we lose the services of a distributor, we may need to seek alternative sales agencies or distributors, or to begin selling directly ourselves, and our sales may be adversely affected. Because of the intense competition for their services, we may be unable to recruit or retain additional qualified distributors to work with us. We may be unable to enter into agreements with them on a timely basis or on favorable or commercially reasonable terms, if at all. Failure to hire or retain qualified distributors would prevent us from expanding our business and generating sales.

As a result of our reliance on third-party sales distributors, we may be subject to disruptions and increased costs due to factors beyond our control, including labor strikes, third-party error and other issues. If the services of any of these third-party distributors become unsatisfactory, we may experience delays in meeting our customers' product demands and we may be unable to find a suitable replacement on a timely basis or on commercially reasonable terms. Any failure to deliver products in a timely manner may damage our reputation and could cause us to lose current or potential customers.

***We obtain some of the components and subassemblies included in our Precision Flow systems from single source suppliers and the partial or complete loss of one or more of these suppliers could cause significant production delays, an inability to meet customer demand and a substantial loss in revenue.***

We utilize single source suppliers for some of the critical components and subassemblies we use in our Precision Flow systems. Disputes (including litigation) could arise with suppliers over a wide range of business and legal issues in our supply agreements, and there may be delays in switching to alternative suppliers if the current supply source expires or terminates. Our dependence on single source suppliers of components may expose us to several risks, including, among other things:

- our suppliers may encounter financial hardships as a result of unfavorable economic and market conditions unrelated to our demand for components, which could inhibit their ability to fulfill our orders and meet our requirements;
- our suppliers may fail to comply with regulatory requirements, be subject to lengthy compliance, validation or qualification periods or make errors in manufacturing components that could negatively affect the efficacy or safety of our products or cause delays in supplying of our products to our customers;
- newly identified suppliers may not qualify under the stringent regulatory standards to which our business is subject;
- heightened risk of commercial disputes (including litigation) if we or our suppliers seek to negotiate changes to the terms of our supply agreements;
- we or our suppliers may not be able to respond to unanticipated changes in customer orders, and if orders do not match forecasts, we or our suppliers may have excess or inadequate inventory of materials and components;
- we may experience delays in delivery by our suppliers due to changes in demand from us or their other customers;
- we or our suppliers may lose access to critical manufacturing equipment, services, and components, resulting in an interruption in the manufacture, assembly and shipment of our systems and in higher cost to us;
- our suppliers may be subject to allegations by other parties of misappropriation of proprietary information in connection with their supply of products to us, which could inhibit their ability to fulfill our orders and meet our requirements;
- fluctuations in demand for products that our suppliers manufacture for others may affect their ability or willingness to deliver components to us in a timely manner;
- we may fail to effectively manage our relationships with our suppliers;
- our suppliers may increase the price of the components we purchase above the then-current market prices;
- our suppliers may wish to discontinue supplying components or services to us; and
- we may not be able to find new or alternative components or reconfigure our system and manufacturing processes in a timely manner if the necessary components become unavailable for any reason, including manufacturing equipment failure.

In addition, we may be deemed to manufacture or contract to manufacture products that contain certain minerals that have been designated as "conflict minerals" under the Dodd-Frank Wall Street Reform and Consumer Protection Act. As a result, in future periods, we may be required to diligence the origin of such minerals and disclose and report whether or not such minerals originated in the Democratic Republic of the Congo or adjoining countries. The implementation of these new requirements could adversely affect the sourcing, availability, and pricing of minerals used in the manufacture of our products. In addition, we may incur additional costs to comply with the disclosure requirements, including costs related to determining the source of any of the relevant minerals and metals used in our products.

If any of these risks materialize, costs could significantly increase and our ability to meet demand for our products could be impacted.

If we are unable to satisfy commercial demand for our Precision Flow systems in a timely manner, our ability to generate revenue would be impaired, market acceptance of our products could be adversely affected and customers may instead purchase or use alternative products. In addition, we could be forced to secure new or alternative components and subassemblies through a replacement supplier. Finding alternative sources for these components and subassemblies could be difficult in certain cases and may entail a significant amount of time, disruption and increased cost. In some cases, we would need to change the components or subassemblies if we sourced them from an alternative supplier. This, in turn, could require a redesign of our Precision Flow systems and, potentially, require additional FDA clearance or approval before we could use any redesigned product with new components or subassemblies, thereby causing further costs and delays that could adversely affect our business, financial condition and operating results.

***We often maintain high levels of inventory from our single source suppliers, which could consume a significant amount of our resources, reduce our cash flows and lead to inventory impairment charges.***

Our Precision Flow systems consist of a substantial number of components. In order to market or sell our Precision Flow systems effectively, we often must maintain high levels of inventory of the product and its components from our single source suppliers. The manufacturing process requires lengthy lead time during which components of our Precision Flow systems may become obsolete, and we may over- or under-estimate the amount needed of a given component, in which case we may expend extra resources or be constrained in the amount of end product that we produce.

***We do not have long-term supply contracts with all our third-party suppliers.***

We purchase components and subassemblies from third-party suppliers, including some of our single source suppliers, through purchase orders and do not have long-term supply contracts with some of these third-party suppliers. These third-party suppliers, therefore, are not obligated to perform services or supply products to us for any specific period, in any specific quantity or at any specific price, except as may be provided in a particular purchase order. For certain of these suppliers, we do not maintain large volumes of inventory. If we inaccurately forecast demand for components or subassemblies, our ability to manufacture and commercialize our Precision Flow systems could be delayed and our competitive position and reputation could be harmed.

***We currently, and in the future may, manufacture a portion of the components of our products in-house and the inability to produce the components we manufacture in-house could cause significant production delays, an inability to meet customer demand and a substantial loss in revenue.***

We currently, and in the future may, manufacture a portion of the components of our products in-house. As a result, we are dependent upon the uninterrupted and efficient operation of our manufacturing facility in Exeter, New Hampshire. The operations at this facility may be disrupted by a number of factors, including:

- delivery problems;
- financial condition or results of operations;
- internal inefficiencies;
- manufacturing equipment failure;
- severe weather;
- fire;
- nature or man-made disasters;

- work stoppages;
- component shortages; and
- FDA compliance or other quality-related issues.

There can be no assurance that the occurrence of these or any other operational problems at our facility would not cause significant production delays, an inability to meet customer demand and a substantial loss in revenue.

Additionally, we recently developed the ability to manufacture a component in house that we historically purchased from a sole-source third-party supplier. Our agreement with the supplier allows us to opt out of continuing to purchase the component from the third-party supplier on a quarterly basis starting in July 2020, and if we opt out of issuing a purchase order for any given quarter, the third-party supplier may elect to terminate our supply agreement. We are unaware of any other supplier who can manufacture this component. If our third-party supplier terminates our agreement and there is a disruption or failure in our manufacturing of this component in our Exeter, New Hampshire facility thereafter, we may not be able to find an alternate supplier or enter into a new manufacturing and supply agreement with our previous supplier on a timely basis or at all, or such agreement may not be on favorable terms. A failure to find an alternate supplier or enter into a new manufacturing and supply agreement with our previous supplier could result in an inability to manufacture our products and cause substantial loss in revenue.

***We may be unable to manage our anticipated growth effectively, which could make it difficult to execute our business strategy.***

We have been growing significantly over the past two years. Our revenue grew from $42.4 million for the year ended December 31, 2018 to $48.1 million for the year ended December 31, 2019. We intend to continue to grow our business operations and may experience periods of rapid growth and expansion. This anticipated growth could create a strain on our organizational, administrative and operational infrastructure, including our supply chain operations, quality control, technical support and customer service, sales force management and general and financial administration. We may be unable to maintain the quality, or delivery timelines, of our products or customer service or satisfy customer demand if our business grows too rapidly, including into markets or countries in which we have limited or no prior operating and commercial experience. Our ability to manage our growth properly will require us to continue to improve our operational, financial and management controls, and our reporting systems and procedures. We may implement new systems in a number of areas affecting a broad range of business processes and functional areas. The time and resources required to implement these new systems is uncertain and failure to complete this in a timely and efficient manner could harm our business.

As our world-wide commercial operations and sales volume grow, we will need to continue to increase our workflow capacity for our supply chain, customer service, training and education personnel, invoicing, reporting and expand our internal quality assurance program, among other things. Because our products require us to devote significant resources to training our customers on the use and educating our customers on the benefits of our products, we will be required to expand these personnel as we increase our sales efforts. We may not successfully implement these increases in scale or the expansion of our personnel, which could harm our business.

***Our operations, and those of our suppliers and customers, are vulnerable to interruption or loss due to natural or other disasters, power loss, strikes and other events beyond our control.***

Our principal executive office, U.S. distribution, and manufacturing operations are located in a leased facility located in Exeter, New Hampshire. We also have access to facilities for our wholly owned United Kingdom subsidiary's personnel and inventory and a manufacturing and distribution site in Tilburg, Netherlands. These facilities and the manufacturing equipment we use to produce our products would be difficult to replace and could require substantial lead-time to repair or replace in the event of a natural or man-made disaster. A disaster (such as an earthquake, fire, flood, hurricane, a volcanic eruption other severe weather, or a pandemic or other outbreak) affecting our facilities, or those of our suppliers, could significantly disrupt our operations, and delay or prevent product shipment or installation during the time required to repair, rebuild or replace the damaged facilities.

Even if we are able to quickly respond to a disaster, the ongoing effects of the disaster could create some uncertainty in the operations of our business. Our customers' facilities could also be negatively impacted by a disaster, which could delay shipments of our products. Additionally, customers may delay purchases of our products until their operations return to normal.

In addition, our facilities may be subject to a shortage of available electrical power and other energy supplies. Any shortages may increase our costs for power and energy supplies or could result in blackouts, which could disrupt the operations of our affected facilities and harm our business. In addition, concerns about terrorism, the effects of a terrorist attack, political turmoil or an outbreak of epidemic diseases could have a negative effect on our operations, those of our suppliers and customers.

***A pandemic, epidemic or outbreak of an infectious disease, such as the coronavirus, or COVID-19, may adversely affect our business.***

If a pandemic, epidemic or outbreak of an infectious disease occurs, our business may be adversely affected. For example, in December 2019, a novel strain of coronavirus, COVID-19, was identified in Wuhan, China. This virus continues to spread globally and, as of March 3, 2020, has spread to over 45 countries, including the United States and the United Kingdom. Such events may result in a period of business and manufacturing disruption, and in reduced sales and operations, any of which could materially affect our business, financial condition and results of operations.

For example, the spread of COVID-19 in the United States or the United Kingdom may result in travel restrictions impacting our direct sales team and clinical educators in those countries. Similarly, spread of COVID-19 in these and other countries may result in travel restrictions impacting our distributors and suppliers. Travel restrictions may also reduce the number of physicians travelling to attend our training programs, which would result in fewer physicians trained on Hi-VNI Technology, and in the United Kingdom and in Europe, on our Oxygen Assist Module. Travel restrictions might also impede our ability to meet with distributors, negatively impacting our business in a number of ways, including without limitation our ability to expand into new geographic territories, and train our existing distributors on new products such as the Oxygen Assist Module. For example, we recently postponed our annual distributor meeting that was scheduled to take place in March 2020 in Malta, due to the risk of travel limitations imposed by certain governments and other organizations. Travel restrictions might also impede our ability to retain new suppliers or audit our existing suppliers, which might have a negative impact on our quality management system and our product quality. In addition, hospitals may reduce staffing or limit access for non-patients, including our sales team and clinical educators in response to COVID-19, which would negatively impact our access to physicians and their patients. Any of the foregoing actions could adversely affect our sales and the revenue we derive as a result.

The spread of an infectious disease, including COVID-19, could result in the inability of our suppliers to deliver components or raw materials to us on a timely basis. Similarly, if our corporate offices need to close, it may limit our ability to manufacture certain components or assemble our products in-house. Even if our offices remain open, local schools might close, which could impact the ability of our employees who may lack adequate childcare to effectively manufacture, assemble, and sell our products. We believe our current supply chain structure mitigates the risk of the COVID-19 outbreak as of the present date and we do maintain a limited supply of materials in house. However, if there is a shortage of supply, the cost of these materials or components may increase and harm our ability to provide our products on a cost-effective basis. In connection with any supply shortages in the future, reliable and cost-effective replacement sources may not be available on short notice or at all, and this may force us to increase prices and face a corresponding decrease in demand for our products. In the event that any of our suppliers were to discontinue production of our key product components, developing alternate sources of supply for these components would be time consuming, difficult and costly.

The full extent to which COVID-19 impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19 and the actions to treat or contain COVID-19 or to otherwise limit its impact, among others.

***Performance issues, service interruptions or price increases by our shipping carriers could adversely affect our business and harm our reputation and ability to provide our services on a timely basis.***

Expedited, reliable shipping is essential to our operations. We rely heavily on providers of transport services for reliable and secure point-to-point transport of our products to our customers and for tracking of these shipments. Should a carrier encounter delivery performance issues such as loss, damage or destruction of any Precision Flow systems, it would be costly to replace such systems in a timely manner and such occurrences may damage our reputation and lead to decreased demand for our products and increased cost and expense to our business. In addition, any significant increase in shipping rates could adversely affect our operating margins and results of operations. Similarly, strikes, severe weather, natural disasters or other service interruptions affecting delivery services we use would adversely affect our ability to process orders for our products on a timely basis.

***The loss of our senior management or our inability to attract and retain highly skilled employees could negatively impact our business.***

Our success depends on the skills, experience and performance of the members of our executive management team, particularly Joseph Army, our Chief Executive Officer. The loss of the services of any of these persons for any reason whatsoever, could impede the achievement of our research, development and commercialization objectives. Also, each of these persons may terminate their employment with us at any time. We do not maintain “key person” insurance for any of our executives or other employees.

Additionally, our business and operations depend on our ability to attract and retain highly skilled employees. We may be unable to attract or retain qualified employees in the future for many reasons, including low regional, domestic, and international unemployment rates, the competition for qualified personnel among medical device businesses, or the cost of hiring qualified employees may exceed industry standards. Recruiting and retention difficulties could limit our ability to support our commercial, supply chain and research and development programs. Any of our employees may terminate his or her employment at any time and for any reason. The loss of key employees, the failure of any key employee to perform, our inability to attract and retain skilled employees, as needed, or an inability to effectively plan for and implement a succession plan for key employees could harm our business.

***Our international operations subject us to certain operating risks, which could adversely impact our results of operations and financial condition.***

We focus our international commercial efforts in the United Kingdom, Germany, Brazil, Mexico, Turkey, Japan and other international markets. Economic or political instability in any of these markets could have a significant impact on our operations. For example, Turkey is currently experiencing a currency crisis and other political unrest that has had a negative impact on our operations in Turkey. Additionally, the sale and shipment of our products across international borders, as well as the purchase of components from international sources, subjects us to U.S. and foreign governmental trade, import and export, and customs regulations and laws.

Compliance with these regulations and laws is costly and exposes us to penalties for non-compliance. Other laws and regulations that can significantly impact us include various anti-bribery laws, including the United Kingdom Bribery Act of 2010 and the U.S. Foreign Corrupt Practices Act, as well as sanctions and export controls laws. Any failure to comply with applicable legal and regulatory obligations could impact us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments, restrictions on certain business activities and exclusion or debarment from government contracting.

Our international operations expose us and our distributors to risks inherent in operating in foreign jurisdictions. These risks include:

- difficulties in enforcing our intellectual property rights and in defending against third-party threats and intellectual property enforcement actions against us, our distributors or any of our third-party suppliers;
- reduced or varied protection for intellectual property rights in some countries;
- pricing pressure that we may experience internationally;
- a shortage of high-quality salespeople, clinical educators and distributors;
- third-party reimbursement policies that may require some of the patients who receive our products to directly absorb medical costs or that may necessitate the reduction of the selling prices of our products;
- competitive disadvantage to competition with established business and customer relationships;
- the imposition of additional U.S. and foreign governmental controls or regulations;
- political or economic instability;
- changes in duties and tariffs, license obligations and other non-tariff barriers to trade;
- the imposition of restrictions on the activities of foreign agents, representatives and distributors;
- scrutiny by foreign tax authorities, which could result in significant fines, penalties and additional taxes being imposed on us;
- laws and business practices favoring local companies;
- longer payment cycles;
- difficulties in maintaining consistency with our internal guidelines;
- difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
- the imposition of costly and lengthy new export licensing requirements;
- the imposition of U.S. or international sanctions against a country, company, person or entity with whom we do business that would restrict or prohibit continued business with the sanctioned country, company, person or entity; and
- the imposition of new trade restrictions.

If we experience any of these risks, our sales in non-U.S. jurisdictions may be harmed and our results of operations would suffer.

***Because we plan to continue using foreign contract manufacturers, our operating results could be harmed by economic, political, regulatory and other factors in foreign countries.***

We currently use foreign contract manufacturers and plan to continue to use foreign contract manufacturers to manufacture current and future products, where appropriate. These international operations are subject to inherent risks, which may adversely affect us, including, but not limited to:

- political and economic instability;
- high levels of inflation, historically the case in a number of countries in Asia;
- burdens and costs of compliance with a variety of foreign laws, regulations and sanctions;
- foreign taxes and duties;
- changes in tariff rates or other trade, tax or monetary policies; and
- changes or volatility in current exchange rates and interest rates.

***If significant tariffs or other restrictions are placed on Chinese imports or any related counter-measures are taken by China, our revenue and results of operations may be materially harmed.***

We contract with several Chinese suppliers for certain components of our Precision Flow systems. If significant tariffs or other restrictions are placed on Chinese imports or any related counter-measures are taken by China, our revenue and results of operations may be materially harmed. Recently, political discourse in the United States has increasingly focused on ways to discourage U.S. competitors from outsourcing manufacturing and production activities to foreign corporations and curb what are considered unfair trade practices. In January 2020, the United States and China entered into Phase One of the Economic and Trade Agreement between the United States of America and the People's Republic of China (the “Phase One Trade Agreement”). The Phase One Trade Agreement takes steps to ease certain trade tensions between the United States and China. Although the Phase One Trade Agreement is an encouraging sign of progress in the trade negotiations between the United States and China, questions still remain as to the enforcement of its terms, the resolution of a number of other points of dispute between the parties, and the prevention of further tensions. If tariffs are imposed on the components used in our Precision Flow systems, we may be required to raise our prices, which may result in the loss of customers and harm our operating performance. Alternatively, we may seek to shift production outside of China, resulting in significant costs and disruption to our operations.

***Efforts to withdraw from or materially modify NAFTA or other international trade agreements, to change tax provisions related to global manufacturing and sales or to impose new tariffs, economic sanctions or related legislation, any of which could adversely affect our financial condition and results of operations.***

Our business benefits from free trade agreements, such as the North American Free Trade Agreement, or NAFTA, and we also rely on various U.S. corporate tax provisions related to international commerce, as we develop, market and sell our products and services globally. On November 30, 2018, the United States, Mexico and Canada signed a replacement trade deal for NAFTA, known as the United States-Mexico-Canada Agreement, or USMCA. The USMCA has been ratified by Mexico and the United States and is pending ratification by Canada. Once ratified by Canada, it will go into effect 90 days later. It is difficult to anticipate the full impact of this agreement on our business, financial condition, cash flows, and results of operations.

Any modification in these areas, any shift in the enforcement or scope of existing regulations or any change in the countries, governments, persons or technologies targeted by such regulations, could result in decreased use of our products by, or in our decreased ability to export or sell our products to, existing or potential end-customers with international operations and could result in increased costs. Any decreased use of our products or limitation on our ability to export or sell our products would likely adversely affect our business, financial condition and results of operations.

***The exit of the United Kingdom from membership in the European Union could adversely affect our financial results and our operations in the United Kingdom and the European Union.***

The United Kingdom formally left the European Union on January 31, 2020, which is commonly known as "Brexit". A transition period through December 31, 2020 has been established to allow the United Kingdom and European Union to negotiate the terms of the United Kingdom's withdrawal. However, there is continued uncertainty surrounding the future relationship between the United Kingdom and the European Union, including trade agreements between the United Kingdom and the European Union. Brexit could lead to legal uncertainty and potentially divergent national laws and regulations as the United Kingdom determines which (if any) European Union laws to replace or replicate, including determining whether to adopt the European Union law that governs the regulatory approval of medical devices such as the Precision Flow systems or related future product offerings we may seek to bring to market in the United Kingdom. The measures could potentially disrupt the markets we serve and the tax jurisdictions in which we operate and adversely change tax benefits or liabilities in these or other jurisdictions and may cause us to lose customers and employees or increase the cost of doing business in the United Kingdom. In addition, as a result of Brexit, other European countries may seek to conduct referenda with respect to their continuing membership with the European Union. Given these possibilities and others we may not anticipate, as well as the absence of comparable precedent, it is unclear what financial, regulatory and legal implications the withdrawal of the United Kingdom from the European Union will have and how such withdrawal will affect our Company, including our United Kingdom subsidiary Solus Medical, and the full extent to which our business could be adversely affected. Furthermore, we translate sales and other results denominated in foreign currency into U.S. dollars for our financial statements. Volatility in stock or currency markets, as well as the strengthening of the U.S. dollar relative to other currencies each could adversely affect our financial results.

***Our results may be impacted by changes in foreign currency exchange rates.***

We have international operations, including a direct sales organization in the United Kingdom, and, as a result, an increase in the value of the U.S. dollar relative to foreign currencies could require us to reduce our selling price or risk making our products less competitive in international markets, or our costs could increase. For example, Turkey is currently experiencing a currency crisis and other political unrest which has in the past and may in the future necessitate our taking such actions. Also, if our international sales increase, we may enter into a greater number of transactions denominated in non-U.S. dollars, which could expose us to increased foreign currency risks, including currency fluctuations and exchange rate risks. For example, following the acquisition of our former distributor, Solus Medical, on February 28, 2019, we began invoicing our United Kingdom customers directly in Great British Pounds. We do not currently engage in any hedging transactions. If we are unable to address these risks and challenges effectively, our international operations may not be successful, and our business could be harmed.

***If we experience significant disruptions in our information technology systems, our business may be adversely affected.***

We depend on our information technology systems for the efficient functioning of our business, including customer management, accounting, data storage, compliance, purchasing and inventory management. We do not have redundant systems at this time. While we will attempt to mitigate interruptions, we may experience difficulties in implementing system upgrades, or experience difficulties in operating our business during the upgrade, either of which could disrupt our operations, including our ability to timely ship and track product orders, project inventory requirements, manage our supply chain and otherwise adequately service our customers. In the event we experience significant disruptions as a result of the current implementation of our information technology systems, we may be unable to repair our systems in an efficient and timely manner. Accordingly, such events may disrupt or reduce the efficiency of our entire operation and have a material adverse effect on our results of operations and cash flows. Currently we carry business interruption coverage to mitigate any potential losses, but we cannot be certain that such potential losses will not exceed our policy limits.

We are increasingly dependent on sophisticated information technology for our infrastructure. Our information systems require an ongoing commitment of significant resources to maintain, protect and enhance existing systems. While we implemented security measures relating to our operations, those measures may not prevent security breaches that could harm our business. Advances in computer capabilities, inadequate technology or facility security measures or other factors may result in a compromise or breach of our systems and the data we store and process. Our security measures may be breached as a result of actions by third parties or employee error or malfeasance. A party who is able to circumvent our security measures or exploit inadequacies in our security measures, could, among other things, misappropriate proprietary information, including information about third parties, cause the loss or disclosure of some or all of this information, cause interruptions in our operations or expose third parties to computer viruses or other disruptions or vulnerabilities. Any compromise of our systems or the data we store or process could result in a loss of confidence in the security of our software, damage our reputation, disrupt our business, lead to legal liability and adversely affect our results of operations. Moreover, a compromise of our systems could remain undetected for an extended period of time, exacerbating the impact of that compromise. Actual or perceived vulnerabilities may lead to claims against us by our customers, or other third parties, including the federal and state governments. While our business agreements typically contain provisions that seek to limit our liability, there is no assurance these provisions will be enforceable and effective under applicable law. In addition, the cost and operational consequences of implementing further data protection measures could be significant.

***We have in the past and may in the future be subject to various litigation claims and legal proceedings.***

We have in the past and we, as well as certain of our officers and distributors, may in the future be subject to various litigation or other claims or lawsuits. The outcomes of legal actions are not within our complete control and may not be known for prolonged periods of time. In some actions, such as our present litigation with our former supplier, claimants may seek damages. Future claimants including suppliers, customers, distributors, competitors, officers or shareholders, among others, may also seek other civil or criminal remedies (including royalties or injunctions barring the sale of products that are subject of the proceeding) in the future. Regardless of the outcome, these lawsuits may result in significant legal fees and expenses, could divert management's time and other resources and could cause us reputational harm. If the claims contained in these lawsuits are successfully asserted against us, we could be liable for damages and be required to alter or cease certain of our business practices or product lines.

***Employment litigation and unfavorable publicity could negatively affect our future business.***

Employees may, from time to time, bring lawsuits against us regarding injury, creating a hostile work place, discrimination, wage and hour, sexual harassment and other employment issues. In recent years there has been an increase in the number of discrimination and harassment claims generally. Coupled with the expansion of social media platforms and similar devices that allow individuals access to a broad audience, these claims have had a significant negative impact on some businesses. Companies that have faced employment or harassment related lawsuits have had to terminate management or other key personnel and have suffered reputational harm that has negatively impacted their sales. If we were to face any employment related claims, our business could be negatively affected.

***If product liability lawsuits are brought against us, our business may be harmed, and we may be required to pay damages that exceed our insurance coverage.***

Our business exposes us to potential product liability claims that are inherent in the testing, manufacture and sale of medical devices for respiratory support. Furthermore, if our customers are not sufficiently trained in the use of our products, they may misuse or ineffectively use our products, which may result in unsatisfactory patient outcomes or patient injury. We could become the subject of product liability lawsuits alleging that component failures, malfunctions, manufacturing flaws, design defects or inadequate disclosure of product-related risks or product-related information resulted in an unsafe condition or injury to patients.

Regardless of the merit or eventual outcome, product liability claims may result in:

- decreased demand for our products;
- injury to our reputation;
- significant litigation costs;
- substantial monetary awards to or costly settlements with patients;
- product recalls;
- material defense costs;
- loss of revenue;
- the inability to commercialize new products; and
- diversion of management attention from pursuing our business strategy.

Our existing product liability insurance coverage may be inadequate to protect us from any liabilities we might incur. If a product liability claim or series of claims is brought against us for uninsured liabilities or in excess of our insurance coverage, our business could suffer. Any product liability claim brought against us, with or without merit, could result in the increase of our product liability insurance rates or the inability to secure coverage in the future. In addition, a recall of some of our products, whether or not the result of a product liability claim, could result in significant costs and loss of customers.

In addition, we may be unable to maintain insurance coverage at a reasonable cost or in sufficient amounts or scope to protect us against losses. Any claims against us, regardless of their merit, could severely harm our financial condition, strain our management and other resources and adversely affect or eliminate the prospects for commercialization or sales of a product that is the subject of any such claim.

***Our business is subject to seasonal fluctuations.***

Our business is subject to seasonal fluctuations in that our revenue is typically higher in our first and fourth quarters, driven primarily by an increase in patients with flu-like symptoms and COPD exacerbations. Sales volume can be affected by the severity of the flu season and variations in the rates of respiratory disease in any given time period. In the event we had product shortages or had to institute a recall of our products during the flu season, our financial results would have an even more detrimental effect. As a result, our financial results for any single quarter or for periods of less than a year are not necessarily indicative of the results that may be achieved for a full fiscal year.

***Our sales volumes and our results of operations may fluctuate within each quarter and over the course of the year.***

We have experienced and continue to experience meaningful variability in our sales and gross profit among quarters, as well as within each quarter, as a result of a number of factors, which may include, among other things:

- the number of products sold in the quarter;
- the unpredictability of sales of capital equipment to our domestic hospital customers and our international distributors;
- timing of our customers' capital budgeting cycle; and
- fluctuation and foreign currency exchange rates.

The foregoing factors are difficult to forecast, and these, as well as other factors, could materially and adversely affect our results of operations. In addition, a significant amount of our operating expenses are relatively fixed due to our manufacturing, research and development and sales and general administrative efforts. Any failure to adjust spending quickly enough to compensate for a revenue shortfall could magnify the adverse impact of such revenue shortfall on our results of operations. Our results of operations may not meet the expectations of research analysts or investors, in which case the price of our common stock could decrease significantly.

***Our insurance policies are expensive and protect us only from some business risks, which will leave us exposed to significant uninsured liabilities.***

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include general liability, foreign liability, employee benefits liability, property, umbrella, workers' compensation, products liability and directors' and officers' insurance. We do not know, however, if these policies will provide us with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.

***We bear the risk of warranty claims on our products.***

We provide customers with a one-year warranty on our Precision Flow systems' capital purchases, with limited exceptions. For the years ended December 31, 2018 and 2019, we incurred warranty expense of $0.4 million and $0.1 million, respectively. We bear the risk of warranty claims on the products we supply. We may not be successful in claiming recovery under any warranty or indemnity provided to us by our suppliers or vendors in the event of a successful warranty claim against us by a customer or any recovery from such vendor or supplier may not be sufficient to cover our losses. In addition, warranty claims brought by our customers related to third-party components may arise after our ability to bring corresponding warranty claims against such suppliers expires, which could result in our inability to recover any costs incurred by us.

***We are an "emerging growth company" and the reduced disclosure requirements applicable to "emerging growth 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 we may take advantage of certain exemptions and relief from various reporting requirements that are applicable to other public companies that are not "emerging growth companies." In particular, while we are an "emerging growth company" (1) we will not be required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, (2) we will be exempt from any rules that could be adopted by the Public Company Accounting Oversight Board requiring mandatory audit firm rotations or a supplement to the auditor's report on financial statements, (3) we will be subject to reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and (4) we will not be required to hold nonbinding advisory votes on executive compensation or stockholder approval of any golden parachute payments not previously approved.

We may remain an "emerging growth company" until as late as December 31, 2023, the fiscal year-end following the fifth anniversary of the completion of our initial public offering, though we may cease to be an "emerging growth company" earlier under certain circumstances, including if (1) we have more than $1.07 billion in annual revenue in any fiscal year, (2) the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of any June 30 or (3) we issue more than $1.0 billion of non-convertible debt over a three-year period.

The exact implications of the JOBS Act are still subject to interpretations and guidance by the SEC and other regulatory agencies, and we cannot assure you that we will be able to take advantage of all of the benefits of the JOBS Act. In addition, investors may find our common stock less attractive to the extent we rely on the exemptions and relief granted by the JOBS Act. 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 decline or become more volatile.

***Because we have opted to take advantage of the JOBS Act provision which allows us to delay implementing new accounting standards, our consolidated financial statements may not be directly comparable to other public companies.***

Pursuant to the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. Because we have elected to take advantage of this provision of the JOBS Act, our consolidated financial statements and the reported results of operations contained therein may not be directly comparable to those of other public companies.

***Our effective tax rate may fluctuate, and we may incur obligations in tax jurisdictions in excess of accrued amounts.***

We are subject to taxation in numerous U.S. states, the United Kingdom and certain other territories. As a result, our effective tax rate is derived from a combination of applicable tax rates in the various places that we operate. In preparing our financial statements, we estimate the amount of tax that will become payable in each of such places. Nevertheless, our effective tax rate may be different than experienced in the past due to numerous factors, including passage of the recently enacted federal income tax law, changes in the mix of our profitability from state to state, the results of examinations and audits of our tax filings, our inability to secure or sustain acceptable agreements with tax authorities, changes in accounting for income taxes and changes in tax laws. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations and may result in tax obligations in excess of amounts accrued in our financial statements.

***If we become profitable, our ability to use our net operating loss carryforwards to offset future taxable income may be subject to limitations.***

As described above under "—Risks Related to Our Business," we have incurred net losses since our inception, and expect to continue to incur significant product development, clinical and regulatory, sales and marketing and other expenses as well as increased administrative expenses. If we become profitable in the future, our ability to use our net operating loss carryforwards, or NOLs, tax credit carryforwards and other tax attributes to offset future taxable income or reduce taxes may be subject to limitations. In general, under Section 382 of the Code, a corporation that undergoes an "ownership change" is subject to an annual limitation on its ability to use its pre-change NOLs and other tax attributes. We have not performed an analysis to determine whether our past issuances of stock and other changes in our stock ownership may have resulted in one or more ownership changes within the meaning of Section 382 of the Code. In addition, future changes in our stock ownership, some of which are outside of our control, could result in one or more ownership changes under Section 382 of the Code. If an ownership change has occurred in the past or occurs in the future, our ability to use our pre-change NOLs and other tax attributes may be subject to limitation under Section 382 of the Code. If we determine that we have not undergone an ownership change, the Internal Revenue Service could challenge our analysis, and determine that our ability to use our NOLs, tax credit carryforwards or other tax attributes to offset taxable income are limited by Section 382 of the Code. For these and other reasons, we may not be able to use a material portion of the NOLs, even if we attain profitability. A full valuation allowance has been provided for the entire amount of our NOLs.

**Risks Related to Government Regulation**

***Our products and operations are subject to extensive government regulation and oversight both in the United States and abroad, and our failure to comply with applicable requirements could harm our business.***

We and our products are subject to extensive regulation in the United States and elsewhere, including by the Food and Drug Administration, or the FDA, and its foreign counterparts. The FDA regulates the design, development, manufacturing, labeling, storage, non-clinical and clinical research, safety, efficacy, packaging, installation, servicing, marketing and distribution, premarket clearance or approval, recordkeeping, advertising, promotion, recalls and field safety corrective actions, adverse event reporting, post-market approval studies, and product import and export to ensure that medical devices distributed domestically are safe and effective for their intended uses and meet other applicable requirements of the Federal Food, Drug, and Cosmetic Act, or the FDCA.

The regulations to which we are subject are complex. Additional regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales. The FDA enforces these regulatory requirements through, among other methods of oversight, periodic unannounced inspections. We do not know whether we will pass any future FDA inspections. Failure to comply with applicable regulations could jeopardize our ability to sell our products and result in enforcement actions such as: warning letters; fines; injunctions; civil penalties; termination of distribution; recalls or seizures of products; delays in the introduction of products into the market; total or partial suspension of production; refusal to grant future clearances or approvals; withdrawals or suspensions of current clearances or approvals, resulting in prohibitions on sales of our products; and in the most serious cases, criminal penalties.

***We may not receive the necessary authorizations to market our future products, and failure to timely obtain such authorizations for our future products would adversely affect our ability to grow our business.***

An element of our business strategy is to continue to develop new products and add new features and expand clearance or approval of our current products to new indications. In the United States, in general, before we can market a new medical device, or a new use of, new claim for or significant modification to a legally marketed device, we must first receive either clearance under Section 510(k) of the FDCA or the grant of a *de novo* request under section 513(f)(2) of the FDCA or a premarket approval application, or PMA, from the FDA, unless an exemption applies. In the 510(k) clearance process, before a device may be marketed, the FDA must determine that a proposed device is "substantially equivalent" to a legally-marketed "predicate" device. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics, not raise different questions of safety or effectiveness than the predicate device and be as safe and as effective as the predicate device. Clinical data are sometimes required to support a substantial equivalence determination. In the *de novo* process, a manufacturer whose novel device under the FDCA would otherwise be automatically classified as Class III and require the submission and approval of a PMA prior to marketing is able to request down-classification of the device to Class I or Class II on the basis that the device presents a low or moderate risk. If the FDA grants the *de novo* petition, the applicant will receive authorization to market the device. This device type may be used subsequently as a predicate device for 510(k) submissions. In the PMA process, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, pre-clinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices.

The PMA approval, the 510(k) clearance and the *de novo* processes can be expensive, lengthy and uncertain. The FDA's 510(k) clearance and *de novo* processes can take from three to 12 months but may last significantly longer. The process of obtaining a PMA is much more costly and uncertain than the 510(k) clearance process and generally takes from one to three years, or even longer, from the time the application is filed with the FDA. In addition, a PMA generally requires the performance of one or more clinical trials. Clinical data may also be required in connection with an application for 510(k) clearance or a *de novo* request. Despite the time, effort and cost, a device may not be approved, reclassified or cleared by the FDA. Any delay or failure to obtain necessary regulatory clearances or approvals could harm our business. Furthermore, even if we are granted regulatory clearances or approvals, they may include significant limitations on the indications for use or intended uses of the device, which may limit the market for the device.

In the United States, we obtained 510(k) premarket clearances from the FDA to market each of our products requiring such clearance. We also obtained a *de novo* grant for an expanded indication for our Precision Flow Hi-VNI system. Any modifications to these existing products may require new 510(k) clearance; however, future modifications may be subject to the substantially more costly, time-consuming and uncertain *de novo* process or PMA process. If the FDA requires us to go through a lengthier, more rigorous premarket review process for future products or modifications to existing products than we had expected, such as with our Oxygen Assist Module, product introductions or modifications could be delayed or canceled, which could cause our sales to decline.

The FDA can delay, limit or deny 510(k) clearance, request for *de novo* classification, or pre-market approval of a device for many reasons, including:

- we may be unable to demonstrate to the FDA's satisfaction that the products or modifications are substantially equivalent to a proposed predicate device or safe and effective for their intended uses;
- FDA or the applicable foreign regulatory body may disagree with the design, conduct or implementation of our clinical trials or the analyses or interpretation of data from pre-clinical studies or clinical trials;
- participants in our clinical trials may experience serious adverse effects;
- the data from our pre-clinical studies and clinical trials may be insufficient to support clearance, *de novo* classification, or approval, where required;

- we may be unable to demonstrate that the clinical and other benefits of the device outweigh the risks;
- an advisory committee, if convened by the applicable regulatory authority, may recommend against authorization for marketing or may recommend that the applicable regulatory authority require, as a condition of marketing authorization, additional preclinical studies or clinical trials, limitations on labeling or distribution and use restrictions, or even if an advisory committee, if convened, makes a favorable recommendation, the respective regulatory authority may still not authorize the product for marketing;
- the applicable regulatory authority may identify deficiencies in our submissions or in the facilities or processes of our third-party contract manufacturers;
- the policies or regulations of the FDA or applicable foreign regulatory bodies may change significantly in a manner rendering our clinical data or regulatory filings insufficient for clearance, *de novo* classification, or approval; and
- the FDA or foreign regulatory authorities may audit our clinical trial data and conclude that the data is not sufficiently reliable to support a submission for marketing authorization.

In addition, the FDA may change its policies, adopt additional regulations or revise existing regulations, or take other actions, or Congress may enact different or additional statutory requirements, which may prevent or delay approval, *de novo* classification, or clearance of our future products under development or impact our ability to modify our currently marketed products on a timely basis. Such policy, statutory or regulatory changes could impose additional requirements upon us that could delay our ability to obtain new 510(k) clearances, *de novo* classifications, or PMA approvals, increase the costs of compliance or restrict our ability to maintain our current marketing authorizations.

In order to sell our products in member countries of the European Economic Area (the 27 member states of the European Union plus Iceland, Liechtenstein and Norway), or the EEA, our products must comply with the essential requirements of the EU Medical Devices Directive (Council Directive 93/42/EEC), or the MDD. Compliance with these requirements is a prerequisite to be able to affix the CE Mark to our products, without which they cannot be sold or marketed in the EEA. To demonstrate compliance with the essential requirements we must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Except for low-risk medical devices (Class I non-sterile, non-measuring devices), where the manufacturer can issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the essential requirements of the MDD, a conformity assessment procedure requires the intervention of an organization accredited by a Member State of the EEA to conduct conformity assessments, or a Notified Body. Depending on the relevant conformity assessment procedure, the Notified Body would typically audit and examine the technical file and the quality system for the manufacture, design and final inspection of our devices. The Notified Body issues a certificate of conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the essential requirements. This certificate entitles the manufacturer to affix the CE Mark to its medical devices after having prepared and signed a related EC Declaration of Conformity.

As a general rule, demonstration of conformity of medical devices and their manufacturers with the essential requirements must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use, that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device are supported by suitable evidence. If we fail to remain in compliance with applicable European laws and directives, we would be unable to continue to affix the CE Mark to our devices, which would prevent us from selling them within the EEA.

Beginning on May 26, 2020 the new EU Medical Devices Regulation (Regulation (EU) 2017/745 of the European Parliament and of the Council), or the MDR, will replace the EU MDD in the European Economic Area. In regard to the UK, because the MDR was codified into UK law at the time of Brexit, the same MDR requirements will apply to our commercial activity in the UK, at least during the post-Brexit transition period.

The new MDR imposes more strict requirements on medical device manufacturers and the Notified Bodies whom they must involve in the conformity assessment procedure (other than self-declaration Class I non-sterile, non-measuring devices and (new) non-reusable surgical instruments). The MDR adds new requirements, such as a reclassification of certain devices, a Unique Device Identification (UDI) system, a wider scope of the Quality Management System including clinical evaluation and post-marketing clinical follow-up, a clinical evaluation procedure for some Class IIb and Class III devices by an independent expert panel, among others. New medical devices introduced after May 26, 2020 must comply with the MDR rules. That means we will need to undergo the applicable conformity assessment procedure according to MDR, through representation by a Notified Body, for all new devices we introduce after that date. The new devices will have to be CE marked pursuant to MDR.

To avoid market disruption and allow a smooth transition from the EU MDD to the EU MDR several transitional provisions are in place (although the transitional processes and the status of the MDR in the UK are uncertain after the post-Brexit transition through the end of 2020 or afterward if extended). Whereas from 26 May 2020, all new certificates will have to be delivered according to MDR, the prior certificates provided under the MDD can be valid until their date of validity for a maximum of four years, i.e., May 27, 2024. In some cases that may be extended until May 27, 2025, provided that the manufacturer follows the new MDR rules for registration, surveillance and vigilance.

Notified Bodies must receive a new designation as a Notified Body under the MDR, but to qualify they will be required to meet more stringent criteria. The process of designation might take 12 months or more. Currently only 11 Notified Bodies are MDR designated, as indicated on the NANDO website (New Approach Notified and Designated Organisations). Pursuant to publicly available information, a number of Notified Bodies, including our Notified Body, DQS, are awaiting their designation under MDR, but there is a risk that they will fail to be so designated. Furthermore, it is expected that many small or local existing Notified Bodies will fail to meet the more stringent criteria or will not seek a new designation. Thus, existing MDR designated Notified Bodies may not have capacity to take on new representations. If our Notified Body is unable to qualify, or is delayed, we would need to change Notified Bodies and may be unable to find one with appropriate capacity and qualification. As a result, we may be delayed or be unable to obtain new MDR certificates for our new products introduced after May 26, 2020 or for our existing products after September 2, 2023, the date our existing certificate expires, and therefore may be delayed or prevented from commercializing our products in the EEA or UK.

The sale and marketing of imported medical device products in China are subject to notifications (for Class I devices) or registrations (for Class II and III devices) with the NMPA. The NMPA's average process time for clearance is 10-18 months for Class II devices and 12-24 months for Class III devices. Manufacturers are likely to be required to conduct local clinical trials in China if their devices are not on the NMPA Clinical Trial Exemption List or are not substantially equivalent to a predicate device on the market. In addition, pre-submission in-country type testing requirement can add at least 3-6 months to the market entry process. There could be challenges in type testing process when applicable Chinese device standards are not harmonized with corresponding international standards. The whole process for obtaining regulatory clearances or approvals in China can be lengthy and expensive, and the results are unpredictable. In addition, uncertain regulatory or political environment changes and healthcare system reforms in China may result in the delay of certain regulatory clearance or approval for some of our products.

We or our distributors will also need to obtain regulatory approval in other foreign jurisdictions in which we plan to market and sell our products. The time required to obtain registrations or approvals, if required by other countries, may be longer than that required for FDA clearance, and requirements for such registrations, clearances or approvals may significantly differ from FDA requirements. If we modify our products, we or our distributors may need to apply for additional regulatory approvals before we are permitted to sell the modified product. In addition, we may not continue to meet the quality and safety standards required to maintain the authorizations that we or our distributors have received. If we or our distributors are unable to maintain our authorizations in a particular country, we will no longer be able to sell the applicable product in that country.

Marketing authorization by the FDA does not ensure clearance or approval by regulatory authorities in other countries, and clearance or approval by one or more foreign regulatory authorities does not ensure marketing authorization by regulatory authorities in other foreign countries or by the FDA. However, a failure or delay in obtaining regulatory clearance or approval or other marketing authorization in one country may have a negative effect on the regulatory process in others.

***Certain modifications to our products may require new 510(k) clearance or other marketing authorizations and may require us to recall or cease marketing our products.***

Once a medical device is permitted to be legally marketed in the United States pursuant to a 510(k) clearance, *de novo* classification, or a PMA, a manufacturer may be required to notify the FDA of certain modifications to the device. Manufacturers determine in the first instance whether a change to a product requires a new premarket submission, but the FDA may review any manufacturer's decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. We have made modifications to our products in the past and have determined based on our review of the applicable FDA regulations and guidance that in certain instances new 510(k) clearances or other premarket submissions were not required. We may make similar modifications or add additional features in the future that we believe do not require a new 510(k) clearance, *de novo* classification, or approval of a PMA or PMA amendments or supplements. If the FDA disagrees with our determinations and requires us to submit new 510(k) notifications, requests for *de novo* classification, or PMAs (or PMA supplements or amendments) for modifications to our previously cleared or reclassified products for which we have concluded that new clearances or approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties.

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

Our products have been cleared by the FDA for specific indications. The FDA and European regulatory authorities strictly regulate the indications for use and associated promotional safety and effectiveness claims, including comparative and superiority claims vis a vis competitors' products, that may be made about legally marketed products. In particular, a medical device may not be promoted in a way that constitutes adulteration or misbranding under the FDCA. We train our marketing personnel and sales representatives and distributors to promote our products consistent with applicable laws and published clinical data. However, a physician, in his or her medical judgment, can prescribe a course of treatment that is outside the product's labeling. There may be increased risk of injury to patients if physicians attempt to use our products in this manner. Furthermore, the use of our products for indications other than those authorized 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 physicians and patients.

If the FDA or any foreign regulatory body determines that our promotional materials, sales practices or training constitute improper promotion of an off-label use, including as a result of their disagreement with our interpretation of published clinical data or the FDA's recent grant of our *de novo* request and corresponding expanded indications for use, they could request that we modify our training, sales practices or promotional materials or subject us to regulatory or enforcement actions, including the issuance or imposition of an untitled letter, 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. Additionally, the FDA might fail to take action against competitors whose promotional materials, sales practices or training mirror our own but who have not yet achieved the expanded indications for use we received in connection with the FDA's recent grant of our *de novo* request. These types of enforcement actions, or enforcement omissions, could have a material adverse impact on our business, product sales and financial results.

***Our products must be manufactured in accordance with federal, state and international regulations, and we could be forced to recall our installed devices or terminate production if we fail to comply with these regulations.***

The methods used in, and the facilities used for, the manufacture of our products must comply with the FDA's Quality System Regulation, or QSR, which is a complex regulatory scheme that covers the procedure and documentation of, among other requirements, the design, testing, validation, verification, complaint handling, production, process controls, quality assurance, labeling, supplier evaluation, packaging, handling, storage, distribution, installation, servicing and shipping of medical devices. Furthermore, we are required to verify that our suppliers maintain facilities, procedures and operations that comply with our quality standards and applicable regulatory requirements. The FDA enforces the QSR through, among other oversight methods, periodic announced or unannounced inspections of medical device manufacturing facilities, which may include the facilities of subcontractors, suppliers, or contract manufacturing organizations. Our products are also subject to similar state regulations and various laws and regulations of foreign countries governing manufacturing. For example, certain of our electrical components in our products are audited pursuant to International Electrotechnical Transmission standard 60601, a widely accepted benchmark for medical electrical equipment compliance that has become a requirement for the commercialization of electrical medical equipment in many countries. We are routinely audited under this standard and negative findings from an audit could prevent us from marketing our products in certain countries.

Our third-party manufacturers may not take the necessary steps to comply with applicable regulations or our specifications, which could cause delays in the delivery of our products. In addition, failure to comply with applicable FDA requirements or later discovery of previously unknown problems with our products or manufacturing processes could result in, among other things: warning letters or untitled letters; customer notifications or repair, replacement, refunds, recall, detention or seizure of our products; fines, injunctions or civil penalties; suspension or withdrawal of approvals or clearances; seizures or recalls of our products; total or partial suspension of production or distribution; administrative or judicially imposed sanctions; the FDA's refusal to grant pending or future clearances or approvals for our products; clinical holds; refusal to permit the import or export of our products; and criminal prosecution of us or our employees.

Any of these actions could significantly and negatively impact supply of our products. If any of these events occurs, our reputation could be harmed, we could be exposed to product liability claims and we could lose customers and suffer reduced revenue and increased costs.

***Our products may cause or contribute to adverse medical events that we are required to report to the FDA and other governmental authorities, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations. The discovery of serious safety issues with our products, or a recall of our products either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us.***

Our products are subject to extensive regulation by the FDA in the United States and by regulatory agencies in other countries where we do business. We will be required to timely file various reports with the FDA, including reports required by the medical device reporting regulations, or MDRs, which require us to report to the FDA when we receive or become aware of information that reasonably suggests that one or more of our products may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur to the device or a similar device that we market, could cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product. If we fail to comply with our reporting obligations, the FDA or other governmental authorities could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearance, seizure of our products or delay in clearance of future products.

The FDA and certain foreign regulatory bodies have the authority to require the recall of commercialized products under certain circumstances. The FDA's authority to require a recall must be based on a finding that there is reasonable probability that the device could cause serious injury or death.

A government-mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies or failures to comply with applicable regulations. We have in the past conducted voluntary recalls of devices with lot-specific quality issues. For example, in September 2014, we initiated a voluntary recall of various lots of the disposable patient circuit due to the device allowing water to leak into the center gas lumen. This recall was terminated in October 2015. Additionally, we received a small number of complaints involving a defect in the disposable patient circuit that allowed water to leak where the delivery tube is connected to the disposable water path. In response, we initiated a voluntary recall of the four affected lots that began on May 4, 2016 and terminated on August 17, 2016. Product defects or other errors resulting in recalls may occur in the future.

Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA or other governmental bodies may require, or we may decide, that we will need to obtain new marketing authorizations for the device before we may market or distribute the corrected device. Seeking such marketing authorizations may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties or civil or criminal proceedings.

Companies are required to maintain certain records of recalls, removals and corrections, even if they are not reportable to the FDA. We may initiate voluntary withdrawals, removals or corrections for our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, it could require us to report those actions and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us and negatively affect our sales. Any corrective action, including product recall, will require the dedication of our time and capital and could harm our reputation and financial results.

In addition, the FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. For example, in December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of medical devices and spur innovation. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump Administration may impact our business and industry. Namely, the Trump Administration has taken several executive actions, including the issuance of a number of executive orders, that could impose significant burdens on, or otherwise materially delay, FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these executive actions affect the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

***Legislative or regulatory reforms in the United States or other jurisdictions in which we market our products 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 Congress that could significantly change the statutory provisions governing the regulation of medical devices. In addition, FDA and other regulatory authorities' regulations and guidance may be revised or reinterpreted 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 clearance or 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.

On April 5, 2017, the European Parliament passed the Medical Devices Regulation (Regulation 2017/745), which repeals and replaces the EU Medical Devices Directive and the Active Implantable Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the EEA member states, the 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 Medical Devices Regulation, 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 Medical Devices Regulation will, however, only become applicable three years after publication (in 2020). Once applicable, the new regulations will 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
- strengthened 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.

These modifications may have an effect on the way we conduct our business in the EEA.

***We are subject to certain federal, state and foreign fraud and abuse laws, transparency laws and state licensure or permit 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 to respond to, and thus could harm our business.***

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 transparency laws. Our business practices and interactions with physicians, hospitals and other healthcare providers are subject to scrutiny under these laws. The significant U.S. healthcare laws and regulations that may affect our ability to operate include:

- 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. 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 or criminal penalties and exclusion from participation in government healthcare programs, including Medicare and Medicaid;

- the federal civil and criminal false claims 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. 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 penalties plus three times the amount of damages which the government sustains because of the submission of a false claim, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;
- the Federal Physician Payments Sunshine Act or Open Payments which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under certain federal healthcare programs such as Medicare and Medicaid to report annually to the DHHS Centers for Medicare & Medicaid Services, or CMS, information related to payments and other transfers of value to teaching hospitals and physicians, which term is defined broadly to include practitioners such as podiatrists and dentists, (and, beginning with transfers of value in 2021, to additional non-physician practitioners) as well as to report annually ownership and investment interests held by physicians and their immediate family members. Manufacturers are required to submit annual reports to CMS and failure to submit required information may result in substantial civil monetary penalties, and may result in liability under other federal laws or regulations;
- the Health Insurance Portability and Accountability Act fraud and abuse provisions, which may impose criminal penalties for defrauding any healthcare benefit program, including public and private payors, or making any 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 in order to have committed a violation;
- 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 third-party 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 that otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require device companies to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and
- state laws that require medical device companies to obtain wholesale distribution or pharmacy permits and other state licensing laws.

These laws and regulations constrain our promotional and other business activities by limiting the kinds of financial interactions, including discount and other commercial transactions, we may have with individuals or entities that use, order, purchase or recommend our products such as patients and healthcare providers. We have a variety of arrangements with our customers that could implicate these laws and regulations. For example, like many medical device companies that have related capital and consumable products, we periodically permit customers that purchase the disposable component of our Precision Flow systems to use the capital component at no upfront cost as part of a bundled discount sale. A small percentage of our company is owned by healthcare professionals, and we also have also entered into consulting agreements with physicians, including some who influence the ordering of or use our products in procedures they perform. To facilitate product discussions, we also provide meals to healthcare practitioners who might use or order services using our products. We arrange for continuing education programs for healthcare practitioners to provide education about our products and the conditions our products are approved to treat. We could be adversely affected if regulatory agencies determine our financial interactions to be in violation of applicable laws. Due to the breadth of these laws, the narrowness of exceptions and/or safe harbors available, and the range of interpretations to which the laws 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. Responding to investigations can be time-and resource-consuming and can divert management's attention from the business. Additionally, as a result of these investigations, healthcare companies or healthcare providers may have to agree to additional compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity and be costly to respond to.

If our operations are found to be in violation of any of the healthcare laws or regulations described above or any other healthcare regulations that apply to us, we may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, imprisonment, contractual damages, reputational harm, disgorgement and the curtailment or restructuring of our operations.

***Certain of our customers are highly dependent on payments from third-party payors, including government sponsored programs, in the U.S. and other countries in which we operate, and reductions in third-party coverage and reimbursement rates for our products (or services provided with our products) could adversely affect our business and results of operations.***

A substantial portion of our revenue depends, in part, on the extent to which the costs of our products purchased by our customers are reimbursed by third-party payors, including Medicare, Medicaid, other U.S. government sponsored programs, non-U.S. governmental payors and private payors. Our customers' ability to obtain appropriate reimbursement for products and services from these third-party payors affects the selection of products they purchase and the prices they are willing to pay. Our products are used in services that are often reimbursed by third-party payors as part of a global payment that covers all costs associated with providing that service. Healthcare providers incur costs in using our products but do not receive separate or additional reimbursement in connection with their use. As a result, certain healthcare providers may be reluctant to adopt our products. Similarly, our customers may not adopt our products if they are more costly than competitor products, including products used to provide alternative treatments. If we lower the prices for our products to obtain or maintain customers' business, we may be adversely affected financially. Similarly, our customers' ability to obtain appropriate productivity credit from their applicable internal administrations affects the selection of products they purchase and the prices they are willing to pay.

***We face significant uncertainty in the industry due to government healthcare reform and other legislative action.***

There have been and continue to be laws enacted by the federal government, state governments, regulators and third-party payors to control healthcare costs, and generally, to reform the healthcare system in the United States. For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Healthcare Reform Act, substantially changed the way healthcare is delivered and financed by both governmental and private insurers. These changes included the creation of demonstration programs and other value-based purchasing initiatives that provide financial incentives for physicians and hospitals to reduce costs. Under the Trump Administration, there have been ongoing efforts to modify or repeal all or part of the Healthcare Reform Act. For example, tax legislation enacted at the end of 2017 includes provisions that eliminated the tax penalty for individuals who do not maintain sufficient health insurance coverage beginning in 2019 (the so-called "individual mandate"). The Healthcare Reform Act has also been subject to judicial challenge. In December 2018, a federal district court, in a challenge brought by a number of state attorneys general, found the Healthcare Reform Act unconstitutional in its entirety because, once Congress repealed the individual mandate provision, there was no longer a basis to rely on Congressional taxing authority to support enactment of the law. In December 2019, a federal appeals court agreed that the individual mandate provision was unconstitutional, but remanded the case back to the district court to assess more carefully whether any provisions of the Healthcare Reform Act were severable and could survive. Pending action by the district court and resolution of any appeals, which could take some time, the Healthcare Reform Act is still operational in all respects. We expect healthcare reform efforts to continue and that there will be additional reform proposals at federal and state levels. We cannot predict whether additional reform proposals will be adopted, when they will be adopted, or what impact they may have on us, but any such proposals could have a negative impact on our business and provide incentives for hospitals and physicians to not use our products.

General legislative action may also affect our business. The Budget Control Act of 2011 includes provisions to reduce the federal deficit. The Budget Control Act, as amended, resulted in the imposition of 2% reductions in Medicare payments to providers which began in April 2013 and will remain in effect through 2029 unless additional congressional action is taken.

***We are subject to various laws protecting the confidentiality and security of certain personal information, and our failure to comply could result in penalties and reputational damage.***

We are subject to various laws and regulations protecting the confidentiality and security of certain patient health information, and our failure to comply with such laws and regulations could result in penalties and reputational damage.

Within the United States, numerous federal and state laws, including, without limitation, the Health Insurance Portability and Accountability Act of 1996 as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations (collectively, HIPAA), state data privacy laws (for example, the CPPA), state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws, govern the collection, use, disclosure and storage of personal information.

Outside the United States, numerous countries in which we operate, manufacture and sell our products have, or are developing, laws protecting data privacy and the confidentiality of certain personal data. For example, the European Union (EU) General Data Protection Regulation (GDPR), which came into force on May 25, 2018, introduced new data protection requirements in the EEA, and substantial fines for violations of the data protection rules. The GDPR expanded significantly the

jurisdictional reach of EEA data protection law by extending the law's application to not only entities that are established in the EEA, but also to entities that process personal data in connection with the offering of goods or services to data subjects located in the EEA or process personal data in connection with monitoring the behavior of data subjects located in the EEA. The GDPR imposes strict obligations and restrictions on controllers and processors of personal data including, for example, expanded disclosures about how personal data is to be used, increased requirements pertaining to health data and pseudonymised (e.g., key-coded) data, mandatory data breach notification requirements, appointment of a data protection officer when sensitive personal data (e.g., health data) are processed on a large scale, requirement to enter into certain types of contracts with service providers processing personal data, implementation of appropriate privacy governance measures, and expanded rights for individuals over their personal data. This could affect our ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting, or could cause our costs to increase, potentially leading to harm to our business and financial condition.

While the GDPR, as a directly effective regulation, was designed to harmonize data protection law across the EEA, it does permit member states to legislate in many areas (particularly with regard to the processing of genetic, biometric or health data), meaning that inconsistencies between different member states will still arise. EEA member states have their own regimes on medical confidentiality and national and EEA-level guidance on implementation and compliance practices is often updated or otherwise revised, which adds to the complexity of processing personal data in the EEA.

Failure to comply with the requirements of the GDPR and the related national data protection laws of the EEA Member States, which may deviate from the GDPR, may result in substantial fines, and in addition to such fines, we may be the subject of litigation initiated by data subjects and/or adverse publicity, which could have a material adverse effect on our reputation and business. As a result of the implementation of the GDPR, we are required to put in place additional mechanisms to ensure compliance with the new data protection rules. For example, the GDPR requires us to make more detailed disclosures to data subjects, requires disclosure of the legal basis on which we can process personal data, may make it harder for us to obtain valid consent for processing, will require the appointment of a data protection officer where sensitive personal data (e.g., health data or data concerning race or ethnicity) is processed on a large scale, introduces mandatory data breach notification requirements throughout the EEA, imposes additional obligations on us when we are contracting with service providers and requires us to adopt appropriate privacy governance including policies, procedures, and training.

European data protection law generally prohibits the transfer of personal data to countries outside of the EEA that are not considered by the European Commission to provide an adequate level of data protection, unless there are specific frameworks or mechanisms in place to safeguard the data, such as the EU-U.S. Privacy Shield or the European Commission-approved standard contractual clauses, or very narrow legal exceptions (such as explicit consent of the data subject) apply. There is currently litigation challenging the EU-U.S. Privacy Shield and the standard contractual clauses, and it is uncertain whether these data transfer mechanisms will be invalidated by the European courts. We could be impacted by changes in law as a result of a future review of these transfer mechanisms by European regulators under the GDPR, as well as current challenges to these mechanisms in the European courts.

Outside of the EEA, 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 that may affect our business. There is a degree of uncertainty associated with the legal and regulatory environment around privacy and data protection laws, which continue to develop in ways we cannot predict, including with respect to evolving technologies, such as cloud computing. Privacy and data protection laws may be interpreted and applied inconsistently from country to country and impose inconsistent or conflicting requirements. Varying jurisdictional requirements could increase the costs and complexity of compliance or require us to change our business practices in a manner adverse to our business. A determination that we have violated privacy or data protection laws could result in significant damage awards, fines and other penalties that could, individually or in the aggregate, materially harm our business and reputation.

***We could be adversely affected by violations of the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act of 2010 and similar world-wide anti-bribery laws.***

The U.S. Foreign Corrupt Practices Act, or the FCPA, the U.K. Bribery Act of 2010 and similar anti-bribery laws in other jurisdictions generally prohibit companies and their intermediaries from making improper payments for the purpose of obtaining or retaining business. Our policies mandate compliance with these anti-bribery laws, including the requirements to maintain accurate information and internal controls. We operate in many parts of the world that have experienced governmental corruption to some degree and in certain circumstances; strict compliance with anti-bribery laws may conflict with local customs and practices. There is no assurance that our internal control policies and procedures will protect us from acts committed by our employees or agents. If we are found to be liable for FCPA or other violations (either due to our own acts or our inadvertence, or due to the acts or inadvertence of others), we could suffer from civil and criminal penalties or other sanctions, including contract cancellations or debarment, and loss of reputation, any of which could have a material adverse impact on our business, financial condition, and results of operations.

***Consolidation in the healthcare industry, group purchasing organizations or integrated distributor networks could lead to demands for price concessions, which may affect our ability to sell our products at prices necessary to support our current business strategies.***

Healthcare costs have risen significantly over the past decade, which has resulted in or led to numerous cost reform initiatives by legislators, regulators and third-party payors. Cost reform has triggered a consolidation trend in the healthcare industry to aggregate purchasing power, which may create more requests for pricing concessions in the future. Failure to meet these concessions may result in our exclusion from these contracts. Additionally, group purchasing organizations, independent delivery networks and large single accounts may continue to use their market power to consolidate purchasing decisions for hospitals by limiting the number of products available under various purchasing categories. We expect that market demand, government regulation, third-party coverage and reimbursement policies and societal pressures will continue to change the healthcare industry world-wide, resulting in further business consolidations and alliances among our customers, which may exert further downward pressure on the prices of our products.

As the healthcare system consolidates the number of health systems and group purchasing organizations controlling the buying process has also constricted. In order to sell to hospitals that belong to these organizations we must be on contract. Not being on contract with these organizations, or choices of these organizations to standardize on a competitive product option or otherwise decline to renew our contract, or the failure of these organizations to differentiate our new Precision Flow Hi-VNI system, which we fully launched in 2019 and is our first product to have the *de novo* expanded indication for use statement, from conventional heated humidified high flow oxygen devices could substantially reduce our revenue opportunity.

**Risks Related to Our Intellectual Property**

***If we are unable to secure and maintain patent or other intellectual property protection for our products, we may lose a significant competitive advantage.***

Our commercial success depends, in part, on obtaining, maintaining and defending patent and other intellectual property protection for the technologies used in our products. The patent positions of medical device companies, including ours, can be highly uncertain and involve complex and evolving legal and factual questions. The process of obtaining patent protection is expensive and time-consuming, and we may not be able to prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We may choose not to seek patent protection for certain innovations or products and may choose not to pursue patent protection for certain products in certain jurisdictions or at all, and under the laws of certain jurisdictions, patents or other intellectual property rights may be unavailable or limited in scope and, in any event, any patent protection we obtain may be limited. As a result, some of our products are not, and in the future may not be, protected by patents. This may mean we may be unable to:

- prevent our competitors from duplicating our products;
- prevent our competitors from gaining access to our proprietary information and technology; or
- gain or maintain a competitive advantage.

We intend to seek additional patents, but our pending and future patent applications may not result in issued patents or be granted on a timely basis. In addition, issued patents may not contain claims sufficiently broad to protect us against third parties with similar technologies or products or provide us with any competitive advantage, including exclusivity in a particular product area. The scope of our patent claims also may vary between countries, as individual countries have distinctive patent laws. We may be subject to challenges by third parties regarding our intellectual property, including, among others, claims regarding validity, enforceability, scope and effective term. Patent prosecution, related proceedings, and litigation in the U.S. and in other countries may be expensive, time consuming and ultimately unsuccessful. In addition, patents issued by foreign countries may afford less protection than is available under U.S. patent law and may not adequately protect our proprietary information. Our competitors may independently develop proprietary technologies and processes that are the same as or substantially equivalent to ours or design around our patents. The technologies we have patented, licensed or developed. Moreover, the expiration of patents on which we rely for protection of key products could diminish our competitive advantage and adversely affect our business and our prospects. Consequently, competitors could develop, manufacture and sell products that directly compete with our products, which could decrease our sales and diminish our ability to compete.

Even if our patents are determined by the U.S. Patent and Trademark Office, USPTO, foreign patent office, or a court to be valid and enforceable, they may not be drafted or interpreted sufficiently broadly enough in scope to prevent others from marketing products and services similar to ours or designing around our patents. For example, third parties may be able to develop therapies, or make systems or devices, that are similar to ours but that are not covered by the claims of our patents. Third parties may assert that we or our licensors were not the first to make the inventions covered by our issued patents or pending patent applications. The claims of our issued patents or patent applications when issued may not cover our commercial technology or the future products and services that we develop. We may not have freedom to operate unimpeded by the patent

rights of others. Third parties may have dominating, blocking or other patents relevant to our technology of which we are not aware. Because an originally filed patent application can be refiled to obtain continuation patents with new claims based on the priority date of the original application, we cannot be certain that our competitors will not file and obtain new continuation patents in an attempt to cover our commercial technology notwithstanding it having been available in the market for over 10 years. In addition, because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after the filing of certain priority documents (or, in some cases, are not published until they issue as patents) and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for our technology or our next generation contemplated technology. Any such patent applications may have priority over our patent applications or issued patents, which could further require us to obtain rights from third parties to issued patents or pending patent applications covering such technologies to allow us to commercialize our technology. If another party has filed a U.S. patent application on inventions similar to ours, depending on when the timing of the filing date falls under certain patent laws, we may have to participate in a priority contest (such as an interference proceeding) declared by the USPTO to determine priority of invention in the United States. There may be prior public disclosures of which we are not aware that could invalidate our patents or one or more claims of our patents. Further, we may not develop additional proprietary technologies and, even if we do, they may not be patentable.

Moreover, in the United States and in foreign jurisdictions, proceedings to enforce our patent rights could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, and our patent applications at risk of not issuing. Additionally, such proceedings could provoke third parties to assert claims against us, or they may assert such claims on their own. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful, or we may be required to pay damages and legal fees of our adversaries. Thus, we may not be able to stop a competitor from marketing and selling products that are the same as or similar to our products, and our competitive position would be harmed.

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

In addition to patent and trademark protection, we also rely on trade secrets, including unpatented manufacturing know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect our trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our consultants and vendors, or our former or current employees. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, however, any of these parties may breach the agreements and disclose our trade secrets and other unpatented or unregistered proprietary information, and once disclosed, we are likely to lose trade secret protection. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. In addition, we may not be able to obtain adequate remedies for any such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to enforce trade secret protection.

Further, our competitors may independently acquire or develop know-how or other technology that is similar, equivalent, or superior to our proprietary technology. Competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology, or develop their own competitive technologies that fall outside of our intellectual property rights. In addition, our key employees, consultants, suppliers or other individuals with access to our proprietary technology may incorporate that technology into projects and inventions developed independently or with third parties. As a result, disputes may arise regarding the ownership of the proprietary rights to such technology, and any such dispute may not be resolved in our favor. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology to compete with us and our competitive position could be adversely affected. If our intellectual property is not adequately protected so as to protect our market against competitors' products and methods, our competitive position could be adversely affected, as could our business.

***If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.***

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks. We may not be able to protect our rights in these trademarks and trade names, which we need in order to build name recognition with potential partners or customers in our markets of interest. In addition, third parties have registered trademarks similar and identical to our trademarks in both the United States and in foreign jurisdictions and may in the future file for registration of such trademarks. If they succeed in registering or developing common law rights in such trademarks, and if we were not successful in challenging such third-party rights, we may not be able to use these trademarks to market our products in those countries. In any case, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected.

***We may in the future become involved in lawsuits to defend ourselves against intellectual property disputes, which could be expensive and time consuming, and ultimately unsuccessful, and could result in the diversion of significant resources, and hinder our ability to commercialize our existing or future products.***

Our success depends in part on not infringing the patents or violating other proprietary rights of others. Intellectual property disputes can be costly to defend, distract leadership, and may cause our business, operating results and financial condition to suffer. Significant litigation regarding patent rights occurs in the medical device industry. Whether merited or not, it is possible that U.S. and foreign patents and pending patent applications controlled by third parties may be alleged to cover our products. We may also face allegations that our employees have misappropriated the intellectual property rights of their former employers or other third parties. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, 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 commercialize our products. These competitors may have one or more patents for which they can threaten and/or initiate patent infringement actions against us. Our ability to defend ourselves may be limited by our financial and human resources, the availability of reasonable defenses, and the ultimate acceptance of our defenses by the courts or juries. Further, if such patents are successfully asserted against us, this may result in an adverse impact on our business, including injunctions, damages, and/or attorneys' fees. From time to time and in the ordinary course of business, we may develop noninfringement and/or invalidity positions with respect to third-party patents, which may or may not be ultimately adjudicated as successful by a judge or jury if such patents were asserted against us.

We have and may receive in the future, particularly as a public company, communications from patent holders, including non-practicing entities, alleging infringement of patents, infringement of other intellectual property rights including misappropriation of trade secrets, offering licenses to such intellectual property, or challenging our intellectual property. For example in 2018 Stamford Devices Limited opposed our European patent—EP2806926 before the parties reached a settlement in 2019. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights. At any given time, we may be involved as either a plaintiff or a defendant in a number of patent infringement actions, the outcomes of which may not be known for prolonged periods of time.

The large number of patents, the rapid rate of new patent applications and issuances, the complexities of the technologies involved and the uncertainty of litigation significantly increase the risks related to any patent litigation. Any potential intellectual property litigation also could force us to do one or more of the following:

- stop selling, making, using, or exporting products that use the disputed intellectual property;
- obtain a license from the intellectual property owner to continue selling, making, exporting, or using products, which license may require substantial payments and may not be available on reasonable terms, or at all;
- incur significant legal expenses;
- pay substantial damages or royalties to the party whose intellectual property rights we may be found to be infringing, potentially including treble damages if the court finds that the infringement was willful;
- if a license is available from a third-party, we may have to pay substantial royalties, upfront fees or grant cross-licenses to intellectual property rights for our products and services;
- pay the attorney fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing;
- find non-infringing substitute products, which could be costly and create significant delay due to the need for FDA regulatory clearance;
- pay substantial damages to our customers or end users to discontinue use or replace infringing technology with non-infringing technology;
- lose the opportunity to opportunity to successfully protect our intellectual property and assert it against others;
- find alternative supplies for infringing products or processes, which could be costly and create significant delay due to the need for FDA regulatory clearance; or
- redesign those products or processes that infringe any third-party intellectual property, which could be costly, disruptive, and/or infeasible.

From time to time, we may be subject to legal proceedings and claims in the ordinary course of business with respect to intellectual property. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock. Finally, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

If any of the foregoing occurs, we may have to withdraw existing products from the market or may be unable to commercialize one or more of our products, all of which could have a material adverse effect on our business, results of operations and financial condition.

In addition, we may indemnify our customers, suppliers and international distributors against claims relating to the infringement of the intellectual property rights of third parties relating to our products, methods, and/or manufacturing processes. Third parties may assert infringement claims against our customers, suppliers, or distributors. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers, suppliers or distributors, regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of our customers, suppliers, or distributors or may be required to obtain licenses for the products they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products, or our suppliers may be forced to stop providing us with products.

Similarly, interference or derivation proceedings provoked by third parties or brought by the USPTO or any foreign patent authority may be necessary to determine the priority of inventions or other matters of inventorship with respect to our patents or patent applications. We may also become involved in other contested proceedings, such as re-examination, inter parties review, or opposition proceedings, before the USPTO or its foreign counterparts relating to our intellectual property or the intellectual property rights of others. An unfavorable outcome in any such proceedings could require us to cease using the related technology or to attempt to license rights to it from the prevailing party or could cause us to lose valuable intellectual property rights. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, if any license is offered at all. Litigation or other proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees.

***Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our existing and future products.***

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. 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, may affect patent litigation, and switched the United States patent system from a “first-to-invent” system to a “first-to-file” system. Under a “first-to-file” system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, in particular, the first-to-file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our patents and applications. Furthermore, the U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by United States and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future.

***Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.***

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. While an unintentional lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our products or procedures, we may not be able to stop a competitor from marketing products that are the same as or similar to our own, which would have a material adverse effect on our business.

***Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time.***

Patents have a limited lifespan, and the protection any patent affords is limited. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. For any patents we have that cover our products (or new patents we obtain), once the patent life has expired we may be open to competition from competitive devices and services. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing devices or services that compete with ours.

***We may not be able to adequately protect our intellectual property rights throughout the world.***

Currently, we own numerous issued patents and pending patent applications that relate to our platform technology. Specifically, as of December 31, 2019, we owned more than 100 issued patents and more than 50 patent applications, totaling an active patent portfolio of over 150 filings granted or pending. Assuming all required fees are paid, issued U.S. patents owned by us will expire between December 2020 and May 2039.

Filing, prosecuting and defending patents on our products in all countries throughout the world would be prohibitively expensive. The requirements for patentability differ in certain countries, particularly developing countries, and the breadth of patent claims allowed can be inconsistent. In addition, the laws of some foreign countries may not protect our intellectual property rights to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories in which we have patent protection that may not be sufficient to terminate infringing activities.

We do not have patent rights in certain foreign countries in which a market may exist. Moreover, in foreign jurisdictions where we do have patent rights, proceedings to enforce such rights could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, and our patent applications at risk of not issuing. Additionally, such proceedings could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Thus, we may not be able to stop a competitor from marketing and selling in foreign countries products that are the same as or similar to our products, and our competitive position in the international market would be harmed.

***We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.***

We could in the future be subject to claims that we or our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other proprietary information of former employers or competitors. Although we have procedures in place that seek to prevent our employees and consultants from using the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may in the future be subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. If our defense to those claims fails, in addition to paying monetary damages, a court could prohibit us from using technologies or features 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 or features that are important or essential to our products would have a material adverse effect on our business and may prevent us from selling our products or from practicing our processes. In addition, we may lose valuable intellectual property rights or personnel. Moreover, any such 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 have an adverse effect on our business, results of operations and financial condition.

**Risks Related to Our Indebtedness**

***Our substantial indebtedness may have a material adverse effect on our business, results of operations and financial condition.***

We have a significant amount of indebtedness. As of December 31, 2019, we had approximately $42.6 million of aggregate principal amount of indebtedness outstanding under our Credit Agreement and Guaranty with Perceptive Credit Holdings II, LP, or Perceptive. We also had $3.5 million outstanding under our Business Financing Agreement with Western Alliance Bank, or the Revolving Facility, as of December 31, 2019.

Our substantial level of indebtedness increases the risk that we may be unable to generate cash sufficient to pay amounts due in respect of our indebtedness. Our substantial indebtedness could have other important consequences to our debt holders and significant effects on our business. For example, it could:

- increase our vulnerability to adverse changes in general economic, industry and competitive conditions;
- require us to dedicate a substantial portion of our cash flow from operations to making payments on our indebtedness, thereby reducing the availability of our cash flow to fund working capital, capital expenditures and other general corporate purposes;
- limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate;
- expose us to the risk of increased interest rates as certain of our borrowings are at variable rates, and we may not be able to enter into interest rate swaps and any swaps we enter into may not fully mitigate our interest rate risk;
- restrict us from capitalizing on business opportunities;
- make it more difficult to satisfy our financial obligations, including payments on our indebtedness;
- place us at a competitive disadvantage compared to our competitors that have less debt; and
- limit our ability to borrow additional funds for working capital, capital expenditures, acquisitions, debt service requirements, execution of our business strategy or other general corporate purposes.

In addition, the credit agreements governing our credit facilities are secured by substantially all of our assets, including our intellectual property, and contain restrictive covenants that limit our ability to engage in activities that may be in our long-term best interests. Our failure to comply with those covenants could result in an event of default that, if not cured or waived, could result in the acceleration of all of our indebtedness.

***Despite our current level of indebtedness, we may still be able to incur substantially more debt. This could further exacerbate the risks associated with our substantial leverage.***

We may be able to incur significant additional indebtedness in the future. Although the credit agreements governing our credit facilities limit our ability and the ability of our present and future subsidiaries to incur additional indebtedness, the terms of the credit facilities permit us to incur significant additional indebtedness. In addition, the credit agreements governing our credit facilities do not prohibit us from incurring obligations that do not constitute indebtedness as defined therein. To the extent that we incur additional indebtedness or such other obligations, the risk associated with our substantial indebtedness described above, including our potential inability to service our debt, will increase.

***We will require a significant amount of cash to service our debt, and our ability to generate cash depends on many factors beyond our control, and any failure to meet our debt service obligations could materially adversely affect our business, results of operations and financial condition.***

Our ability to make payments on and to refinance our indebtedness and to fund working capital needs and planned capital expenditures will depend on our ability to generate cash in the future. This, to a certain extent, is subject to general economic, financial, competitive, business, legislative, regulatory and other factors that are beyond our control.

If our business does not generate sufficient cash flow from operations or if future borrowings are not available to us in an amount sufficient to enable us to pay our indebtedness or to fund our other liquidity needs, we may need to refinance all or a portion of our indebtedness on or before the maturity thereof, sell assets, reduce or delay capital investments or seek to raise additional capital, any of which could have a material adverse effect on our business, results of operations and financial condition. In addition, we may not be able to effect any of these actions, if necessary, on commercially reasonable terms or at all. Our ability to restructure or refinance our indebtedness will depend on the condition of the capital markets and our financial condition at such time. Any refinancing of our debt could be at higher interest rates and may require us to comply with more onerous covenants, which could further restrict our business operations. The terms of existing or future debt instruments, including the credit agreements governing our credit facilities, may limit or prevent us from taking any of these actions. In addition, any failure to make scheduled payments of interest and principal on our outstanding indebtedness would likely result in a reduction of our credit rating, which could harm our ability to incur additional indebtedness on commercially reasonable terms or at all. Our inability to generate sufficient cash flow to satisfy our debt service obligations, or to refinance or restructure our obligations on commercially reasonable terms or at all, would have an adverse effect, which could be material, on our business, results of operations and financial condition, as well as on our ability to satisfy our obligations in respect of the credit facilities and our other indebtedness.

***Our failure to comply with the agreements relating to our outstanding indebtedness, including as a result of events beyond our control, could result in an event of default that could materially adversely affect our business, results of operations and financial condition.***

If there were an event of default under any of the agreements relating to our outstanding indebtedness, the holders of the defaulted debt could cause all amounts outstanding with respect to that debt to be due and payable immediately. We cannot guarantee that our assets or cash flow would be sufficient to fully repay borrowings under our outstanding debt instruments if accelerated upon an event of default.

Further, if we are unable to repay, refinance or restructure our indebtedness under our secured debt, the holders of such debt could proceed against the collateral securing that indebtedness. In addition, any event of default or declaration of acceleration under one debt instrument could also result in an event of default under one or more of our other debt instruments.

As a result, any default by us on our indebtedness could have a material adverse effect on our business, results of operations and financial condition.

***The credit agreements governing our credit facilities restrict our current and future operations, particularly our ability to respond to changes or to take certain actions.***

The credit agreements governing our credit facilities are secured by substantially all of our assets, including our intellectual property, and impose significant operating and financial restrictions and limit our ability and our other restricted subsidiaries' ability to, among other things:

- incur additional indebtedness and guarantee indebtedness;
- pay dividends or make other distributions in respect of, or repurchase or redeem, capital stock;
- enter into any new line of business not reasonably related to our existing business;
- pay, prepay, redeem or repurchase certain debt;
- make loans and investments;
- sell or otherwise dispose of assets or enter into sale and lease-back transactions;
- incur liens;
- enter into transactions with affiliates;

- enter into agreements restricting our subsidiaries' ability to pay dividends;
- change our fiscal year or make any significant changes in accounting treatment or reporting practices;
- amend, modify or terminate material agreements and organizational documents;
- enter into certain inbound and outbound licenses; and
- consolidate, merge or sell all or substantially all of our assets.

As a result of these covenants and restrictions, we are and will be limited in how we conduct our business, and we may be unable to raise additional debt or equity financing to compete effectively or to take advantage of new business opportunities. In addition, each of our credit facilities requires us to comply with a minimum liquidity covenant at all times and a minimum revenue covenant measured at the end of each fiscal quarter. The operating and financial restrictions and covenants in the credit facilities, as well as any future financing agreements that we may enter into, may restrict our ability to finance our operations, engage in business activities or expand or fully pursue our business strategies. Our ability to comply with these covenants may be affected by events beyond our control, and we may not be able to meet those covenants. We cannot guarantee that we will be able to maintain compliance with these covenants in the future and, if we fail to do so, that we will be able to obtain waivers from the lenders and/or amend the covenants.

Our failure to comply with the restrictive covenants described above as well as others contained in our future debt instruments from time to time could result in an event of default, which, if not cured or waived, could result in our being required to repay these borrowings before their due date. If we are forced to refinance these borrowings on less favorable terms, our business, results of operations and financial condition could be adversely affected.

***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 LIBOR rates after 2021. As a result, LIBOR may be discontinued by 2021. While there is no consensus on 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 ("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. At this time, it is impossible to predict whether the SOFR or another reference rate will become an accepted alternative to LIBOR. The manner and impact of this transition may materially adversely affect the trading market for LIBOR-based securities, including our Credit Agreement and Guarantee with Perceptive, as well as the applicable interest rate on and the amount of interest paid on our current or future debt obligations, including our Credit Agreement and Guarantee with Perceptive.

**Risks Related to Our Common Stock**

***The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock.***

The trading price of our common stock may be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. Factors that could cause volatility in the market price of our common stock include, but are not limited to:

- actual or anticipated fluctuations in our financial condition and operating results;
- actual or anticipated changes in our growth rate relative to our competitors;
- commercial success and market acceptance of our products;
- success of our competitors in developing or commercializing products;
- ability to commercialize or obtain regulatory approvals for our products, or delays in commercializing or obtaining regulatory approvals;
- strategic transactions undertaken by us;
- additions or departures of key personnel;
- product liability claims;

- prevailing economic conditions;
- disputes concerning our intellectual property or other proprietary rights;
- FDA or other U.S. or foreign regulatory actions affecting us or the healthcare industry;
- healthcare reform measures in the United States;
- sales of our common stock by our officers, directors or significant stockholders;
- future sales or issuances of equity or debt securities by us;
- international trade disputes;
- international political and economic instability, including wars with foreign countries;
- domestic political and economic instability, including without limitation instability caused by the recently concluded impeachment proceedings and/or the 2020 U.S. Presidential election;
- business disruptions caused by earthquakes, fires or other natural disasters; and
- issuance of new or changed securities analysts' reports or recommendations regarding us.

In addition, the stock market in general, and the market for companies like ours in particular, have from time to time experienced extreme volatility that has been often unrelated to the operating performance of particular companies. A certain degree of stock price volatility can be attributed to being a newly public company. These broad market and industry fluctuations may negatively impact the price or liquidity of our common stock, regardless of our operating performance. For these reasons, we believe comparisons of our financial results from various reporting periods are not necessarily meaningful and should not be relied upon as an indication of our future performance.

***We have incurred and expect to continue to incur significant costs as a result of operating as a public company and our management expects to devote substantial time to public company compliance programs.***

To comply with the requirements imposed on us as a public company, we have incurred and expect to continue to incur significant legal, insurance, accounting and other expenses. We have invested and intend to continue to invest resources to comply with evolving laws, regulations and standards, and this investment will result in increased general and administrative expenses and may divert management's time and attention from product development activities. These laws, regulations and standards are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters, enforcement proceedings and higher costs necessitated by ongoing revisions to disclosure and governing practices. The costs associated with maintaining directors' and officers' insurance has risen and may continue to rise in the future, which may require us to accept reduced coverage or incur substantially higher costs to obtain coverage. We also expect the rules and regulations associated with being a public company to make it more expensive for us to maintain directors' and officers' insurance. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

The Sarbanes-Oxley Act requires that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are continuing to develop and refine our disclosure controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that information required to be disclosed in reports under the Securities Exchange Act of 1934, as amended, is accumulated and communicated to our principal executive and financial officers. Any failure to develop or maintain effective controls could adversely affect the results of periodic management evaluations. In the event that we are not able to demonstrate compliance with the Sarbanes-Oxley Act, that our internal control over financial reporting is perceived as inadequate, or that we are unable to produce timely or accurate financial statements, investors may lose confidence in our operating results and the price of our common stock could decline. In addition, if we are unable to continue to meet these requirements, we may not be able to remain listed on the NYSE.

As a public company, we are required to comply with certain of the SEC's rules that implement Section 404 of the Sarbanes-Oxley Act, require management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of our internal control over financial reporting commencing with our second annual report. This assessment will need to include the disclosure of any material weaknesses in our internal control over financial reporting identified by our management or our independent registered public accounting firm. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion.

Our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting until, at earliest, the later of our second annual report or the first annual report required to be filed with the SEC following the date we are no longer an "emerging growth company" as defined in the JOBS Act. We cannot assure you that there will not be material weaknesses in our internal controls in the future.

***We may be subject to securities litigation, which is expensive and could divert our management's attention.***

The market price of our securities may be volatile, and in the past companies that have experienced volatility in the market price of their securities have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns.

***Our principal stockholders and management own a significant percentage of our stock and are able to exercise significant influence over matters subject to stockholder approval.***

As of December 31, 2019, our executive officers, directors and stockholders who owned more than 5% of our outstanding common stock, together with their respective affiliates, beneficially owned approximately 54.8% of our common stock, including shares subject to outstanding options and warrants that are exercisable within 60 days after such date. Accordingly, these stockholders will be able to exert a significant degree of influence over our management and affairs and over matters requiring stockholder approval, including the election of our board of directors and approval of significant corporate transactions. This concentration of ownership could have the effect of entrenching our management or board of directors, delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material and adverse effect on the fair market value of our common stock.

***A significant portion of our total outstanding shares may be sold into the public market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is doing well.***

Sales of a substantial number of shares of our common stock in the public market could occur at any time after the expiration of the lock-up agreements entered into by each of our directors, officers and the majority of our other stockholders in connection with our initial public offering and follow-on offering. These sales, or the market perception that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. We have also registered all shares of common stock that we may issue under our equity compensation plans. Upon expiration of the lock-up agreements entered into in connection with our initial public offering, these shares can be freely sold in the public market subject to volume limitations applicable to affiliates. If any of these shares are sold, or if it is perceived that they will be sold, the market price of our common stock could decline.

Moreover, holders of an aggregate of 9,898,290 shares of our common stock have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. If such holders, by exercising their registration rights, cause a large number of securities to be registered and sold into the public market, these sales could have an adverse effect on the market price for our common stock.

***We do not anticipate paying any cash dividends on our common stock in the foreseeable future; therefore, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.***

We have never declared or paid any cash dividends on our common stock and do not intend to do so in the foreseeable future. We currently intend to retain all available funds and any future earnings to finance the growth and development of our business. In addition, our credit facilities contain and the terms of any future credit agreements we enter into may contain, terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

***If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, our stock price and trading volume could decline.***

The trading market for our common stock will depend, in part, on the research and reports that securities or industry analysts publish about us or our business. As a recently public company, we may be slow to attract securities and industry analysts coverage. If no or a limited number of securities or industry analysts commence coverage of the Company, the price for our common stock could be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who cover us downgrade our common stock or publish inaccurate or unfavorable research about our business, our stock price could decline. In addition, if our operating results fail to meet the forecast of analysts, our stock price could decline. If one or more of these analysts cease coverage of the Company or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our stock price and trading volume to decline.

***Provisions in our amended and restated certificate of incorporation, our amended and restated by-laws and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.***

Our amended and restated certificate of incorporation, amended and restated by-laws and Delaware law contain provisions that may have the effect of discouraging, delaying or preventing a change in control of us or changes in our management that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. Our amended and restated certificate of incorporation and amended and restated by-laws, include provisions that:

- authorize "blank check" preferred stock, which could be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend and other rights superior to our common stock;
- create a classified board of directors whose members serve staggered three-year terms;
- specify that special meetings of our stockholders can be called only by our board of directors;
- prohibit stockholder action by written consent;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- provide that our directors may be removed only for cause;
- specify that no stockholder is permitted to cumulate votes at any election of directors;
- expressly authorized our board of directors to modify, alter or repeal our amended and restated by-laws; and
- require supermajority votes of the holders of our common stock to amend specified provisions of our amended and restated certificate of incorporation and amended and restated by-laws.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock.

In addition, because we are incorporated in the State of Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, or the DGCL, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Any provision of our amended and restated certificate of incorporation, amended and restated by-laws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

***Our amended and restated certificate of incorporation designates the state or federal courts within the State of Delaware as the exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.***

Our amended and restated certificate of incorporation provides that, subject to limited exceptions, the state or federal courts within the State of Delaware will be exclusive forums for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (3) any action asserting a claim against us arising pursuant to any provision of the DGCL, our amended and restated certificate of incorporation or our amended and restated by-laws or (4) any other action asserting a claim against us that is governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our amended and restated certificate of incorporation described above. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and employees. Alternatively, if a court were to find these

provisions of our amended and restated certificate of incorporation inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business and financial condition. For example, the Court of Chancery of the State of Delaware recently determined that a provision stating that federal district courts of the United States are the exclusive forum for resolving any complaint asserting a cause of action under the Securities Act of 1934, as amended, is not enforceable. However, this decision may be reviewed and ultimately overturned by the Delaware Supreme Court.

**Item 1B. Unresolved Staff Comments.**

None.

**Item 2. Properties.**

Our principal office is located at 100 Domain Drive, Exeter, New Hampshire 03833, where we lease approximately 84,140 square feet of office, manufacturing, research & development and warehouse space. We lease this space under an agreement that terminates on January 28, 2025. We intend to lease additional space as we add employees, and we believe that suitable additional or substitute space will be available as needed to accommodate any such expansion of our operations. Solus Medical leases approximately 453 square meters of office and warehouse space at 2 Dryden Loan, Bilston Glen Industrial Estate, Loanhead, United Kingdom. We lease this space under a lease that terminates on February 15, 2022.

**Item 3. Legal Proceedings.**

From time to time we may become involved in various legal proceedings, including those that may arise in the ordinary course of business. We recently settled a litigation with Engineered Medical Systems, Inc., or EMS, a former supplier of a component of our Precision Flow systems. EMS filed a complaint against us in Indiana state court on June 12, 2018 alleging breach of contract and other causes of action and seeking damages of at least $0.8 million and all other forms of just and appropriate relief. This matter was subsequently removed to the United States District Court for the Southern District of Indiana. We filed a complaint against EMS in Superior Court in Rockingham County, New Hampshire on June 15, 2018 alleging breach of contract, violation of the New Hampshire Consumer Protection Act, and other causes of action and seeking damages of at least $2.1 million and all other forms of just and appropriate relief. Each party filed a motion to dismiss against the other party's complaint. EMS' motion to dismiss in Superior Court in Rockingham County, New Hampshire was denied. Following this decision, EMS withdrew its complaint in Indiana. The parties reached a settlement agreement on December 16, 2019 whereby EMS agreed to pay Vapotherm $0.65 million and the Rockingham Superior Court approved the parties' stipulation of dismissal with prejudice on January 2, 2020.

We believe there is no other litigation pending that could have, individually, or in the aggregate, a material adverse effect on our results of operations or financial condition.

**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.

**Market Information**

Our common stock has been listed on the NYSE under the symbol "VAPO" since November 14, 2018. Prior to that date, there was no established public trading market for our common stock.

**Holders**

As of February 27, 2020, there were 152 holders of record of our common stock. The actual number of holders of our common stock is greater than this number of record holders and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers or held by other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

**Issuer Purchases of Equity Securities**

None.

**Recent Sales of Unregistered Securities**

None.

**Use of Proceeds**

On November 13, 2018, the SEC declared effective our Registration Statement on Form S-1 (File No. 333-227897), as amended, filed in connection with our initial public offering, or the Registration Statement. Pursuant to the Registration Statement, we registered the offer and sale of 4,000,000 shares of our common stock with an aggregate offering price of approximately $56.0 million. Merrill Lynch, Pierce, Fenner & Smith Incorporated and William Blair & Company, L.L.C. acted as representatives of the underwriters for the offering. On November 13, 2018, the underwriters fully exercised their option to purchase 600,000 additional shares of common stock with an aggregate offering price of approximately $8.4 million pursuant to the underwriting agreement. On November 14, 2018, we issued and sold 4,600,000 shares of our common stock at a price to the public of $14.00 per share. Upon completion of the initial public offering on November 16, 2018, we received net proceeds of approximately $57.4 million, after deducting the underwriting discount of $4.5 million and offering expenses of $2.5 million. No payments for such expenses were made directly or indirectly to (i) any of our officers or directors or their associates, (ii) any persons owning 10% or more of any class of our equity securities or (iii) any of our affiliates.

The offering terminated after the sale of all securities registered pursuant to the Registration Statement. The net proceeds of approximately $57.4 million from our initial public have been invested in short-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government. There has been no material change in the expected use of the net proceeds from our initial public as described in our final prospectus, dated November 13, 2018, filed with the SEC pursuant to Rule 424(b) relating to our Registration Statement on Form S-1.

### Item 6. Selected Financial Data.

We are a smaller reporting company as defined in Item 10(f)(1) of Regulation S-K and are not required to provide information under this item.

**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 financial statements and the related notes to those statements included elsewhere in this Annual Report on Form 10-K. In addition to historical financial information, the following discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Some of the numbers included herein have been rounded for the convenience of presentation. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors, including those discussed under Part I., "Item 1A. Risk Factors" and elsewhere in this Annual Report on Form 10-K.*

**Overview**

We are a global medical technology company focused on the development and commercialization of our proprietary Hi-VNI Technology products that are used to treat patients of all ages suffering from respiratory distress. Our Hi-VNI Technology delivers non-invasive ventilatory support by providing heated, humidified and oxygenated air at a high velocity to patients through a comfortable small-bore nasal interface. Our Precision Flow systems, which use Hi-VNI Technology, are clinically validated alternatives to, and address many limitations of, the current standard of care for the treatment of respiratory distress in a hospital setting. As of December 31, 2019, more than 2.1 million patients have been treated with our Precision Flow systems, and we have a global installed base of over 16,000 capital units.

We currently offer four versions of our Precision Flow systems: Precision Flow Hi-VNI, Precision Flow Plus, Precision Flow Classic and Precision Flow Heliox. We also initiated a limited release of our Oxygen Assist Module to certain United Kingdom accounts in February 2020 and we may expand that limited release to certain European accounts in the second quarter of 2020. The Oxygen Assist Module can be used with all versions of our Precision Flow systems except for the Precision Flow Heliox. Our Oxygen Assist Module helps clinicians maintain the pulse oxygen saturation, or SpO2, within the target SpO2 range over a significantly greater proportion of time while requiring significantly fewer manual adjustments to the equipment. Maintenance of the prescribed oxygen saturation range may reduce the health risks associated with dosing too much, or too little, oxygen, such as visual or developmental impairment and mortality in neonates. We intend to fully launch the Oxygen Assist Module commercially throughout the United Kingdom and Europe by the end of 2020, at which time we believe we will begin generating revenue from the product.

We generate revenue primarily from sales of the disposable products utilized with our proprietary Precision Flow systems. We also generate revenue from the capital units themselves. We offer different options to our hospital customers for acquiring Precision Flow capital units, ranging from the purchase of the Precision Flow capital units with payment in full at the time of purchase, to financed purchases of the Precision Flow capital units, to bundled discounts involving the placement of Precision Flow capital units for use by the customer at no upfront charge in connection with the customer's ongoing purchase of disposable products.

We sell our Precision Flow systems to hospitals through a direct sales organization in the United States and in the United Kingdom and through distributors in other select countries outside of the United States and United Kingdom. We intend to fully launch our Oxygen Assist Module commercially throughout the United Kingdom and Europe by the end of 2020 through a direct sales organization in the United Kingdom and through distributors in other select countries in Europe. In addition, we have clinical educators who are experienced users of Hi-VNI Technology and who focus on our medical education efforts to facilitate adoption and increase utilization. We focus on physicians, respiratory therapists and nurses who work in acute hospital settings, including the ED and adult, pediatric and neonatal ICUs. Our relationship with these clinicians is particularly important, as it enables our products to follow patients through the care continuum. We have sold our Precision Flow systems to over 1,500 hospitals across the United States, where they have been primarily deployed in the ICU setting.

We assemble our Precision Flow systems in our facility in New Hampshire and we rely on third-party suppliers for a majority of the components of our products, including many single source suppliers. We maintain higher levels of inventory to protect ourselves from supply interruptions, and, as a result, we are subject to the risk of inventory obsolescence and expiration, which could lead to inventory impairment charges. We currently ship our Precision Flow systems from our facility in New Hampshire directly to our United States customers and many of our international distributors on a purchase order basis. Warehousing and shipping operations for some of our international distributors are handled by a third-party vendor with facilities located in the Netherlands. While our customers have the right to return purchased products subject to a restocking fee, our historical return experience has been immaterial.

Since inception, we have financed our operations primarily through public offerings of our common stock, private placements of our convertible preferred stock, sales of our Precision Flow systems and amounts borrowed under our credit facilities. We have devoted the majority of our resources to research and development activities related to our Precision Flow systems including regulatory initiatives and sales and marketing activities. We have invested heavily in our sales and marketing function by increasing the number of sales representatives and clinical educators to facilitate adoption and increase utilization of our Hi-VNI Technology products and expanded our digital marketing initiatives and medical education programs. For the year ended December 31, 2019, we generated revenue of $48.1 million and had a net loss of $51.1 million compared to revenue of $42.4 million and a net loss of $42.5 million for the year ended December 31, 2018. Our accumulated deficit as of December 31, 2019 was $265.4 million. In 2019, 76.0% of our revenue was derived in the United States and 24.0% was derived outside the United States. No single customer accounted for more than 10% of our revenue.

We intend to continue to make significant investments in our sales and marketing organization by increasing the number of U.S. sales representatives, expanding our international marketing programs and expanding direct to clinician digital marketing efforts to help facilitate further adoption among existing hospital accounts as well as broaden awareness of our products to new hospitals. We also expect to continue to make investments in research and development, regulatory affairs and clinical studies to develop future generations of our Hi-VNI Technology products, support regulatory submissions and demonstrate the clinical efficacy of our new products. Because of these and other factors, we expect to continue to incur net losses for the next several years and we expect to require additional funding, which may include future equity and debt financings.

**Components of Our Results of Operations**

***Revenue***

Our revenue consists primarily of the sale of products, leases and services.

*Product Revenue*

We primarily derive our revenue from the sale of our products to hospitals in the United States and United Kingdom and through distributors in select countries outside of the United States. Product sales consist of the following:

*Capital Revenue*

Our capital revenue is derived from the sale of our capital equipment, which consists of the Precision Flow Hi-VNI, Precision Flow Plus, Precision Flow Classic, Precision Flow Heliox, Vapotherm Transfer Unit 2.0 and Q50 compressor. Capital equipment sales include a one-year warranty.

*Disposable Revenue*

Our disposable revenue is derived from the sale of single-use disposables, nasal interfaces, or cannulas, and adaptors used in conjunction with the Precision Flow capital units.

*Lease Revenue*

We enter into agreements to lease our capital equipment. We assess and classify these transactions as sales-type or operating leases based on whether the lease transfers ownership of the equipment to the lessee. Equipment included in arrangements which provide for the transfer of title at, or shortly after, the end of the lease term in exchange for the payment of a nominal fee are accounted for as a sales-type lease. We record the current value of future lease payments as a component of prepaid expenses and other current assets in our consolidated balance sheets. Equipment included in arrangements that do not transfer title are accounted for as operating leases and we recognize revenue on a straight-line basis as it becomes due over the lease term.

*Service Revenue*

This revenue consists of service, component part and freight revenue offset by rebates and fees payable to GPOs, Integrated Delivery Networks, or IDNs and distributor partners. Service revenue consists of fees associated with routine service of capital units and the sale of extended service contracts and preventative maintenance plans. In addition, we sell small quantities of component parts in the United States, United Kingdom, and to third-party international service centers who service Precision Flow capital units outside of the United States. Freight revenue is based upon actual freight costs plus a percentage markup of these costs associated with the shipment of products domestically, and to a lesser extent, internationally.

Recent revenue growth has been driven by, and we expect continued growth as a result of, increasing revenue from product sales due to our growing installed base of Precision Flow systems and related disposables sales. Our revenue has fluctuated, and we expect our revenue to continue to fluctuate, from quarter to quarter due to a variety of factors including seasonality. We have historically experienced seasonality in our first quarter due to the impact of the flu season in the Northern Hemisphere and in our fourth quarter, which coincides with our customers' fiscal year-end and often drives higher purchases of capital equipment as previously approved but unspent capital budgets typically expire at year-end.

***Cost of Revenue and Gross Margin***

Cost of revenue consists primarily of costs incurred in the production process, including costs of component materials, assembly labor and overhead, warranty, provisions for slow-moving and obsolete inventory, facilities-related expenses, depreciation and freight costs for items sold. Within the overhead costs we include personnel-related expenses, including salaries, bonuses, benefits and stock-based compensation for our procurement, quality control and operations personnel. We provide a one-year warranty on capital equipment, and we establish a reserve for warranty repairs based on historical warranty repair costs incurred. Provisions for warranty obligations, which are included in cost of revenue, are provided for at the time of shipment. Cost of revenue in absolute dollars will increase as our sales volume increases.

We calculate gross margin as gross profit divided by revenue. Our gross margin has been, and we expect it will continue to be, affected by a variety of factors, including manufacturing costs, the average selling price of our Precision Flow systems, the implementation of disposable cost-reduction initiatives, sales volume and inventory obsolescence costs. Sales mix also impacts our gross margins as our average selling price in the United States is typically higher than for our international sales given our distribution model. In addition, sales of our single-use disposables carry a higher margin than that of our capital equipment sales. Our gross margin may increase over the long-term to the extent our production volumes increase, we launch new products and we continue to experience cost savings derived from supply chain and manufacturing efficiencies. However, our gross margin may fluctuate from quarter to quarter due to seasonality.

***Operating Expenses***

*Research and Development*

Research and development expenses consist primarily of product development, engineering, regulatory expenses, testing, laboratory supplies, consulting services and other costs associated with future generations of products using our Hi-VNI Technology. These expenses include personnel-related expenses, including salaries, bonuses, benefits and stock-based compensation for employees in our research and development, regulatory, quality assurance and innovation functions. We expect research and development expenses to increase in the future as we develop future generations of products using our Hi-VNI Technology and companion products. We expect research and development expenses as a percentage of revenue to vary over time depending on the level and timing of new product development initiatives.

*Sales and Marketing*

Our sales and marketing expenses consist primarily of personnel-related expenses, including salaries, commissions and bonuses, travel expenses, benefits and stock-based compensation for employees in our sales and marketing, customer service and medical education functions. Other sales and marketing expenses include consulting services, education, training, tradeshows, digital marketing, medical education and clinical studies. We expect sales and marketing expenses to continue to increase in absolute dollars as we continue to expand our sales and marketing organization to both drive and support our planned growth in revenue. We expect sales and marketing expenses to continue to decrease as a percentage of revenue primarily as, and to the extent, our revenue grows.

*General and Administrative*

General and administrative expenses consist primarily of personnel-related expenses, including salaries, bonuses, benefits, and stock-based compensation, for employees in our finance, administration, human resources, information technology, and legal functions. Other general and administrative expenses include professional services fees, audit fees, travel expenses, insurance costs and general corporate expenses including facilities-related expenses. We expect our general and administrative expenses will increase in absolute dollars as we expand our headcount to support our growth and operations as a public company, upgrade our director and officer insurance coverage to be commensurate with other publicly listed companies and incur additional expenses related to audit, legal, and tax-related services associated with maintaining compliance with exchange listing and SEC requirements. Over time, we expect general and administrative expenses to decrease as a percentage of revenue primarily as, and to the extent, our revenue grows.

***(Gain) Loss on Disposal of Property and Equipment***

The (gain) loss on disposal of property and equipment is calculated by comparing the net proceeds received for the disposed property and equipment against the net book value of the disposed property and equipment on the date of disposal with the difference being recorded as a (gain) loss as a component of operating expenses. We expect (gain) loss on disposal of property and equipment to vary over time.

***Other Expense, Net***

Other expense, net consists primarily of interest expense related to our credit facilities offset by interest income driven by the interest accruing on cash and cash equivalents. Other expense, net also includes the gain on litigation settlement, loss on the extinguishment of debt, the fair value adjustment of our previously outstanding convertible preferred stock warrants, which were accounted for as a liability and marked to market at each reporting period and foreign currency gains or losses arising from transactions denominated in foreign currencies.

Immediately prior to the closing of our initial public offering, our outstanding convertible preferred stock warrants automatically converted into warrants to purchase shares of our common stock.

***Benefit for Income Taxes***

The benefit for income taxes represents a benefit for net deferred income tax assets deemed more likely than not to be realized by our foreign subsidiary. We have not recorded any federal or state income tax benefits related to domestic operating losses due to uncertainty about future taxable income.

**Results of Operations**

| | Year Ended December 31, | |
|---|---|---|
| | 2019 | 2018 |
| | (in thousands) | |
| Net revenue | $ 48,104 | $ 42,377 |
| Cost of revenue | 26,793 | 25,605 |
| Gross profit | 21,311 | 16,772 |
| Operating expenses | | |
| Research and development | 13,376 | 8,771 |
| Sales and marketing | 37,689 | 33,927 |
| General and administrative | 18,410 | 11,186 |
| Loss on disposal of property and equipment | - | 121 |
| Total operating expenses | 69,475 | 54,005 |
| Loss from operations | (48,164) | (37,233) |
| Other expense, net | (3,041) | (5,235) |
| Net loss before income taxes | (51,205) | (42,468) |
| Benefit for income taxes | (146) | - |
| Net loss | $ (51,059) | $ (42,468) |

***Fiscal Years Ended December 31, 2019 and 2018***

*Revenue*

| | Year Ended December 31, | | | | | |
|---|---|---|---|---|---|---|
| | 2019 | | 2018 | | Change | |
| | (in thousands, except percentages) | | | | | |
| | Amount | % of Revenue | Amount | % of Revenue | $ | % |
| **Product Revenue** | | | | | | |
| Capital | $ 9,324 | 19.4% | $ 10,780 | 25.4% | $ (1,456) | -13.5% |
| Disposable | 35,055 | 72.9% | 28,453 | 67.1% | 6,602 | 23.2% |
| Subtotal Product Revenue | 44,379 | 92.3% | 39,233 | 92.5% | 5,146 | 13.1% |
| **Lease Revenue** | 1,721 | 3.5% | 1,334 | 3.2% | 387 | 29.0% |
| **Service Revenue** | 2,004 | 4.2% | 1,810 | 4.3% | 194 | 10.7% |
| **Total Revenue** | $ 48,104 | 100.0% | $ 42,377 | 100.0% | $ 5,727 | 13.5% |

Revenue increased $5.7 million, or 13.5%, to $48.1 million for the year ended December 31, 2019 compared to $42.4 million for the year ended December 31, 2018. The increase in revenue was primarily attributable to a $6.6 million increase in disposable revenue as a result of an increase in the installed base of Precision Flow capital units world-wide offset by a decrease in capital product revenue due to a decrease in sales volume of Precision Flow capital units. The $0.4 million increase in lease revenue was primarily attributable to a higher volume of lease contracts, as a higher percentage of Precision Flow capital units were leased versus sold for the year ended December 31, 2019 compared to the year ended December 31, 2018.

Revenue information by geography is summarized as follows:

| | Year Ended December 31, | | | | | |
|---|---|---|---|---|---|---|
| | 2019 | | 2018 | | Change | |
| | (in thousands, except percentages) | | | | | |
| | Amount | % of Revenue | Amount | % of Revenue | $ | % |
| United States | $ 36,583 | 76.0% | $ 33,010 | 77.9% | $ 3,573 | 10.8% |
| International | 11,521 | 24.0% | 9,367 | 22.1% | 2,154 | 23.0% |
| **Total Revenue** | $ 48,104 | 100.0% | $ 42,377 | 100.0% | $ 5,727 | 13.5% |

Revenue generated in the United States increased $3.6 million, or 10.8%, to $36.6 million for the year ended December 31, 2019, compared to $33.0 million for the year ended December 31, 2018. Revenue growth in the United States was primarily due to increased disposable sales resulting from a larger installed base, higher average selling prices and increased utilization of Precision Flow units, and to a lesser extent, an increase in lease revenue, partially offset by a decrease in the sale of Precision Flow units.

Revenue generated in our international markets increased $2.2 million, or 23.0%, to $11.5 million for the year ended December 31, 2019 compared to $9.4 million for the year ended December 31, 2018. Revenue growth outside the United States was primarily due to increased disposable sales resulting from a larger installed base of Precision Flow units and increased average selling prices.

*Cost of Revenue and Gross Margin*

Cost of revenue increased $1.2 million, or 4.6%, to $26.8 million in fiscal year 2019 compared to $25.6 million in fiscal year 2018. The increase was primarily due to increased product costs, primarily due to higher sales volumes of our disposables.

Gross margin increased to 44.3% in fiscal year 2019 compared to 39.6% in fiscal year 2018. The increase in gross margin was driven by a decrease in disposable component costs, increased average selling prices on disposables and a favorable sales mix of disposables. Additionally, we improved operating efficiency by holding operating overhead constant while increasing throughput in our manufacturing facility to support continued sales growth.

*Research and Development Expenses*

Research and development expenses increased $4.6 million, or 52.5%, to $13.4 million in fiscal year 2019 compared to $8.8 million in fiscal year 2018. As a percentage of revenue, research and development expenses increased to 27.8% in fiscal year 2019 compared to 20.7% in fiscal year 2018. The increase in research and development expenses was due to new product development costs and increases in research and development employee-related expenses and stock-based compensation.

*Sales and Marketing Expenses*

Sales and marketing expenses increased $3.8 million, or 11.1%, to $37.7 million in fiscal year 2019 compared to $33.9 million in fiscal year 2018. As a percentage of revenue, sales and marketing expenses decreased to 78.3% in fiscal year 2019 compared to 80.1% in fiscal year 2018. The increase in sales and marketing expenses was primarily due to increased sales headcount and employee-related expenses in our sales and marketing organizations, increased stock-based compensation and increased investments in sales and marketing initiatives in 2019 compared to 2018.

*General and Administrative Expenses*

General and administrative expenses increased $7.2 million, or 64.6%, to $18.4 million in fiscal year 2019 compared to $11.2 million in fiscal year 2018. As a percentage of revenue, general and administrative expenses increased to 38.3% in fiscal year 2019 compared to 26.4% in fiscal year 2018. The increase in general and administrative expenses was primarily due to increased public company costs including headcount and other employee-related expenses, including stock-based compensation, and legal, accounting, insurance and consulting fees.

*Loss on Disposal of Property and Equipment*

The loss on disposal of property and equipment for the year ended December 31, 2018 was attributable to the loss on the disposal of property and equipment associated with our facility consolidation. We expect loss on disposal of property and equipment to vary over time.

*Other Expense, Net*

Other expense, net decreased by $2.2 million, or 41.9%, to $3.0 million in fiscal year 2019 compared to $5.2 million in fiscal year 2018. The decrease in other expense, net was primarily due to one-time items recorded in each fiscal year. Other expense, net, in fiscal year 2019 included a $1.2 million gain on litigation settlement. Other expense, net, in fiscal year 2018 included a $2.8 million loss on extinguishment of debt partially offset by a $0.6 million gain recorded due to the change in the fair value adjustment of our outstanding convertible preferred stock warrants that had been outstanding prior to our initial public offering. Interest expense increased in 2019 due to additional borrowing under our credit facilities and was partially offset by increased interest income in 2019 due to higher cash balances resulting from proceeds received from our initial public offering of common stock in the fourth quarter of 2018 and the public offering of our common stock in the third quarter of 2019.

*Benefit for Income Taxes*

The benefit for income taxes for the year ended December 31, 2019 totaled $0.1 million and there was no income tax provision or benefit recorded for the year ended December 31, 2018. The amounts recorded in 2019 relate to a benefit for net deferred income tax assets deemed more likely than not to be realized by our foreign subsidiary. We have not recorded any federal or state income tax benefits related to domestic operating losses due to uncertainty about future taxable income.

**Seasonality**

Historically, we have experienced seasonality in our first and fourth quarters, and we expect this trend to continue. We have experienced and may in the future experience higher sales in the fourth quarter as a result of increased sales from hospitals nearing their fiscal year-end that have not fully utilized the funds allocated to purchases of our Precision Flow systems. In the first quarter of each year we have experienced and may in the future experience higher sales in direct correlation with the number of patients presenting with respiratory distress due to the severity of the flu season, especially in the Northern Hemisphere.

**Liquidity and Capital Resources**

As of December 31, 2019, we had cash, cash equivalents and restricted cash of $73.5 million and an accumulated deficit of $265.4 million. Our primary sources of capital to date have been from public offerings of our common stock, private placements of our convertible preferred stock, sales of our Precision Flow systems and amounts borrowed under credit facilities. Since inception, we have raised a total of $162.6 million in net proceeds from private placements of our convertible preferred stock. On November 16, 2018, we completed an initial public offering of 4,600,000 shares of common stock at a price of $14.00 per share, which raised net proceeds of $57.4 million after deducting the underwriting discount of $4.5 million and offering expenses of $2.5 million. In August 2019, we completed a public offering of 3,570,750 shares of common stock, which included the full exercise by the underwriters of their option to purchase 465,750 shares of common stock, at a price of $14.50 per share, which raised net proceeds of $48.3 million after deducting the underwriting discount of $3.1 million and offering expenses of $0.4 million.

As of December 31, 2019, we had $3.5 million of outstanding borrowings and $0.8 million availability under the Amended Revolver Agreement. As of December 31, 2019, we had $42.6 million of term debt outstanding under our Credit Agreement and Guaranty.

We believe that our existing cash resources and availability under our line of credit facility will be sufficient to meet our capital requirements and fund our operations for at least the next 12 months. If these sources are insufficient to satisfy our liquidity requirements, we may seek to sell additional equity or make additional borrowings under our existing line of credit facility or enter new debt financing arrangements. If we raise additional funds by issuing equity securities, our stockholders would experience dilution. Debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. Additional financing may not be available at all, or in amounts or on terms unacceptable to us. If we are unable to obtain additional financing, we may be required to delay the development, commercialization and marketing of our Precision Flow systems.

***Cash Flows***

The following table presents a summary of our cash flow for the periods indicated:

| | Year Ended December 31, | |
|---|---|---|
| | 2019 | 2018 |
| | (in thousands) | |
| Net cash provided by (used in): | | |
| Operating activities | $ (39,662) | $ (40,018) |
| Investing activities | (6,307) | (5,180) |
| Financing activities | 59,449 | 76,860 |
| Effect of exchange rate changes on cash, cash equivalents and restricted cash | 5 | - |
| Net increase in cash, cash equivalents, and restricted cash | $ 13,485 | $ 31,662 |

*Operating Activities*

The net cash used in operating activities was $39.7 million in 2019 and consisted primarily of a net loss of $51.1 million, offset by a decrease of $4.5 million in net operating assets and $6.9 million in non-cash charges. Non-cash charges consisted primarily of depreciation and amortization and stock-based compensation expense.

The net cash used in operating activities was $40.0 million in 2018 and consisted primarily of a net loss of $42.5 million and an increase of $3.4 million in net operating assets partially offset by $3.1 million in non-cash charges and $2.8 million loss on the extinguishment of debt. Non-cash charges consisted primarily of depreciation and amortization expense.

*Investing Activities*

Net cash used in investing activities for 2019 and 2018 consisted of purchases of property and equipment of $4.7 million and $5.2 million, respectively. In addition, net cash used in investing activities in 2019 also included $1.6 million to acquire Solus Medical.

*Financing Activities*

Net cash provided by financing activities was $59.4 million in 2019 and consisted primarily of net proceeds of $48.3 million related to a public offering of shares of our common stock and borrowings of $10.8 million under our credit facilities.

Net cash provided by financing activities was $76.9 million in 2018 and consisted primarily of $57.4 million in net proceeds from the initial public offering, borrowings of $32.1 million under our credit facilities and $9.9 million in proceeds from the issuance of Series D-1 convertible preferred stock and $0.5 million in proceeds from the exercise of equity-based awards, offset by $22.3 million in repayment of loans.

Effective January 1, 2019, and further described in Note 2 to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K, we consider restricted cash as a component of cash and cash equivalents as presented on our consolidated statements of cash flows. Previously the net change in restricted cash was considered an investing activity. Prior period presentations have been reclassified to conform to current year presentation.

***Indebtedness***

*Revolving Line of Credit*

In November 2016, we entered into the Revolving Facility, which provided for $7.0 million of available borrowings. Availability under the Revolving Facility is calculated based upon 80% of the eligible receivables (net of pre-paid deposits, pre-billed invoices, other offsets, and contras related to each specific account debtor).

Interest is paid monthly on the average outstanding balance at the Wall Street Journal Prime Rate plus 1.75%, floating, subject to a floor of 3.5%. The interest rate was 6.5% at December 31, 2019.

On April 6, 2018, we amended and restated the Revolving Facility (the "Amended Revolving Facility") to primarily extend the maturity date from September 30, 2018 to September 30, 2020 and increase the revolving line of credit to $7.5 million. On March 22, 2019, we amended and restated the Amended Revolving Facility, which increased the allowable permitted indebtedness under the agreement in connection with our credit card program from $0.3 million to $0.5 million.

The outstanding balance under the Amended Revolving Facility, as amended, was $3.5 million at December 31, 2019. The remaining amount available to borrow based on eligible receivables was $0.8 million at December 31, 2019. The Amended Revolving Facility is secured by substantially all of our personal property, excluding intellectual property.

*Term Debt*

In November 2016, we entered into a Loan and Security Agreement with Solar Capital Ltd., or Solar, for a total facility amounting to $20.0 million, available in three tranches. The first tranche was drawn down in the amount of $10.0 million on the effective date which paid off in full our previous term loan facility of $6.0 million. We achieved the minimum revenue threshold required to draw down the second tranche of $5.0 million of term debt financing which we did in January 2017. In addition, we obtained a signed term sheet for an equity financing in excess of $10.0 million which allowed us to draw down the third and final tranche of $5.0 million term debt financing, which we elected to do in March 2017, bringing our total balance outstanding under this facility to $20.0 million. Pursuant to the Loan and Security Agreement with Solar, interest was to be paid monthly, and the interest rate for all principal amounts advanced under the loan is equal to "LIBOR Rate" plus 8.99%. The facility had a 24-month period from the date of funding where interest only payments were payable. This debt was extinguished in April 2018.

On April 6, 2018, we entered into the Credit Agreement and Guaranty with Perceptive. The Credit Agreement and Guaranty initially provided for a term loan facility in the amount of $42.5 million, available in three tranches, of which the first tranche of $20.0 million was drawn upon closing. This first tranche paid off the borrowings under the Loan and Security Agreement with Solar in full. A second tranche of $10.0 million was drawn on July 20, 2018. The availability of the final tranche of $12.5 million was dependent upon the Company achieving a minimum of $43.2 million in revenue in 2018. On September 27, 2018, the Credit Agreement and Guaranty was amended (the "Amended Credit Agreement and Guaranty") to remove this revenue requirement and extend the final draw down date to March 31, 2019. We borrowed $2.0 million from this third tranche on September 27, 2018. On March 22, 2019, we drew the remaining $10.5 million under the Amended Credit Agreement and Guaranty increasing the total outstanding balance to $42.5 million. We also entered into a second amendment to the Amended Credit Agreement and Guaranty increasing the allowable permitted indebtedness in connection with our credit card program from $0.3 million to $0.5 million.

The outstanding principal amount of the Amended Credit Agreement and Guaranty accrues interest at an annual rate equal to the applicable margin of 9.06% plus the greater of (a) one-month LIBOR and (b) 1.75% per year. The term loan is secured by substantially all our personal property, including intellectual property. All unpaid and accrued unpaid interest with respect to each such term loan is due and payable in full on the maturity date at April 6, 2023. On the maturity date, in addition to the payment principal and accrued interest, we will be required to make a payment of 0.5% of the total amount borrowed under the Amended Credit Agreement and Guaranty, unless we have already made such payment in connection with an acceleration or prepayment of borrowings under the term loan. In the event we prepay all or part of this term loan facility prior to the maturity date, we will be subject to additional prepayment fees which decrease as the time to maturity decreases.

We issued warrants to Perceptive to purchase 37,693, 18,846 and 3,769 shares of our Series D convertible preferred stock at an exercise price of $15.92 per share in April 2018, July 2018 and September 2018, respectively. In connection with our initial public offering in November 2018 these warrants converted to common stock warrants at an exercise price of $15.92. Each of the warrants has a term of 10 years. In connection with the draw down on March 22, 2019, we granted warrants to purchase 19,790 shares of common stock. The warrants have an exercise price of $15.92 per share, were fully vested upon issuance, are exercisable at the option of the holder, in whole or in part, and expire in March 2029.

We were in compliance with all debt covenants under both the Amended Revolving Facility and Amended Credit Agreement and Guaranty at December 31, 2019.

**Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements, as defined by applicable regulations of the SEC, that are reasonably likely to have a current or future material effect on our financial condition, results of operations, liquidity, capital expenditures or capital resources.

**Critical Accounting Policies and Estimates**

The preparation of the financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the audited financial statements and accompanying notes included elsewhere in this Annual Report on Form 10-K. Management believes that such estimates have been based on reasonable and supportable assumptions and the resulting estimates are reasonable for use in the preparation of the audited financial statements. Actual results could differ from these estimates.

Significant areas requiring management estimates or judgments include the following key financial areas:

***Revenue Recognition***

Our revenue consists primarily of the sale of products, leases and services. Product revenue consists of capital equipment and disposables that are shipped and billed to customers both domestically and internationally. Our main capital equipment products are the Precision Flow systems, the Vapotherm Transfer Unit 2.0 and Q50 compressor. Our main disposable products are the single-use disposables and nasal interfaces, or cannulas. Lease revenue consists of capital equipment that we lease out to our customers. Service revenue consists of fees associated with routine service of capital units and the sale of extended service contracts and preventative maintenance plans, which are purchased by a small portion of our customer base. In addition, we sell small quantities of component parts in the United States, United Kingdom and to third-party international service centers who provide service on Precision Flow capital units outside of the United States. Freight revenue is based upon actual freights costs plus a percentage markup of these costs associated with the shipment of products domestically, and to a lesser extent, internationally, and is included in service revenue. Rebates and fees consist of contractually obligated administrative fees and percentage-of-sales rebates paid to GPOs, IDNs and distributor partners and accounted for as a reduction of service revenue.

Under Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 606 ("ASC 606"), revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, we performed the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract and assess whether each promised good or service is distinct and determine those that are performance obligations. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. Sales, value-added, and other taxes collected on behalf of third parties are excluded from revenue. Our standard payment term is generally 30 days from date of sale.

Contracts with customers may contain multiple performance obligations. For such arrangements, the transaction price is allocated to each performance obligation based on the estimated relative stand-alone selling prices of the promised products or services underlying each performance obligation. We determined stand-alone selling prices based on the price at which the performance obligation is sold separately. If the stand-alone selling price is not observable through past transactions, we estimate the stand-alone selling price taking into account available information such as market conditions and internally approved pricing guidelines related to the performance obligations maximizing the use of observable inputs.

When determining the transaction price of a contract, an adjustment is made if payment from a customer occurs either significantly before or significantly after performance, resulting in a significant financing component. Applying the practical expedient in paragraph 606-10-32-18, we do not assess whether a significant financing component exists if the period between when we perform our obligations under the contract and when the customer pays is one year or less. None of our contracts contained a significant financing component as of December 31, 2019 or 2018.

Our contracts with our customers have a duration of less than one year. Therefore, we have elected to apply the practical expedient in paragraph ASC 340-40-25-4 and recognizes the incremental costs of obtaining contracts as an expense. These costs are included in sales and marketing expense in the accompanying consolidated statements of comprehensive loss. Our contracts with our customers have a duration of less than one year. Therefore, we have elected to apply the practical expedient in paragraph ASC 340-40-25-4, and we recognize the incremental costs of obtaining contracts as an expense. These costs are included in sales and marketing expense in the consolidated statements of comprehensive loss.

***Lease Revenue***

We also enter into agreements to lease our Precision Flow System equipment. For such sales, we account for revenue under ASC 840, Leases, and assess and classify these transactions as sales-type or operating leases based on whether the lease transfers ownership of the equipment to the lessee by the end of the lease term. This criterion is met in situations in which the lease agreement provides for the transfer of title at or shortly after the end of the lease term in exchange for the payment of a nominal fee, for example, the minimum required by statutory regulation to transfer title. Equipment included in arrangements including the transfer of title are accounted for as sales-type leases and we recognize the total value of the lease payments due over the lease term to revenue at the inception of the lease. We record the current value of future lease payments under the prepaid expenses and other current assets in our consolidated balance sheets. Equipment included in arrangements that do not include transfer of title, nor any of the capital lease criteria, are accounted for as operating leases and revenue is recognized on a straight-line basis as it becomes receivable monthly over the term of the lease.

***Timing and Amount of Revenue Recognition***

We recognize revenue on product sales and service of capital equipment and product sales of disposables. In each instance, revenue is generally recognized when the customer obtains control of our product, which generally occurs at a point in time upon shipment based on the contractual shipping terms of a contract.

Product and service revenue are measured as the amount of consideration we expect to receive in exchange for transferring products or services to a customer. To the extent the transaction price includes variable consideration, we estimate the amount of variable consideration that should be included in the transaction price utilizing the expected value amount method to which we expect to be entitled. As such, revenue on sales are recorded net of prompt pay discounts and payments made to GPOs, IDNs and distributors. Variable consideration is included in the transaction price if, in our judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. Determination of whether to include estimated amounts in the transaction price are based largely on an assessment of our anticipated performance and all information (historical, current and forecasted) that is reasonably available. We believe that the estimates we have established are reasonable based upon current facts and circumstances. Applying different judgments to the same facts and circumstances could result in the estimated amounts to vary.

***Product Returns***

We provide our customers with the right to return products for a refund of the purchase price or for an account credit, if the return is made within a specified number of days from the original invoice date. We record a product return liability based upon an estimate of specific returns and a review of historical returns experienced. Adjustments are made to the product return liability as returns data and historical experience change. The provision for product return estimates is recorded as a reduction of revenue. The product return liability was less than $0.1 million at both December 31, 2019 and 2018 and is included in other current liabilities in the consolidated balance sheets.

***Stock-Based Compensation***

We maintain an equity incentive plan to provide long-term incentives for employees, consultants, and members of the board of directors. The plan allows for the issuance of non-statutory and incentive stock options to employees and non-statutory stock options to consultants and non-employee directors.

We recognize stock-based compensation expense for awards of equity instruments based on the grant date fair value of those awards in accordance with ASC Topic 718, Stock Compensation ("ASC 718"). ASC 718 requires all equity-based compensation awards to employees and non-employee directors, including grants of restricted shares and stock options, to be recognized as expense in the statements of comprehensive loss based on their grant date fair values. The fair value of each option grant is estimated on the grant date using the Black-Scholes option pricing model. The fair value is then amortized on a straight-line basis over the requisite service period of the awards, which is generally the vesting period. For performance-based awards, the related compensation cost is amortized over the performance period on an accelerated attribution basis. Compensation cost associated with performance awards is based on fair value on the date of grant and the number of units expected to be earned after assessing the probability that certain performance criteria will be met and the associated targeted payout level that is forecasted will be achieved, net of expected forfeitures. Cumulative adjustments are recorded each quarter to reflect estimated outcomes of the performance-related conditions until the results are determined and settled. Use of a valuation model requires us to make certain assumptions with respect to selected model inputs, including the expected life (weighted average period of time that the options granted are expected to be outstanding), the volatility of our common stock and an assumed risk-free interest rate. Expected volatility is calculated based on historical volatility of a group of publicly traded companies that we consider a peer group. The expected life is estimated using the simplified method for "plain vanilla" options. The risk-free interest rate is based on U.S. Treasury rates with a remaining term that approximates the expected life assumed at the date of grant. No dividend yield is assumed as we do not pay, and do not expect to pay, dividends on our common stock. We estimate forfeitures based on historical experience with pre-vested forfeitures. To the extent actual forfeitures differ from the estimate, the difference is recorded to compensation expense in the period of the forfeiture.

***Income Taxes***

We account for income taxes using 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 consolidated financial statements or in our tax returns. Deferred taxes are determined based on the difference between the financial reporting 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. We assess the likelihood that our deferred tax assets will be recovered from future taxable income and, to the extent we believe, based upon the weight of available evidence, that it is more likely than not that all or a portion of 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 estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

We account for uncertainty in income taxes recognized in the consolidated 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 consolidated financial statements. The amount of the 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.

**Recent Accounting Pronouncements**

A discussion of recent accounting pronouncements is included in Note 2 to our audited financial statements included elsewhere in this Annual Report on Form 10-K.

**JOBS Act**

As a company with less than $1.07 billion in revenue during our last fiscal year, we qualify as an "emerging growth company," as defined in the JOBS Act. An emerging growth company may take advantage of reduced reporting requirements that are otherwise applicable to public companies. These provisions include:

- being permitted to present only two years of audited financial statements and only two years of related Management's Discussion and Analysis of Financial Condition and Results of Operations in this Annual Report on Form 10-K;

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act;
- reduced disclosure obligations regarding executive compensation in this Annual Report on Form 10-K and in our periodic reports, proxy statements and registration statements; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We may take advantage of these provisions until December 31, 2023. However, if certain events occur prior to the end of such date, including if we become a "large accelerated filer," our annual gross revenue exceeds $1.07 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to December 31, 2023.

We have elected to take advantage of certain of the reduced disclosure obligations in this registration statement and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our stockholders may be different from what you might receive from other public reporting companies in which you hold equity interests.

In addition, under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption and, as a result, our financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies. Section 107 of the JOBS Act provides that we can elect to opt out of the extended transition period at any time, which election is irrevocable.

**Item 7A. Quantitative and Qualitative Disclosures About Market Risk.**

We are a smaller reporting company as defined in Item 10(f)(1) of Regulation S-K and are not required to provide information under this item.

**Item 8. Financial Statements and Supplementary Data.**

The financial statements required to be filed pursuant to this Item 8 are appended to this report. An index of those financial statements is found in Item 15 of Part IV of this Annual Report on Form 10-K.

**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 Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2019. 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, 2019, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

***Management's Report on Internal Controls over Financial Reporting***

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, our principal executive and principal financial officers, or persons performing similar functions, 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 generally accepted accounting principles and includes policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the consolidated financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. We continue to review our internal control over financial reporting and may from time to time make changes aimed at enhancing their effectiveness and to ensure that our systems evolve with our business.

Under the supervision and with the participation of management, including the Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in "Internal Control — Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Based on this assessment, our senior management has concluded that the internal control over financial reporting was effective as of December 31, 2019.

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 rules of the SEC for "emerging growth companies".

***Changes in Internal Controls Over Financial Reporting***

There was no change in the Company's internal control over financial reporting that occurred during the quarter ended December 31, 2019 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.**

Other than the information regarding our executive officers provided in Part I of this report under the heading "Business – Information about our Executive Officers," the information required by this Item is incorporated by reference to our definitive proxy statement for our 2020 annual meeting of stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2019.

**Item 11. Executive Compensation.**

The information required by this Item is incorporated by reference to our definitive proxy statement for our 2020 annual meeting of stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2019.

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

The information required by this Item is incorporated by reference to our definitive proxy statement for our 2020 annual meeting of stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2019.

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

The information required by this Item is incorporated by reference to our definitive proxy statement for our 2020 annual meeting of stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2019.

**Item 14. Principal Accounting Fees and Services.**

The information required by this Item is incorporated by reference to our definitive proxy statement for our 2020 annual meeting of stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2019.

## PART IV

**Item 15. Exhibits, Financial Statement Schedules.**

The following documents are included on pages F-1 through F-28 attached hereto and are filed as part of this Annual Report on Form 10-K.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**(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.**

| Exhibit Number | Description |
|---|---|
| 3.1 | Tenth Amended and Restated Certificate of Incorporation (previously filed as Exhibit 3.1 to the Current Report Form 8-K filed on November 20, 2018 (File No. 001-38740) and incorporated herein by reference) |
| 3.2 | Amended and Restated Bylaws (previously filed as Exhibit 3.2 to the Current Report Form 8-K filed on November 20, 2018 (File No. 001-38740) and incorporated herein by reference) |
| 4.1 | Form of Certificate of Common Stock (previously filed as Exhibit 4.1 to the Registration Statement on Form S-1 filed on November 5, 2018 (File No. 333-227897) and incorporated herein by reference) |
| 4.2 | Tenth Amended and Restated Registration Rights Agreement dated September 27, 2018, among Vapotherm, Inc. and the Investors party thereto (previously filed as Exhibit 4.2 to the Registration Statement on Form S-1 filed on October 19, 2018 (File No. 333-227897) and incorporated herein by reference) |
| 4.3 | Form of Warrant to Purchase Series A Preferred Stock, dated March 14, 2012, issued by Vapotherm, Inc. (previously filed as Exhibit 4.4 to the Registration Statement on Form S-1 filed on October 19, 2018 (File No. 333-227897) and incorporated herein by reference) |
| 4.4 | Form of Warrant to Purchase Series A Preferred Stock, dated July 30, 2012, issued by Vapotherm, Inc. (previously filed as Exhibit 4.5 to the Registration Statement on Form S-1 filed on October 19, 2018 (File No. 333-227897) and incorporated herein by reference) |
| 4.5 | Warrant to Purchase Series A Preferred Stock, dated September 7, 2012, issued by Vapotherm, Inc. to Vapotherm Investors, LLC (previously filed as Exhibit 4.6 to the Registration Statement on Form S-1 filed on October 19, 2018 (File No. 333-227897) and incorporated herein by reference) |
| 4.6 | Warrant to Purchase Series A Preferred Stock, dated September 27, 2013, issued by Vapotherm, Inc. to Bridge Bank, National Association (previously filed as Exhibit 4.7 to the Registration Statement on Form S-1 filed on October 19, 2018 (File No. 333-227897) and incorporated herein by reference) |
| 4.7 | Form of Warrant to Purchase Series B Preferred Stock, issued by Vapotherm, Inc. to Comerica Bank (previously filed as Exhibit 4.8 to the Registration Statement on Form S-1 filed on October 19, 2018 (File No. 333-227897) and incorporated herein by reference) |
| 4.8 | Warrant to Purchase Series C Preferred Stock, dated July 28, 2015, issued by Vapotherm, Inc. to Comerica Bank (previously filed as Exhibit 4.9 to the Registration Statement on Form S-1 filed on October 19, 2018 (File No. 333-227897) and incorporated herein by reference) |
| 4.9 | Form of Warrant to Purchase Series D Preferred Stock, issued by Vapotherm, Inc. to Perceptive Credit Holdings II, LP (previously filed as Exhibit 4.10 to the Registration Statement on Form S-1 filed on October 19, 2018 (File No. 333-227897) and incorporated herein by reference) |
| 4.10* | Description of Securities of Vapotherm, Inc. |
| 10.1 | Lease, dated September 30, 2016, between Vapotherm, Inc. and Albany Road – 100 Domain LLC (previously filed as Exhibit 10.1 to the Registration Statement on Form S-1 filed on October 19, 2018 (File No. 333-227897) and incorporated herein by reference) |
| 10.2 | First Amendment to Lease, dated September 11, 2017, between Vapotherm, Inc. and Albany Road – 100 Domain LLC (previously filed as Exhibit 10.2 to the Registration Statement on Form S-1 filed on October 19, 2018 (File No. 333-227897) and incorporated herein by reference) |
| 10.3 | Second Amendment to Lease, dated June 6, 2018, between Vapotherm, Inc. and 100 Domain Drive EI, LLC (previously filed as Exhibit 10.3 to the Registration Statement on Form S-1 filed on October 19, 2018 (File No. 333-227897) and incorporated herein by reference) |
| 10.4 | Credit Agreement and Guaranty, dated April 6, 2018, among Vapotherm, Inc., certain subsidiaries that may be required to provide guarantees from time to time thereunder, the lenders from time to time party thereto and Perceptive Credit Holdings II, LP (previously filed as Exhibit 10.4 to the Registration Statement on Form S-1 filed on October 19, 2018 (File No. 333-227897) and incorporated herein by reference) |
| 10.5 | Amended and Restated Business Financing Agreement dated April 6, 2018, between Vapotherm, Inc. and Western Alliance Bank (previously filed as Exhibit 10.5 to the Registration Statement on Form S-1 filed on October 19, 2018 (File No. 333-227897) and incorporated herein by reference) |

| Exhibit Number | Description |
|---|---|
| 10.6 † | Vapotherm, Inc. Amended and Restated 2005 Stock Incentive Plan, as amended (previously filed as Exhibit 10.6 to the Registration Statement on Form S-1 on October 19, 2018 (File No. 333-227897) and incorporated herein by reference) |
| 10.7 † | Form of Incentive Stock Option Agreement pursuant to the Vapotherm, Inc. 2005 Stock Incentive Plan (previously filed as Exhibit 10.7 to the Registration Statement on Form S-1 filed on October 19, 2018 (File No. 333-227897) and incorporated herein by reference) |
| 10.8 † | Vapotherm, Inc. Amended and Restated 2015 Stock Incentive Plan, as amended (previously filed as Exhibit 10.8 to the Registration Statement on Form S-1 on October 19, 2018 (File No. 333-227897) and incorporated herein by reference) |
| 10.9 † | Form of Incentive Stock Option Agreement pursuant to the Vapotherm, Inc. 2015 Stock Incentive Plan (previously filed as Exhibit 10.9 to the Registration Statement on Form S-1 filed on October 19, 2018 (File No. 333-227897) and incorporated herein by reference) |
| 10.10 † | Amended and Restated Employment Agreement dated October 17, 2018, between Vapotherm, Inc. and Joseph Army (previously filed as Exhibit 10.10 to the Registration Statement on Form S-1 filed on October 19, 2018 (File No. 333-227897) and incorporated herein by reference) |
| 10.11 | Form of Indemnification Agreement between Vapotherm, Inc. and its directors and officers (previously filed as Exhibit 10.11 to the Registration Statement on Form S-1 filed on October 19, 2018 (File No. 333-227897) and incorporated herein by reference) |
| 10.12 | Third Amendment to Lease, dated July 26, 2018, between Vapotherm, Inc. and 100 Domain Drive EI, LLC (previously filed as Exhibit 10.12 to the Registration Statement on Form S-1 filed on October 19, 2018 (File No. 333-227897) and incorporated herein by reference) |
| 10.13 | Amendment No. 1 to Credit Agreement and Guaranty, dated September 27, 2018, between Vapotherm, Inc. and Perceptive Credit Holdings II, LP (previously filed as Exhibit 10.13 to the Registration Statement on Form S-1 filed on October 19, 2018 (File No. 333-227897) and incorporated herein by reference) |
| 10.14 † | Letter Agreement dated October 17, 2018, between Vapotherm, Inc. and John Landry (previously filed as Exhibit 10.16 to the Registration Statement on Form S-1 filed on October 19, 2018 (File No. 333-227897) and incorporated herein by reference) |
| 10.15 † | Vapotherm, Inc. 2018 Employee Stock Purchase Plan (previously filed as Exhibit 10.17 to the Registration Statement on Form S-1 filed on November 5, 2018 (File No. 333-227897) and incorporated herein by reference) |
| 10.16 † | Vapotherm, Inc. 2018 Equity Incentive Plan (previously filed as Exhibit 10.18 to the Registration Statement on Form S-1 filed on November 5, 2018 (File No. 333-227897) and incorporated herein by reference) |
| 10.17 † | Vapotherm, Inc. 2018 Cash Incentive Plan (previously filed as Exhibit 10.19 to the Registration Statement on Form S-1 filed November 5, 2018 (File No. 333-227897) and incorporated herein by reference) |
| 10.18 † | Form of Non-Statutory Employee Stock Option Agreement pursuant to the Vapotherm, Inc. 2018 Equity Incentive Plan (previously filed as Exhibit 10.20 to the Registration Statement on Form S-1 filed on November 5, 2018 (File No. 333-227897) and incorporated herein by reference) |
| 10.19 † | Form of Non-Statutory Non-Employee Director Stock Option Agreement pursuant to the Vapotherm, Inc. 2018 Equity Incentive Plan (previously filed as Exhibit 10.21 to the Registration Statement on Form S-1 filed on November 5, 2018 (File No. 333-227897) and incorporated herein by reference) |
| 10.20 † | Form of Incentive Stock Option Agreement pursuant to the Vapotherm, Inc. 2018 Equity Incentive Plan (previously filed as Exhibit 10.22 to the Registration Statement on Form S-1 filed on November 5, 2018 (File No. 333-227897) and incorporated herein by reference) |
| 10.21 † | Proprietary Rights Agreement dated July 30, 2012, between Vapotherm, Inc. and Joseph Army (previously filed as Exhibit 10.23 to the Registration Statement on Form S-1 filed on November 5, 2018 (File No. 333-227897) and incorporated herein by reference) |
| 10.22 † | Confidentiality and Non-Disclosure Agreement dated January 28, 2014, between Vapotherm, Inc. and John Coolidge (previously filed as Exhibit 10.24 to the Registration Statement on Form S-1 filed on November 5, 2018 (File No. 333-227897) and incorporated herein by reference) |

| Exhibit Number | Description |
|---|---|
| 10.23 † | Form of Confidentiality, Non-Compete and Assignment of Inventions Agreement (previously filed as Exhibit 10.25 to the Registration Statement on Form S-1 filed on November 5, 2018 (File No. 333-227897) and incorporated herein by reference) |
| 10.24 † | Vapotherm, Inc. 2015 Stock Incentive Plan French Qualifying Subplan (previously filed as Exhibit 10.26 to the Registration Statement on Form S-1 filed on November 5, 2018 (File No. 333-227897) and incorporated herein by reference) |
| 10.25 † | Vapotherm, Inc. 2018 Equity Incentive Plan French Qualifying Subplan (previously filed as Exhibit 10.27 to the Annual Report on Form 10-K filed on March 22, 2019 (File No. 001-38740) and incorporated herein by reference) |
| 10.26 | Amendment No. 2 to Credit Agreement and Guaranty, dated March 22, 2019 between Vapotherm, Inc. and Perceptive Credit Holdings II, LP (previously filed as Exhibit 10.28 to the Annual Report on Form 10-K filed on March 22, 2019 (File No. 001-38740) and incorporated herein by reference) |
| 10.27 | First Amendment to Amended and Restated Business Finance Agreement, dated March 22, 2019, between Vapotherm, Inc. and Western Alliance Bank (previously filed as Exhibit 10.29 to the Annual Report on Form 10-K filed on March 22, 2019 (File No. 001-38740) and incorporated herein by reference) |
| 10.28 † | Indefinite Term Employment Contract by and between Vapotherm, Inc. and Gregoire Ramade, dated March 14, 2016 (previously filed as Exhibit 10.1 to the Quarterly Report on Form 10-Q filed on July 29, 2019 (File No. 001-38740) and incorporated herein by reference) |
| 10.29 † | Letter Agreement by and between Vapotherm, Inc. and David Blouin, dated December 8, 2017 (previously filed as Exhibit 10.2 to the Quarterly Report on Form 10-Q filed on July 29, 2019 (File No. 001-38740) and incorporated herein by reference) |
| 21.1 | Subsidiaries of Vapotherm, Inc. (previously filed as Exhibit 21.1 to the Annual Report on Form 10-K filed on March 22, 2019 (File No. 001-38740) and incorporated herein by reference) |
| 23.1* | Consent of Grant Thornton LLP |
| 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

** Furnished herewith

† Indicates management contract or compensatory plan

\+ 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**.**

Vapotherm, Inc.

Date: March 4, 2020

By: /s/ Joseph Army
Name: Joseph Army
Title: President and Chief Executive Officer
(*Principal Executive Officer*)

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/ Joseph Army<br>Joseph Army | President, Chief Executive Officer and Director<br>(*Principal Executive Officer*) | March 4, 2020 |
| /s/ John Landry<br>John Landry | Chief Financial Officer<br>(*Principal Accounting Officer and Principal Financial Officer*) | March 4, 2020 |
| /s/ Anthony Americh<br>Anthony Americh | Director | March 4, 2020 |
| /s/ Lance Berry<br>Lance Berry | Director | March 4, 2020 |
| /s/ Marina Hahn<br>Marina Hahn | Director | March 4, 2020 |
| /s/ James Liken<br>James Liken | Director | March 4, 2020 |
| /s/ Geoff Pardo<br>Geoff Pardo | Director | March 4, 2020 |
| /s/ Craig Reynolds<br>Craig Reynolds | Director | March 4, 2020 |
| /s/ Elizabeth Weatherman<br>Elizabeth Weatherman | Director | March 4, 2020 |

**VAPOTHERM, INC.**

**Index to Financial Statements**


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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders
Vapotherm, Inc.

**Opinion on the financial statements**
We have audited the accompanying consolidated balance sheets of Vapotherm, Inc. (a Delaware corporation) and subsidiary (the "Company") as of December 31, 2019 and 2018, the related consolidated statements of comprehensive loss, redeemable convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the two years in the period ended December 31, 2019, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

**Basis for opinion**
These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's 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 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 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 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 supporting the amounts and disclosures in the 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 financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ GRANT THORNTON LLP

We have served as the Company's auditor since 2016.

Boston, Massachusetts
March 4, 2020

**VAPOTHERM, INC.**

**CONSOLIDATED BALANCE SHEETS**
**(In thousands, except share amounts)**

| | December 31, 2019 | December 31, 2018 |
|---|---|---|
| **Assets** | | |
| Current assets | | |
| Cash and cash equivalents | $ 71,655 | $ 58,223 |
| Accounts receivable, net | 8,243 | 7,107 |
| Inventories | 9,137 | 13,710 |
| Prepaid expenses and other current assets | 4,066 | 2,683 |
| Total current assets | 93,101 | 81,723 |
| Property and equipment, net | 15,086 | 13,416 |
| Restricted cash | 1,852 | 1,799 |
| Goodwill | 588 | - |
| Intangible assets, net | 353 | - |
| Deferred income tax assets | 66 | - |
| Other long-term assets | 844 | 308 |
| Total assets | $ 111,890 | $ 97,246 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities | | |
| Accounts payable | $ 2,753 | $ 3,148 |
| Contract liabilities | 137 | 79 |
| Accrued expenses and other liabilities | 9,809 | 7,653 |
| Short-term line of credit | 3,491 | 3,163 |
| Total current liabilities | 16,190 | 14,043 |
| Long-term loans payable, net | 41,787 | 31,317 |
| Other long-term liabilities | 174 | 325 |
| Total liabilities | 58,151 | 45,685 |
| Commitments and contingencies (Note 11) | | |
| Stockholders' equity | | |
| Preferred stock ($.001 par value) 25,000,000 shares authorized; no shares issued and outstanding as of December 31, 2019 and 2018 | - | - |
| Common stock ($.001 par value) 175,000,000 shares authorized as of December 31, 2019 and 2018; 20,851,531 and 16,782,837 shares issued and outstanding as of December 31, 2019 and 2018, respectively | 21 | 17 |
| Additional paid-in capital | 319,115 | 265,926 |
| Accumulated other comprehensive income | 44 | - |
| Accumulated deficit | (265,441) | (214,382) |
| Total stockholders' equity | 53,739 | 51,561 |
| Total liabilities and stockholders' equity | $ 111,890 | $ 97,246 |

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

**VAPOTHERM, INC.**

**CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**
**(In thousands, except share and per share amounts)**

| | Year Ended December 31, | |
|---|---|---|
| | 2019 | 2018 |
| Net revenue | $ 48,104 | $ 42,377 |
| Cost of revenue | 26,793 | 25,605 |
| Gross profit | 21,311 | 16,772 |
| Operating expenses | | |
| Research and development | 13,376 | 8,771 |
| Sales and marketing | 37,689 | 33,927 |
| General and administrative | 18,410 | 11,186 |
| Loss on disposal of property and equipment | - | 121 |
| Total operating expenses | 69,475 | 54,005 |
| Loss from operations | (48,164) | (37,233) |
| Other (expense) income | | |
| Foreign currency gain | 44 | - |
| Interest income | 860 | 118 |
| Gain on litigation settlement | 1,151 | - |
| Interest expense | (5,096) | (3,064) |
| Loss on extinguishment of debt | - | (2,842) |
| Gain on change in fair value of warrant liabilities | - | 553 |
| Net loss before income taxes | $ (51,205) | $ (42,468) |
| Benefit for income taxes | (146) | - |
| Net loss | $ (51,059) | $ (42,468) |
| Accretion of preferred stock to redemption value | - | (81) |
| Net loss attributable to common stockholders | $ (51,059) | $ (42,549) |
| Other comprehensive income, net of tax: | | |
| Foreign currency translation adjustments | 44 | - |
| Total other comprehensive income | $ 44 | $ - |
| Total comprehensive loss | $ (51,015) | $ (42,468) |
| | | |
| Net loss per share attributable to common stockholders - basic and diluted | $ (2.74) | $ (14.65) |
| Weighted-average number of shares used in calculating net loss per share, basic and diluted | 18,604,707 | 2,905,085 |

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

**VAPOTHERM, INC.**

**CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)**
**(In thousands, except share amounts)**

| | Redeemable Convertible Preferred Stock | | Common Stock | | Additional Paid-in Capital | Accumulated Deficit | Accumulated Other Comprehensive Income | Stockholders' Equity (Deficit) |
|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | | | | |
| **Balance at December 31, 2017** | 10,515,351 | $ 152,637 | 672,321 | $ 1 | $ 45,056 | $ (171,914) | $ - | $ (126,857) |
| Issuance of Series D redeemable convertible preferred stock, net | 714,285 | 9,919 | - | - | - | - | - | - |
| Accretion of Series D issuance costs | - | 81 | - | - | (81) | - | - | (81) |
| Conversion of redeemable convertible preferred stock | (11,229,636) | (162,637) | 11,229,636 | 11 | 162,626 | - | - | 162,637 |
| Reclassification of warrants | - | - | - | - | (24) | - | - | (24) |
| Issuance of common stock in initial public offering, net | - | - | 4,600,000 | 5 | 57,389 | - | - | 57,394 |
| Issuance of stock upon exercise of options | - | - | 66,392 | - | 98 | - | - | 98 |
| Issuance of restricted stock | - | - | 214,488 | - | 360 | - | - | 360 |
| Stock-based compensation expense | - | - | - | - | 502 | - | - | 502 |
| Net loss | - | - | - | - | - | (42,468) | - | (42,468) |
| **Balance at December 31, 2018** | - | $ - | 16,782,837 | $ 17 | $ 265,926 | $ (214,382) | $ - | $ 51,561 |
| Issuance of common stock in connection with public offering of common stock, net | - | - | 3,570,750 | 4 | 48,272 | - | - | 48,276 |
| Issuance of common stock warrants | - | - | - | - | 293 | - | - | 293 |
| Issuance of stock upon repayment of nonrecourse loans | - | - | 79,854 | - | 144 | - | - | 144 |
| Issuance of stock upon exercise of warrants | - | - | 12,164 | - | - | - | - | - |
| Issuance of stock upon exercise of options | - | - | 150,176 | - | 242 | - | - | 242 |
| Issuance of restricted stock | - | - | 255,750 | - | 402 | - | - | 402 |
| Stock-based compensation expense | - | - | - | - | 3,836 | - | - | 3,836 |
| Foreign currency translation adjustments | - | - | - | - | - | - | 44 | 44 |
| Net loss | - | - | - | - | - | (51,059) | - | (51,059) |
| **Balance at December 31, 2019** | - | $ - | 20,851,531 | $ 21 | $ 319,115 | $ (265,441) | $ 44 | $ 53,739 |

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

**VAPOTHERM, INC.**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**
**(In thousands)**

| | Year Ended December 31, | |
|---|---|---|
| | 2019 | 2018 (As Adjusted) |
| **Cash flows from operating activities** | | |
| Net loss | $ (51,059) | $ (42,468) |
| Adjustments to reconcile net loss to net cash used in operating activities | | |
| Depreciation and amortization | 3,078 | 2,167 |
| Stock-based compensation expense | 3,836 | 502 |
| Amortization of discount on debt | 234 | 123 |
| Loss on disposal of property and equipment | 101 | 511 |
| Provision for bad debts | 104 | 273 |
| Loss on extinguishment of debt | - | 2,842 |
| Gain on litigation settlement | (1,151) | - |
| Deferred income taxes | (147) | |
| Change in fair value of warrants | - | (553) |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | (833) | (425) |
| Inventories | 5,063 | (2,252) |
| Prepaid expenses and other assets | (1,218) | (443) |
| Accounts payable | 98 | 896 |
| Contract liabilities | 58 | 15 |
| Accrued expenses and other liabilities | 2,174 | (1,206) |
| Net cash used in operating activities | (39,662) | (40,018) |
| **Cash flows from investing activities** | | |
| Acquisition of business, net of cash acquired | (1,560) | - |
| Purchases of property and equipment | (4,747) | (5,180) |
| Net cash used in investing activities | (6,307) | (5,180) |
| **Cash flows from financing activities** | | |
| Proceeds from issuance of common stock in connection with public offering, net | 48,669 | 59,892 |
| Proceeds on loans | 10,500 | 32,000 |
| Proceeds from issuance of redeemable convertible preferred stock, net | - | 9,919 |
| Repayment of loans payable | - | (22,328) |
| Public offering costs | (393) | (2,498) |
| Debt issuance costs | (29) | (800) |
| Short-term line of credit | 316 | 136 |
| Proceeds from exercise of stock options and purchase of restricted stock | 386 | 539 |
| Net cash provided by financing activities | 59,449 | 76,860 |
| Effect of exchange rate changes on cash, cash equivalents and restricted cash | 5 | - |
| Net increase in cash, cash equivalents, and restricted cash | 13,485 | 31,662 |
| **Cash, cash equivalents and restricted cash** | | |
| Beginning of year | 60,022 | 28,360 |
| End of year | $ 73,507 | $ 60,022 |
| **Supplemental disclosures of cash flow information** | | |
| Interest paid during the period | $ 4,793 | $ 3,028 |
| Issuance of common stock upon vesting of restricted stock | $ 402 | $ 360 |
| Issuance of warrants in conjunction with debt draw down | $ 293 | $ - |
| Property and equipment purchases in accrued expenses | $ 135 | $ 21 |
| Conversion of preferred stock to common stock | $ - | $ 162,637 |

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

## 1. Description of Business

Vapotherm, Inc. (the "Company") was founded in 1993 and reincorporated under the laws of the State of Delaware in 2013. Since inception, the Company has focused on the development and commercialization of its proprietary Hi-VNI Technology products that are used to treat patients of all ages suffering from respiratory distress. The Company's Hi-VNI Technology delivers non-invasive ventilatory support by providing heated, humidified and oxygenated air at a high velocity to patients through a comfortable small-bore nasal interface. The Company's Precision Flow systems, which use Hi-VNI Technology, are clinically validated alternatives to, and address many limitations of, the current standard of care for the treatment of respiratory distress in a hospital setting.

The Company offers four versions of its Precision Flow systems: Precision Flow Hi-VNI, Precision Flow Plus, Precision Flow Classic and Precision Flow Heliox. The Company generates revenue primarily from sales of disposable products utilized with its proprietary Precision Flow systems. The Company also generates revenue from the capital units themselves, and to a lesser extent, sales of its companion products, which include the Vapotherm Transfer Unit 2.0, the Q50 compressor and various adaptors. The Company offers different options to its hospital customers for acquiring Precision Flow capital units, ranging from the purchase of the Precision Flow capital units with payment in full at the time of purchase, to financed purchases of the Precision Flow capital units, to bundled discounts involving the placement of Precision Flow capital units for use by the customer at no upfront charge in connection with the customer's ongoing purchase of disposable products.

The Company sells Precision Flow systems to hospitals through a direct sales force in the United States and in the United Kingdom and through distributors in select other countries outside of the United States and United Kingdom In addition, the Company utilizes clinical educators who are typically experienced users of Hi-VNI Technology and who focus on medical education efforts to facilitate adoption and increase utilization. The Company is focused on physicians, respiratory therapists and nurses who work in acute hospital settings, including the emergency department and adult, pediatric and neonatal intensive care units (the "ICUs"). The Company's relationship with these clinicians is particularly important, as it enables its products to follow patients through the care continuum.

Since inception, the Company has financed its operations primarily through public offerings of its common stock, private placements of its convertible preferred stock, sales of its Precision Flow systems and amounts borrowed under its credit facilities. The Company has devoted the majority of its resources to research and development activities related to its Precision Flow systems, including regulatory initiatives and sales and marketing activities. The Company has invested heavily in its sales and marketing function by increasing the number of sales representatives and clinical educators to facilitate adoption and increase utilization of its Hi-VNI Technology products and expanded its digital marketing initiatives and medical education programs.

The Company is subject to risks common to companies in the medical device industry, including, but not limited to, the successful development and commercialization of its Precision Flow products, fluctuations in operating results and financial risks, protection of proprietary knowledge and patent risks, dependence on key personnel and collaborative partners, competition, technological and manufacturing risks, customer acceptance and demand, compliance with the Food and Drug Administration and other governmental regulations, management of growth and effectiveness of marketing by the Company and by third parties.

On November 16, 2018, the Company completed an initial public offering of 4,600,000 shares of common stock, which included the full exercise by the underwriters of their option to purchase 600,000 shares of common stock, at a price of $14.00 per share, which raised net proceeds of $57.4 million after deducting the underwriting discount of $4.5 million and offering expenses of $2.5 million.

On February 28, 2019, the Company acquired its United Kingdom based distributor. See Note 3 "Business Combinations" to these consolidated financial statements for details of this transaction.

In August 2019, the Company completed a public offering of 3,570,750 shares of common stock, which included the full exercise by the underwriters of their option to purchase 465,750 shares of common stock, at a price of $14.50 per share, which raised net proceeds of $48.3 million after deducting the underwriting discount of $3.1 million and offering expenses of $0.4 million.

**2. Significant Accounting Policies**

***Basis of Presentation***

The consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP").

***Principles of Consolidation***

These consolidated financial statements include the financial statements of Solus Medical Ltd. ("Solus"), a wholly owned subsidiary of the Company based in the United Kingdom, which was acquired in the first quarter of 2019. All intercompany accounts and transactions have been eliminated upon consolidation.

***Segment Information***

Operating segments are defined as components of an enterprise for which separate discrete financial information is available and evaluated regularly by the chief operating decision maker in deciding how to allocate resources and in assessing performance. The Company globally manages the business within one reporting segment, Vapotherm, Inc. and two reporting units, Vapotherm and Solus. Segment information is consistent with how management reviews the business, makes investing and resource allocation decisions and assesses operating performance.

The majority of the Company's long-term assets are located in the United States. Long-term assets located outside the United States total $0.1 million at December 31, 2019.

***Use of Estimates***

The preparation of consolidated financial statements in conformity with U.S. GAAP requires the Company to make judgments, assumptions, and estimates that affect the reported amounts of assets, liabilities, revenue and expenses, and the related disclosure of contingent assets and liabilities. The Company evaluates its estimates on an ongoing basis. The Company bases its estimates on historical experience and various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Significant estimates relied upon in preparing these consolidated financial statements include calculation of stock-based compensation, valuation of warrants, fair values of acquired assets and liabilities, including goodwill and intangibles assets, realizability of inventories, allowance for bad debt, accrued expenses and the valuation allowances against deferred income tax assets. Actual results may differ from these estimates.

***Concentrations of Credit Risk***

As of December 31, 2019 and 2018, the Company's financial instruments were comprised of cash and cash equivalents, restricted cash, accounts receivable, accounts payable and debt, the carrying amounts of which approximated fair value due to the short-term nature and market interest rates. All of the Company's cash and cash equivalents are maintained at creditworthy financial institutions. At December 31, 2019 and 2018, deposits exceed the amount of any insurance provided.

The Company extends credit to customers in the normal course of business but does not require collateral or any other security to support amounts due. Management performs ongoing credit evaluations of its customers. An allowance for potentially uncollectible accounts is provided based on history, economic conditions, and composition of the accounts receivable aging. In some cases, the Company makes allowances for specific customers based on these and other factors. Provisions for the allowance for doubtful accounts are recorded in general and administrative expenses in the accompanying consolidated statements of comprehensive loss.

***Supplier Risk***

The Company obtains some of the components and subassemblies included in its Precision Flow systems from single source suppliers and the partial or complete loss of one or more of these suppliers could cause significant production delays, an inability to meet customer demand and a substantial loss in revenue.

***Foreign Currency and Foreign Operations***

The functional currency of the Company is the currency of the primary economic environment in which the entity operates, which is the U.S. dollar. For our non-U.S. subsidiary that transacts in a functional currency other than the U.S. dollar, assets and liabilities are translated at current rates of exchange at the balance sheet date. Income and expense items are translated at the average foreign currency exchange rates for the period. Adjustments resulting from the translation of the financial statements of its foreign operations into U.S. dollars are excluded from the determination of net loss and are recorded in accumulated other comprehensive income, a separate component of stockholders' equity.

There were no assets or liabilities of foreign subsidiaries that were translated at period-end exchange rates as of December 31, 2018. See Note 3 "Business Combinations" to these consolidated financial statements for details of the Solus acquisition. The functional currency of Solus is its local currency, Pound Sterling (GBP).

Realized foreign currency gains or losses arising from transactions denominated in foreign currencies are recorded in other (expense) income in the consolidated statements of comprehensive loss. Unrealized foreign currency gains or losses arising from transactions denominated in foreign currencies are recorded in accumulated other comprehensive income.

***Cash, Cash Equivalents, and Restricted Cash***

The Company considers all highly liquid temporary investments purchased with original maturities of 90 days or less to be cash equivalents. The Company holds restricted cash related to certificates of deposits and collateral in relation to lease agreements. As of December 31, 2019, $0.3 million of our $73.5 million of cash, cash equivalents and restricted cash balance was located outside the U.S.

The following table presents the components of total cash, cash equivalents, and restricted cash as set forth in the Company's consolidated statements of cash flows:

| | December 31, | |
|---|---|---|
| | 2019 | 2018 |
| Cash and cash equivalents | $ 71,655 | $ 58,223 |
| Restricted cash | 1,852 | 1,799 |
| Total cash, cash equivalents, and restricted cash | $ 73,507 | $ 60,022 |

***Inventories***

Inventories consist of finished goods and component parts and are valued at the lower of cost or net realizable value, determined by the first-in, first-out ("FIFO") method. On a quarterly basis, the Company evaluates the carrying costs of both finished goods and component part items. To the extent that such costs exceed future demand estimates, exhibit historical turnover at rates less than current inventory levels, or exceed estimated selling prices less costs to sell, the Company reduces the carrying value of inventories to its net realizable value. The Company only capitalizes pre-launch inventories when purchased for commercial sale and it deems regulatory approval to be probable.

***Public Offering Costs***

The Company incurs public offering costs consisting of legal, accounting and other costs directly attributable to the Company's public offerings and defers such costs until the closing of the offerings. Upon closing of offerings, such costs are netted against the proceeds received. As of December 31, 2019 and 2018, no amounts were deferred.

***Property and Equipment***

Property and equipment are recorded at cost. Depreciation is recognized over the estimated useful lives of the related assets on a straight-line basis. Amortization of leasehold improvements is computed on a straight-line basis over the shorter of the remaining lease term or the estimated useful lives of the improvements and is included in depreciation expense. Demonstration equipment represents internally manufactured capital equipment that is used on-site at trade shows and at customer locations to demonstrate the Precision Flow system. Depreciation expense on demonstration equipment is recorded in sales and marketing expense in the consolidated statements of comprehensive loss. Placement and evaluation systems represent capital equipment placed at customer locations under placement or evaluation agreements for which depreciation expense is included in cost of revenue in the accompanying consolidated statements of comprehensive loss.

When impairment indicators are present, the Company evaluates the recoverability of its long-lived assets. If the assessment indicates an impairment, the affected assets are written down to fair value. There were no impairments during 2019 or 2018.

Repairs and maintenance are expensed as incurred. Expenditures that increase the value or productive capacity of assets are capitalized. When property and equipment are retired, sold, or otherwise disposed of, the asset's carrying amount and related accumulated depreciation are removed from the accounts and any gain or loss is included in operating expenses.

The lives used in computing straight-line depreciation are as follows:

| | Number of Years |
|---|---|
| Equipment | 3 - 7 |
| Furniture | 5 - 7 |
| Manufacturing equipment | 3 - 10 |
| Software | 3 |
| Demonstration, placements and evaluation units | 3 - 5 |
| Leasehold improvements | Lesser of life of lease or 10 years |

The Company's policy is to periodically review the estimated useful life of all property and equipment. This review during fiscal year 2019 indicated that the estimated useful life of all property and equipment is consistent with fiscal year 2018, with the exception of certain manufacturing equipment placed in service in 2019, for which the maximum useful life increased from 7 years to 10 years. Property and equipment are evaluated for impairment whenever events or circumstances indicate an asset may be impaired. There were no impairments during 2019 or 2018.

***Intangible Assets***

Intangible assets related to customer agreements are amortized on a straight-line basis over their useful lives. Amortization is recorded within sales and marketing expenses in the consolidated statements of comprehensive loss. Intangible assets are evaluated for impairment whenever events or circumstances indicate an asset may be impaired. There were no impairments of intangible assets during 2019, and the Company had no intangible assets during 2018.

***Goodwill***

Goodwill represents the difference between the purchase price and the fair value of the identifiable tangible and intangible net assets when accounted for using the purchase method of accounting. Goodwill is not amortized but reviewed for impairment. Goodwill is reviewed annually, as of October 1, and whenever events or changes in circumstances indicate that the carrying value of the goodwill may not be recoverable.

The Company compares the fair value of our reporting units to their carrying values. If the carrying value of the net assets assigned to a reporting unit exceeds the fair value of the reporting unit, the Company would record an impairment loss equal to the difference. There was no impairment of goodwill during 2019, and the Company had no goodwill during 2018.

***Leases & Deferred Rent***

Leases are classified at their inception as either operating or capital leases based on the economic substance of the agreement. Lease payments made under operating leases are recognized as an expense on a straight-line basis over the lease term. Any differences between the lease payments and the expense recognized on a straight-line basis is recorded as deferred rent. Deferred rent is recorded in accrued expenses and other liabilities in the consolidated balance sheets. Deferred rent totaled $0.2 million at both December 31, 2019 and 2018.

***Product Warranty***

The Company provides its customers with a standard one-year warranty on its capital equipment sales. Warranty costs are accrued based on actual historical trends and estimated at time of sale. The warranty liability is included within accrued expenses and other liabilities in the consolidated balance sheets. A roll-forward of the Company's warranty liability is as follows:

| | | |
|---|---|---|
| **Balance at December 31, 2017** | $ | 317 |
| Provisions for warranty obligations | | 355 |
| Settlements | | (343) |
| **Balance at December 31, 2018** | | 329 |
| Provisions for warranty obligations | | 125 |
| Settlements | | (229) |
| **Balance at December 31, 2019** | $ | 225 |

***Deferred Financing Costs***

Direct financing costs are deferred and amortized as a component of interest expense, over the term of the related debt. The balance of unamortized costs is presented as a reduction of the related borrowing arrangement liability. Unamortized costs totaled $0.8 million and $0.7 million at December 31, 2019 and 2018, respectively.

***Revenue Recognition***

The Company's revenue consists primarily of the sale of products, leases and services. Product revenue consists of capital equipment and single-use disposables that are shipped and billed to customers both domestically and internationally. The Company's main capital equipment products are the Precision Flow Hi-VNI, Precision Flow Plus, Precision Flow Classic, Vapotherm Transfer Unit 2.0 and Q50 compressor. The Company's main disposable products are single-use disposables and nasal interfaces, or cannulas, and adaptors. Lease revenue consists of capital equipment that the Company leases out to its customers. Service revenue consists of fees associated with routine service of capital units and the sale of extended service contracts and preventative maintenance plans, which are purchased by a small portion of the Company's customer base. In addition, the Company sells small quantities of component parts in the United States, United Kingdom and to third-party international service centers who provide service on Precision Flow capital units outside of the United States. Freight revenue is based upon actual freight costs plus a percentage markup of such costs associated with the shipment of products domestically, and to a lesser extent, internationally, and is included in service revenue. Rebates and fees consist of contractually obligated administrative fees and percentage-of-sales rebates paid to Group Purchasing Organizations ("GPOs"), Integrated Delivery Networks ("IDNs") and distributor partners and accounted for as a reduction of service revenue.

Under Financial Accounting Standard Board ("FASB") Accounting Standards Codifications ("ASC") 606, Revenue from Contracts with Customers ("ASC 606"), revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and assesses whether each promised good or service is distinct and determines those that are performance obligations. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. Sales, value-added, and other taxes collected on behalf of third parties are excluded from revenue. The Company's standard payment term is generally 30 days from date of sale.

Contracts with customers may contain multiple performance obligations. For such arrangements, the transaction price is allocated to each performance obligation based on the estimated relative stand-alone selling prices of the promised products or services underlying each performance obligation. The Company determines stand-alone selling prices based on the price at which the performance obligation is sold separately. If the stand-alone selling price is not observable through past transactions, the Company estimates the stand-alone selling price taking into account available information such as market conditions and internally approved pricing guidelines related to the performance obligations.

When determining the transaction price of a contract, an adjustment is made if payment from a customer occurs either significantly before or significantly after performance, resulting in a significant financing component. Applying the practical expedient in paragraph 606-10-32-18, the Company does not assess whether a significant financing component exists if the period between when the Company performs its obligations under the contract and when the customer pays is one year or less. None of the Company's contracts contained a significant financing component during the years ended December 31, 2019 or 2018.

The Company's contracts with its customers have a duration of less than one year. Therefore, the Company has elected to apply the practical expedient in paragraph ASC 340-40-25-4 and recognizes the incremental costs of obtaining contracts as an expense. These costs are included in sales and marketing expense in the accompanying consolidated statements of comprehensive loss.

***Lease Revenue***

The Company also enters into agreements to lease its capital equipment. For such sales, the Company accounts for revenue under ASC 840, Leases, and assesses and classifies these transactions as sales-type or operating leases based on whether the lease transfers ownership of the equipment to the lessee by the end of the lease term. This criterion is met in situations in which the lease agreement provides for the transfer of title at or shortly after the end of the lease term in exchange for the payment of a nominal fee, for example, the minimum required by statutory regulation to transfer title. Equipment included in arrangements including transfer of title are accounted for as sales-type leases and the Company recognizes the total value of the lease payments due over the lease term to revenue at the inception of the lease. The Company records the current value of future lease payments under prepaid expenses and other current assets in the accompanying consolidated balance sheets and these amounts totaled $0.9 million at both December 31, 2019 and 2018. Equipment included in arrangements that do not include the transfer of title, nor any of the capital lease criteria, are accounted for as operating leases and revenue is recognized on a straight-line basis as it becomes receivable monthly over the term of the lease.

***Shipping and Handling Costs***

Amounts billed to customers for shipping and handling are included in service revenue. Shipping and handling costs are included in costs of sales. The total costs of shipping and handling at both December 31, 2019 and 2018 amounted to $1.0 million.

***Sales and Value-Added Taxes***

When required by local jurisdictions, the Company bills its customers for sales tax and value-added tax calculated on each sales invoice and records a liability for the sales and value-added tax payable, which is included in accrued expenses and other liabilities in the consolidated balance sheets. Sales tax and value-added tax billed to a customer is not included in the Company's revenue.

***Timing and Amount of Revenue Recognition***

The Company recognizes revenue on product sales and service of its capital equipment and product sales of disposables to its end users. In each instance, revenue is generally recognized when the customer obtains control of the Company's product, which generally occurs at a point in time upon shipment based on the contractual shipping terms of a contract.

Product and service revenue is measured as the amount of consideration the Company expects to receive in exchange for transferring products or services to a customer. To the extent the transaction price includes variable consideration, the Company estimates the amount of variable consideration that should be included in the transaction price utilizing the expected value amount method to which the Company expects to be entitled. As such, revenue on sales are recorded net of prompt pay discounts and payments made to GPOs, IDNs and distributors. Variable consideration is included in the transaction price if, in the Company's judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. Determination of whether to include estimated amounts in the transaction price are based largely on an assessment of the Company's anticipated performance and all information (historical, current and forecasted) that is reasonably available. The Company believes that the estimates it has established are reasonable based upon current facts and circumstances. Applying different judgments to the same facts and circumstances could result in the estimated amounts to vary.

***Product Returns***

The Company provides its customers with the right to return products for a refund of the purchase price or for an account credit, if the return is made within a specified number of days from the original invoice date. The Company records a product return liability based upon an estimate of specific returns and a review of historical returns experienced. Adjustments are made to the product return liability as returns data and historical experience change. The provision for product return estimates is recorded as a reduction of revenue. The product return liability totaled less than $0.1 million at both December 31, 2019 and 2018 and is included in other current liabilities in the accompany consolidated balance sheets.

***Research and Development Costs***

Research and development costs are expensed when incurred and are related primarily to product design, prototype development and testing, the investigation of possible follow-on product enhancements and new product releases, and investigation of complementary technologies potentially available to enhance the Company's offerings in the marketplace.

***Stock-Based Compensation***

The Company maintains an equity incentive plan to provide long-term incentives for employees, consultants, and members of the board of directors. The plan allows for the issuance of non-statutory and incentive stock options to employees and non-statutory stock options to consultants and non-employee directors.

The Company recognizes stock-based compensation expense for awards of equity instruments to employees and non-employees based on the grant date fair value of those awards in accordance with ASC Topic 718, Stock Compensation (ASC 718). ASC 718 requires all equity-based compensation awards, including grants of restricted shares and stock options, to be recognized as expense in the statements of comprehensive loss based on their grant date fair values.

The fair value of each option grant is estimated on the grant date using the Black-Scholes option pricing model. The fair value is then amortized on a straight-line basis over the requisite service period of the awards, which is generally the vesting period. For performance-based awards, the related compensation cost is amortized over the performance period on an accelerated attribution basis. Compensation cost associated with performance awards is based on fair value on the date of grant and the number of units expected to be earned after assessing the probability that certain performance criteria will be met and the associated targeted payout level that is forecasted will be achieved, net of expected forfeitures. Cumulative adjustments are recorded each quarter to reflect estimated outcomes of the performance-related conditions until the results are determined and settled. Use of a valuation model requires management to make certain assumptions with respect to selected model inputs, including the expected life (weighted average period of time that the options granted are expected to be outstanding), the volatility of the Company's common stock and an assumed risk-free interest rate. Expected volatility is calculated based on historical volatility of a group of publicly traded companies that the Company considers a peer group. The expected life is estimated using the simplified method for "plain vanilla" options. The risk-free interest rate is based on U.S. Treasury rates with a remaining term that approximates the expected life assumed at the date of grant. No dividend yield is assumed as the Company does not pay, and does not expect to pay, dividends on its common stock. Company estimates forfeitures based on historical experience with pre-vested forfeitures. To the extent actual forfeitures differ from the estimate, the difference is recorded to compensation expense in the period of the forfeiture.

***Net Income (Loss) per Share***

The Company had followed the two-class method when computing net income (loss) per share as the Company 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 shareholders 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.

Basic net income (loss) per share attributable to common shareholders is computed by dividing the net income (loss) attributable to common shareholders by the weighted average number of common shares outstanding for the period. Diluted net income (loss) attributable to common shareholders is computed by adjusting net income (loss) attributable to common shareholders to reallocate undistributed earnings based on the potential impact of dilutive securities. Diluted net income (loss) per share attributable to common shareholders is computed by dividing the diluted net income (loss) attributable to common shareholders by the weighted average number of common shares outstanding for the period, including potential dilutive common shares. For purpose of this calculation, outstanding options, unvested restricted common shares and convertible preferred shares are considered potential dilutive common shares.

The Company's convertible preferred shares 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 attributable to common shareholders, such losses were not allocated to such participating securities. In periods in which the Company reported a net loss attributable to common shareholders, diluted net loss per share attributable to common shareholders was the same as basic net loss per share attributable to common shareholders, 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 shareholders for the years ended December 31, 2019 and 2018.

On November 16, 2018, the Company completed an initial public offering. All preferred stock outstanding as of the initial public offering automatically converted into 11,229,636 shares of common stock. As a result, the Company no longer had any participating securities outstanding subsequent to November 16, 2018.

***Freestanding Preferred Stock Warrants***

Warrants to purchase the Company's preferred stock were previously classified as a liability on the consolidated balance sheets. These warrants were subject to remeasurement at each balance sheet date and any change in fair value was recognized as a gain or loss on change in fair value of the warrant liabilities. Pursuant to the Company's initial public offering in November 2018, all preferred stock warrants automatically converted into warrants to purchase common stock, were reclassified to stockholders' equity, and were no longer required to be marked to market.

***Stock Split***

On November 2, 2018, the Company's Board of Directors and stockholders approved a 14:1 reverse stock split. The effect of this event has been reflected in all of the share quantities and per share amounts throughout these financial statements. The shares of common stock retained a par value of $0.001.

***Income Tax***

The Company accounts for income taxes using 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 consolidated financial statements or in the Company's tax returns. Deferred taxes are determined based on the difference between the financial reporting 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 recovered from future taxable income 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 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 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 consolidated 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 consolidated financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

***Recently Adopted Accounting Pronouncements***

*Statement of Cash Flows (Topic 230): Restricted Cash*

In November 2016, the FASB issued Accounting Standards Update ("ASU") No. 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash ("ASU 2016-18"). ASU 2016-18 amends Accounting Standards Codification to add or clarify guidance on the classification and presentation of restricted cash in the statement of cash flows. The new standard requires cash and cash equivalents balances on the statement of cash flows to include restricted cash and cash equivalent balances. ASU 2016-18 requires the Company to provide appropriate disclosures about its accounting policies pertaining to restricted cash in accordance with U.S. GAAP. Additionally, changes in restricted cash and restricted cash equivalents that result from transfers between cash, cash equivalents, and restricted cash and restricted cash equivalents should not be presented as cash flow activities in the statement of cash flows. A company with a material balance of amounts generally described as restricted cash and restricted cash equivalents must disclose information about the nature of the restrictions. The new standard is effective for interim and annual periods beginning after December 15, 2018. The Company had not previously included restricted cash as a component of cash and cash equivalents as presented on its consolidated statements of cash flows. The Company adopted the new standard in the first quarter of fiscal 2019, under the retrospective adoption method, and the prior year restricted cash presentation has been reclassified to conform to current year presentation.

*Clarifying the Definition of a Business (Topic 805):*

In January 2017, the FASB issued ASU No. 2017-01, Clarifying the Definition of a Business (Topic 805) ("ASU 2017-01"). The new guidance changed the definition of a business to assist entities with evaluating when a set of transferred assets and activities is a business. The guidance requires an entity to evaluate if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or a group of similar identifiable assets; if so, the set of transferred assets and activities is not a business. The guidance also requires a business to include at least one substantive process and narrows the definition of outputs by more closely aligning it with how outputs are described in Accounting Standards Codification, Topic 606, *Revenue from Contracts with Customers*. The Company adopted ASU 2017-01 effective January 1, 2019. Adoption of ASU 2017-01 did not have a significant impact on the Company's consolidated financial statements and related disclosures.

*Compensation - Stock Compensation (Topic 718):*

In June 2018, the FASB issued ASU 2018-07, Stock-based Compensation: Improvements to Nonemployee Share-based Payment Accounting ("ASU 2018-07"). This guidance amends the existing accounting standards for share-based payments to nonemployees and aligns much of the guidance on measuring and classifying nonemployee awards with that of awards to employees. Under the new guidance, the measurement of nonemployee equity awards is fixed on the grant data. The Company adopted ASU 2018-07 on January 1, 2019 and the adoption had no impact to our consolidated financial statements as there were no share-based awards to non-employees outstanding at that time.

***Recently Issued Accounting Pronouncements***

*Leases (Topic 842):*

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842) ("ASU 2016-02"). ASU 2016-02 establishes a comprehensive new lease accounting model. The new standard clarifies the definitions of a lease, requires a dual approach to lease classification similar to current lease classifications, and causes lessees to recognize leases on the balance sheet as a lease liability with a corresponding right-of-use asset for leases with a lease term of more than twelve months. In July 2018, the FASB issued ASU No. 2018-11 Leases (Topic 842) ("ASU 2018-11") which provided another transition method in addition to the existing transition method by allowing entities to initially apply the new leases standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. In November 2019, the FASB issued ASU 2019-10, Financial Instruments-Credit Losses (Topic 326), Derivative and Hedging (Topic 815) and Leases (Topic 842), which defers the effective date for ASU 2016-02 to annual periods beginning after December 15, 2020 and interim periods beginning after December 15, 2021. The new standard originally required a modified retrospective transition for capital or operating leases existing at or entered into after the beginning of the earliest comparative period presented in the financial statements, but it does not require transition accounting for leases that expire prior to the date of the initial application. The Company has not yet determined the effects that the adoptions of ASU 2016-02 and ASU 2018-11 will have on its financial position, results of operations, cash flows, or disclosures.

*Credit Losses (Topic 326):*

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments ("ASU 2016-13"). This standard requires that credit losses be reported using an expected losses model rather than the incurred losses model that is currently used and establishes additional disclosures related to credit risks. In November 2019, the FASB issued ASU 2019-10, Financial Instruments-Credit Losses (Topic 326), Derivative and Hedging (Topic 815) and Leases (Topic 842), which defers the effective date for ASU 2016-13 to interim and annual periods beginning after December 15, 2022. The Company has not yet determined the effects, if any, that the adoption of ASU 2016-13 may have on its financial position, results of operations, cash flows, or disclosures.

**3. Business Combinations**

On February 28, 2019, the Company completed the acquisition of all outstanding equity securities of Solus, whose principal assets included intangible assets related to supplier agreements. The Company undertook the acquisition to accelerate its penetration in the United Kingdom market. The purchase price, net of cash acquired, of $2.0 million was funded with an initial cash payment of approximately $1.6 million and settlement of a $0.4 million receivable from a preexisting relationship. Additionally, the Company recognized $1.0 million in contingent consideration as compensation expense during 2019. These amounts are included in sales and marking expense in the accompanying consolidated statement of comprehensive loss. In addition, the Company expects to recognize additional contingent consideration of $1.2 million as compensation expense during 2020. The acquisition has been accounted for as an acquisition of a business.

The Company has not yet finalized the purchase accounting for the Solus acquisition. The following table summarizes the preliminary purchase price allocation that includes the fair values of the separately identifiable assets acquired and liabilities assumed as of February 28, 2019:

| | | |
|---|---|---|
| Cash | $ | 466 |
| Accounts receivable | | 411 |
| Inventory | | 492 |
| Prepaids and other assets | | 3 |
| Property and equipment | | 1 |
| Goodwill | | 592 |
| Intangible assets | | 455 |
| Total assets acquired | | 2,420 |
| Accounts payable and accrued expenses | | (241) |
| Contract liabilities | | (75) |
| Deferred taxes | | (78) |
| Total liabilities assumed | | (394) |
| Total purchase price | $ | 2,026 |

The excess of purchase consideration over the fair value of net tangible and identifiable intangible assets acquired was recorded as goodwill. The fair values assigned to tangible and identifiable intangible assets acquired and liabilities assumed are based on management's estimates and assumptions. The fair values of assets acquired and liabilities assumed, including income taxes payable and deferred taxes, may be subject to change as additional information is received and certain tax returns are finalized. Accordingly, the provisional measurements of fair value of the income taxes payable and deferred taxes set forth above are subject to change. The Company expects to finalize the valuation as soon as practicable, but not later than one year from the acquisition date.

In determining the purchase price allocation, the Company considered, among other factors, the opportunity provided by a supplier agreement with the National Health Service. The fair value of the intangible assets associated with this agreement were estimated using a discounted cash flow method with the application of the multi-period excess earnings method. Under this method, an intangible asset's fair value is equal to the present value of the incremental after-tax cash flows attributable to only the subject intangible assets after deducting contributory asset charges. An income and expenses forecast was built based upon specific intangible asset revenue and expense estimates.

The rate used to discount the estimated future net cash flows to their present values for each intangible asset was based upon a weighted average cost of capital calculation. The discount rate was determined after consideration of market rates of return on debt and equity capital, the weighted average return on invested capital and the risk associated with achieving forecasted sales related to the assets acquired from Solus.

The total weighted average amortization period for the intangible assets is approximately 3.83 years. The intangible assets are being amortized on a straight-line basis, which is consistent with the pattern that the economic benefits of the intangible assets are expected to be utilized based upon estimated cash flows generated from such assets. Goodwill associated with the acquisition was primarily attributable to the market expansion opportunity in the United Kingdom. The goodwill attributable to the United Kingdom jurisdiction is not deductible for tax purposes.

The Company has included the financial results of Solus in the consolidated financial statements from the date of acquisition. Net revenue and net loss related of Solus since the date of acquisition totaled $2.7 million and $0.6 million, respectively. The transaction costs associated with the acquisition were approximately $0.2 million and were recorded in general and administrative expense as incurred.

***Pro Forma Financial Information (Unaudited)***

The following unaudited pro forma information for the years ended December 31, 2019 and 2018, respectively, presents consolidated information as if the Solus acquisition occurred on January 1, 2018, which is the first day of the Company's fiscal year 2018:

| | Year Ended December 31, | |
|---|---|---|
| | 2019 | 2018 |
| Net revenue | $ 48,341 | $ 43,637 |
| Net loss | $ (51,003) | $ (42,078) |
| Net loss per share, basic | $ (2.74) | $ (14.48) |

**4. Fair Value Measurements**

In accordance with ASC 820, Fair Value Measurements and Disclosures, the Company generally defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date (exit price). The Company uses a three-tier fair value hierarchy, which classifies the inputs used in measuring fair values. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements), and the lowest priority to unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy are described below:

- *Level 1* – inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date.
- *Level 2* – inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly. If the asset or liability has a specified (contractual) term, a Level 2 input must be observable for substantially the full term of the asset or liability.
- *Level 3* – inputs are unobservable inputs for the asset or liability in which there is little, if any, market activity for the asset or liability at the measurement date.

As of December 31, 2019 and 2018, the Company had only one item, cash equivalents, measured at fair value on a recurring basis. The Company's cash equivalents primarily consist of money market deposits which total approximately $70.8 million and $57.6 million at December 31, 2019 and 2018, respectively, and are valued based on Level 1 of the fair value hierarchy.

As described in Note 14 "Warrants", during 2019, the Company granted warrants to purchase 19,790 shares of common stock in connection with an amendment to its financing arrangement described in Note 10 "Debt". These equity-classified warrants were valued using the Black-Scholes pricing model, which falls within Level 3 of the fair value hierarchy.

The assumptions used in the Black-Scholes pricing model were as follows at the date of grant:

| | |
|---|---|
| Expected dividend yield | 0.0% |
| Risk free interest rate | 2.4% |
| Expected stock price volatility | 60.9% |
| Expected term (years) | 10.0 |

**5. Accounts Receivable**

Accounts receivable consists of the following:

| | December 31, | |
|---|---|---|
| | 2019 | 2018 |
| United States | $ 5,574 | $ 4,948 |
| International | 2,908 | 2,493 |
| Total accounts receivable | 8,482 | 7,441 |
| Less: Allowance for doubtful accounts | (239) | (334) |
| Accounts receivable, net of allowance for doubtful accounts | $ 8,243 | $ 7,107 |

No individual customers accounted for 10% or more of revenue or accounts receivable as of or for the years ended December 31, 2019 or 2018.

**6. Inventories**

Inventories consist of the following:

| | December 31, | |
|---|---|---|
| | 2019 | 2018 |
| Component parts | $ 4,948 | $ 5,601 |
| Finished goods | 4,189 | 8,109 |
| | $ 9,137 | $ 13,710 |

**7. Property and Equipment**

Property and equipment are carried at cost less accumulated depreciation and amortization. A summary of the components of property and equipment is as follows:

| | December 31, | |
|---|---|---|
| | 2019 | 2018 |
| Equipment | $ 1,050 | $ 924 |
| Furniture | 989 | 957 |
| Manufacturing equipment | 9,394 | 4,166 |
| Software | 718 | 655 |
| Demonstration, placements and evaluation units | 10,215 | 7,135 |
| Leasehold improvements | 2,085 | 2,025 |
| Construction in process | 612 | 4,663 |
| Total property and equipment | 25,063 | 20,525 |
| Less: Accumulated depreciation and amortization | (9,977) | (7,109) |
| Total property and equipment, net | $ 15,086 | $ 13,416 |

Depreciation of property and equipment was $3.0 million and $2.1 million during the years ended December 31, 2019 and 2018, respectively. Depreciation expense included in cost of revenue was $1.9 million and $1.2 million during the years ended December 31, 2019 and 2018, respectively.

**8. Goodwill and Intangible Assets**

The changes in the carrying amount of goodwill and intangible assets during 2019 are as follows:

| | Goodwill | Intangible Assets |
|---|---|---|
| **Balance at December 31, 2018** | | |
| Acquired during the period | $ 592 | $ 455 |
| Amortization | - | (95) |
| Foreign currency exchange rate changes | (4) | (7) |
| **Balance at December 31, 2019** | $ 588 | $ 353 |

The following table presents a summary of acquired intangible assets:

| | As of December 31, 2019 | | |
|---|---|---|---|
| | Period of amortization | Gross Carrying Amount | Accumulated Amortization |
| Customer agreements | 3.83 | $ 448 | $ (95) |
| Total identifiable intangible assets | | $ 448 | $ (95) |

The Company recognized $0.1 million of amortization expense within sales and marketing expenses related to the intangible assets during the year ended December 31, 2019. The Company did not recognize any amortization expense related to the intangible assets during the year ended December 31, 2018 as the assets were acquired as part of the acquisition of Solus in February 2019.

The estimated amortization expense for intangible assets for future years is as follows:

| | |
|---|---|
| 2020 | $ 118 |
| 2021 | 118 |
| 2022 | 117 |
| Total | $ 353 |

**9. Accrued Expenses and Other Liabilities**

Accrued expenses and other liabilities consist of the following:

| | December 31, | |
|---|---|---|
| | 2019 | 2018 |
| Accrued bonuses | $ 3,071 | $ 1,692 |
| Accrued commissions | 1,100 | 1,464 |
| Accrued professional fees | 1,092 | 305 |
| Accrued taxes | 983 | 305 |
| Accrued inventory | 620 | 1,070 |
| Accrued vacation liability | 490 | 427 |
| Accrued employee-related costs | 381 | 86 |
| Deferred revenue | 344 | 251 |
| Product warranty reserve | 225 | 329 |
| Refundable purchase price of unvested stock | 212 | 346 |
| Accrued rent and restoration costs | 208 | 174 |
| Accrued capital equipment | 135 | 21 |
| Accrued employee reimbursement | 102 | 178 |
| Other | 846 | 1,005 |
| Total accrued expenses and other liabilities | $ 9,809 | $ 7,653 |

**10. Debt**

***Revolving Credit Line***

On November 16, 2016, the Company entered a Business Financing Agreement (the "Revolver Agreement") with Western Alliance Bank, an Arizona Corporation, which replaced its then existing revolving line of credit. The Revolver Agreement made available $7.0 million of revolving credit upon the closing date. Availability under the Revolver Agreement is calculated based upon 80% of the eligible receivables (net of pre-paid deposits, pre-billed invoices, other offsets, and contras related to each specific account debtor). The original maturity date was September 30, 2018. The Company refinanced the Revolver Agreement in April 2018, increasing the credit line to $7.5 million and extending the maturity date to September 30, 2020. The principal is due upon maturity. On March 22, 2019, the Company entered into an amendment to the Revolver Agreement (as amended, the "Amended Revolver Agreement"), which increased the allowable permitted indebtedness under the Amended Revolver Agreement in connection with the Company's credit card program from $0.3 million to $0.5 million.

At December 31, 2019, the interest rate was 6.50%. The outstanding balance under the Amended Revolver Agreement was $3.5 million at December 31, 2019 and there was $0.8 million remaining availability based on eligible receivables. The outstanding balance under the Revolver Agreement was $3.2 million at December 31, 2018 and the remaining availability based on eligible receivables was $1.0 million. The Amended Revolver Agreement requires the Company to comply with a minimum liquidity covenant at all times. As of December 31, 2019, the Company was in compliance with all covenants. The Amended Revolving Facility is secured by substantially all of the Company's personal property, excluding intellectual property.

***Term Loans***

On November 16, 2016, the Company entered into a Loan and Security Agreement (the "Loan Agreement") with Solar Capital Ltd. ("Solar"). Pursuant to the Loan Agreement, a total of $20.0 million was available in three tranches. The first tranche was drawn down in the amount of $10.0 million upon closing which paid off the Company's then existing term loan balance of $6.0 million in full. The Company achieved the minimum revenue threshold required to draw down the second tranche of $5.0 million of term debt financing and obtained a signed term sheet for an equity financing in excess of $10.0 million, which allowed the Company to draw down the third and final tranche of $5.0 million term debt financing. The Company drew down $5.0 million tranches in each of January 2017 and March 2017.

On April 6, 2018, the Company entered into a Credit Agreement and Guaranty (the "Credit Agreement and Guaranty") with Perceptive Credit Holdings II, LP ("Perceptive"). Pursuant to the Credit Agreement and Guaranty, a total of $42.5 million was available in three tranches. The first tranche was drawn down in the amount of $20.0 million on the closing date, April 6, 2018, which paid off the Loan Agreement in full. In connection with this draw down, the Company granted Perceptive warrants to purchase 37,693 shares of Series D preferred stock which were converted into warrants to purchase shares of common stock at the time of the initial public offering. The warrants have an exercise price of $15.92 per share, were fully vested upon issuance, are exercisable at the option of the holder, in whole or in part, and expire in April 2028.

On July 20, 2018, pursuant to the Credit Agreement and Guaranty, the Company drew down the second tranche of $10.0 million. In connection with this draw down, the Company granted Perceptive warrants to purchase 18,846 shares of Series D preferred stock which were converted into warrants to purchase shares of common stock at the time of the initial public offering. The warrants have an exercise price of $15.92 per share, were fully vested upon issuance, are exercisable at the option of the holder, in whole or in part, and expire in July 2028.

On September 27, 2018, the Company entered into the first amendment to the Credit Agreement and Guaranty (the "Amendment", together with the Credit Agreement and Guaranty, the "Amended Credit Agreement and Guaranty") with Perceptive. Pursuant to the Amended Credit Agreement and Guaranty, the Company was permitted to draw the final $12.5 million of availability at any time through March 31, 2019 and the minimum 2018 revenue requirement of $43.2 million that was required to draw down the final tranche was eliminated. Concurrently with the closing of the Amendment, the Company drew down $2.0 million of the remaining $12.5 million available. In connection with this draw down, the Company granted to Perceptive warrants to purchase 3,769 shares of its Series D preferred stock which were converted into warrants to purchase shares of common stock at the time of the initial public offering. The warrants have an exercise price of $15.92 per share, were fully vested upon issuance, are exercisable at the option of the holder, in whole or in part, and expire in September 2028.

As of December 31, 2018, the Company had drawn $32.0 million of the $42.5 million available under the Credit Agreement and Guaranty, and on March 22, 2019, the Company drew the remaining $10.5 million. In connection with this draw down, the Company granted Perceptive warrants to purchase 19,790 shares of common stock. The warrants have an exercise price of $15.92 per share, were fully vested upon issuance, are exercisable at the option of the holder, in whole or in part, and expire in March 2029. The estimated fair value at the time of issuance was approximately $0.3 million, is recorded as a discount against the principal owed on the related debt, and is being amortized over the contractual term of the debt instrument.

On March 22, 2019, the Company entered into a second amendment to the Amended Credit Agreement and Guaranty increasing the allowable permitted indebtedness in connection with the Company's credit card program from $0.3 million to $0.5 million.

Pursuant to the Amended Credit Agreement and Guaranty, the outstanding principal amount accrues interest at an annual rate equal to 9.06% plus the greater of (a) one-month LIBOR and (b) 1.75% per year. At December 31, 2019, the interest rate was 10.81%. The outstanding balance, including accretion of the additional final payment due upon maturity and described below, was $42.6 million at December 31, 2019 and there was no remaining availability. The Amended Credit Agreement and Guaranty is secured by substantially all of the Company's personal property, including intellectual property.

On the maturity date, in addition to the payment of principal and accrued interest, the Company will be required to make a payment of 0.5% of the total amount borrowed under the Amended Credit Agreement and Guaranty unless the Company has already made such a payment in connection with an acceleration or prepayment of borrowings under the agreement. In the event the Company prepays all or part of this term loan facility prior to the maturity date, the Company will be subject to additional prepayment fees which decrease as the time to maturity decreases. The Amended Credit Agreement and Guaranty requires the Company to comply with a minimum liquidity covenant at all times and a minimum revenue covenant measured at the end of each fiscal quarter. As of December 31, 2019, the Company was in compliance with all covenants.

The annual principal maturities of the Company's term loan as of December 31, 2019 are as follows:

| | | |
|---|---|---|
| 2020 | | - |
| 2021 | | - |
| 2022 | | - |
| 2023 | $ | 42,571 |
| Less: Discount on loans payable | | (784) |
| Long-term loans payable | $ | 41,787 |

**11. Commitments and Contingencies**

In May 2016, the Company entered a lease agreement for 5,529 square feet of office space and 25,670 of storage space at 100 Domain Drive, Exeter New Hampshire. In September 2016, the Company entered into a new lease with its landlord for the space originally leased in May 2016 as well as an additional 16,550 of manufacturing space (including final assembly and inspection) and an additional 3,130 square feet of warehousing and storage space. In September 2017, the Company entered a first lease amendment with its landlord to add two additional expansion premises and extend the term of the lease. The first expansion premises consisted of an additional 16,823 rentable square feet of office space and 3,279 square feet of research and development space, for a total of 20,102 rentable square feet. The second expansion premises consisted of an additional 8,971 square feet of office space. In June 2018, the Company entered a second lease amendment with its landlord to add an additional 3,016 rentable square feet of general-purpose space. In July 2018, the Company entered a third lease amendment with its landlord to add an additional 1,172 rentable square feet of research and development space. In total the Company occupies 84,140 square feet of space at this facility. As amended, the lease will expire on January 28, 2025. The Company has the option to renew the lease for two additional five year terms by providing written notice twelve months prior to end of the initial or first lease extension term.

In October 2019, the Company entered into an assignation and variation agreement for a lease of 453 square meters of office and warehouse space at 2 Dryden Loan, Bilston Glen Industrial Estate, Loanhead in the United Kingdom. The lease terminates on February 15, 2022.

The following table summarizes the future minimum combined lease payments:

| | | Total Due |
|---|---|---|
| **Years Ended December 31,** | | |
| 2020 | $ | 1,621 |
| 2021 | | 1,645 |
| 2022 | | 1,630 |
| 2023 | | 1,652 |
| 2024 | | 1,679 |
| Thereafter | | 140 |
| Total | $ | 8,367 |

Rent expense for the years ended December 31, 2019 and 2018 was $2.0 million and $1.9 million, respectively.

***Legal Matters***

From time to time, the Company may become involved in various legal proceedings, including those that may arise in the ordinary course of business. The Company recently settled a litigation with Engineered Medical Systems, Inc., or EMS, a former supplier of a component of our Precision Flow systems. EMS filed a complaint against the Company in Indiana state court on June 12, 2018 alleging breach of contract and other causes of action and seeking damages of at least $0.8 million and all other forms of just and appropriate relief. This matter was subsequently removed to the United States District Court for the Southern District of Indiana. The Company filed a complaint against EMS in Superior Court in Rockingham County, New Hampshire on June 15, 2018 alleging breach of contract, violation of the New Hampshire Consumer Protection Act, and other causes of action and seeking damages of at least $2.1 million and all other forms of just and appropriate relief. Each party filed a motion to dismiss against the other party's complaint. EMS' motion to dismiss in Superior Court in Rockingham County, New Hampshire was denied. Following this decision, EMS withdrew its complaint in Indiana. The parties reached a settlement agreement on December 16, 2019 whereby EMS agreed to pay the Company $0.65 million in a series of monthly payments through December 2021, and the both the Company and EMS agreed to release each from any other outstanding claims, which included $0.5 million of accounts payable the Company had previously recorded. The Rockingham Superior Court approved the parties' stipulation of dismissal with prejudice on January 2, 2020. As a result, the Company recorded a gain of $1.2 million in the consolidated statement of comprehensive loss during the fourth quarter of 2019.

The Company believes there are no other litigation pending that could have, individually, or in the aggregate, a material adverse effect on the results of our operations or financial condition.

**12. Redeemable Convertible Preferred Stock**

Prior to the completion of the Company's initial public offering in November 2018, the Company was authorized to issue Series A, Series B, Series C, and Series D preferred stock.

On September 27, 2018, the Company entered into an equity financing agreement for Series D-1 preferred stock with its existing institutional investors whereby it offered to sell in the aggregate 714,285 shares of Series D-1 preferred stock for the purchase price of $15.92 per share in exchange for aggregate proceeds of $10.0 million.

Pursuant to the initial public offering in November 2018, all outstanding redeemable convertible preferred stock converted to common stock on a one-to-one basis. In connection with certain of its redeemable convertible preferred stock issuances the Company had issued warrants for shares of its redeemable convertible preferred stock. Such warrants were recorded as liabilities as a result of non-standard anti-dilution rights and were carried at their estimated fair value using the Black-Scholes valuation model. Pursuant to the initial public offering in November 2018, these warrants converted to common stock warrants and were reclassified to stockholders' equity.

**13. Stockholders' Equity**

***Preferred Stock***

As of December 31, 2019 and 2018, the Company has authorized 25,000,000 shares of preferred stock, at a par value of $0.001. As of December 31, 2019 and 2018, there are no shares of preferred stock outstanding.

***Common Stock***

As of December 31, 2019 and 2018, the Company has authorized 175,000,000 shares of common stock. The Company has 20,851,531 and 16,782,837 issued and outstanding shares of common stock as of December 31, 2019 and 2018, respectively, at a par value of $0.001. Each share of common stock is entitled to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available and when declared by the Board of Directors, subject to the prior rights of holders of all classes of stock outstanding.

**14. Warrants**

The table below sets forth the Company's warrant activity for the year ended December 31, 2019:

| | Common Stock Warrants | |
|---|---|---|
| | Number of Shares | Weighted Average Exercise Price |
| **Outstanding at December 31, 2018** | 230,295 | $ 14.50 |
| Warrants granted | 19,790 | 15.92 |
| Warrants exercised | (68,009) | (14.00) |
| **Outstanding at December 31, 2019** | 182,076 | $ 14.84 |

The Company has the following warrants outstanding at December 31, 2019:

| Dates of Expiration | Exercise Price | Number of Warrants |
|---|---|---|
| Periods ranging from September 27, 2020 to July 28, 2025 | $ 14.00 | 101,979 |
| Periods ranging from April 6, 2028 through March 22, 2029 | $ 15.92 | 80,097 |
| **Total Common Stock Warrants** | | 182,076 |

On March 22, 2019, in connection with an amendment to the Credit Agreement and Guaranty as further described in Note 10 “Debt”, the Company granted warrants to purchase 19,790 shares of common stock. The warrants have an exercise price of $15.92 per share, were fully vested upon issuance, are exercisable at the option of the holder, in whole or in part, and expire in March 2029. The estimated fair value at the time of issuance was approximately $0.3 million, is recorded as a discount against the principal owed on the related debt, and is being amortized over the contractual term of the debt instrument.

During 2019, warrants to purchase 68,009 shares of common stock were net exercised, which resulted in the issuance of 12,164 shares of common stock.

**15. Disaggregated Revenue**

The following table shows the Company’s net revenue disaggregated into categories the Company considers meaningful to depict how the nature, amount, timing and uncertainty of revenue and cash flows are affected by economic factors:

| | For the Year Ended December 31, 2019 | | |
|---|---|---|---|
| | US | International | Total |
| **Net revenue by:** | | | |
| Product Revenue | | | |
| Capital | $ 6,144 | $ 3,180 | $ 9,324 |
| Disposable | 27,753 | 7,302 | 35,055 |
| Subtotal Product Revenue | 33,897 | 10,482 | 44,379 |
| Lease Revenue | 1,721 | - | 1,721 |
| Service Revenue | 965 | 1,039 | 2,004 |
| Total Revenue | $ 36,583 | $ 11,521 | $ 48,104 |

| | For the Year Ended December 31, 2018 | | |
|---|---|---|---|
| | US | International | Total |
| **Net revenue by:** | | | |
| Product Revenue | | | |
| Capital | $ 7,293 | $ 3,487 | $ 10,780 |
| Disposable | 23,024 | 5,429 | 28,453 |
| Subtotal Product Revenue | 30,317 | 8,916 | 39,233 |
| Lease Revenue | 1,334 | - | 1,334 |
| Service Revenue | 1,359 | 451 | 1,810 |
| Total Revenue | $ 33,010 | $ 9,367 | $ 42,377 |

Net revenue by U.S. and International is based on the customer location to which the product is shipped. No individual foreign country represents more than 10% of the Company’s aggregated revenue.

**16. Stock Plans and Stock-Based Compensation**

The Company’s 2005 Stock Incentive Plan (the “2005 SI Plan”) allowed for the granting of restricted stock and incentive and non-statutory stock options to purchase shares of common stock. On July 22, 2015, the Company established the Company’s 2015 Stock Incentive Plan (the “2015 SI Plan”) which allowed for the granting of restricted stock and incentive and non-statutory stock options to purchase shares of common stock. The 2015 SI Plan reserved 1,413,749 shares plus any shares available for grant under the Company’s 2005 SI Plan for issuance under the plan.

On July 18, 2018, the Company established a French Qualifying Subplan that sits underneath the 2015 SI Plan which allows for the granting of stock options to purchase shares of common stock for employees and officers who are residents of France. The options under the French Qualifying Subplan reside under the umbrella of the 2015 SI Plan.

On October 17, 2018, the Company established the Company’s 2018 Stock Incentive Plan (the “2018 SI Plan”) which allows for the granting of restricted stock and incentive and non-statutory stock options to purchase shares of common stock. The 2018 SI Plan reserved 998,900 shares plus any shares available for grant under the Company’s 2015 SI Plan for issuance under the plan. As of December 31, 2018, the Company has reserved 3,279,682 shares of its common stock for issuance collectively under the 2000 LTI Plan, 2005 SI Plan, 2015 SI Plan and the 2018 SI Plan to eligible employees, officers, directors, advisors, and consultants.

On January 23, 2019, the Company established a French Qualifying Subplan which allows for the granting of stock options to purchase shares of common stock for employees and officers who are residents of France. The options under the French Qualifying Subplan reside under the umbrella of the 2018 Stock Incentive Plan.

As of December 31, 2018 and 2019, no shares of common stock remain available for issuance under the 2000 LTI Plan, the 2005 SI Plan or the 2015 SI Plan. As of December 31, 2019, 834,423 shares of common stock remain available for issuance under the 2018 SI Plan. Under the terms of the 2018 SI Plan, the exercise price of the options is determined by the Board of Directors at the time of grant. Options granted under the plans vest ratably over a period of one to four years from the date of grant and are exercisable over a period of not more than ten years from the date of grant.

**Stock Options**

Stock option activity for the year ended December 31, 2019 is as follows:

| | Number of Underlying Common Shares | Weighted Average Exercise Price | Weighted Average Remaining Contractual Term | Aggregate Intrinsic Value |
|---|---|---|---|---|
| **Outstanding at December 31, 2018** | 786,989 | $ 2.41 | 7.87 | $ 13,801 |
| Options granted | 969,646 | 16.61 | | |
| Options exercised | (150,176) | 1.62 | | |
| Options canceled | (576,311) | 15.10 | | |
| **Outstanding at December 31, 2019** | 1,030,148 | $ 8.91 | 8.18 | $ 5,544 |
| **Exercisable at December 31, 2019** | 407,120 | $ 2.37 | 6.90 | $ 4,025 |
| **Vested and unvested expected to vest at December 31, 2019** | 1,030,148 | $ 8.91 | 8.18 | $ 5,544 |

The weighted average grant date fair value of options granted during the years ended December 31, 2019 and 2018 was $9.20 and $3.26 per share, respectively. The aggregate intrinsic value of options exercised during the year ended December 31, 2019 was $2.3 million. As of December 31, 2019, the Company had unrecognized stock-based compensation expense related to its unvested stock options awards of $2.9 million, which is expected to be recognized over the remaining weighted average vesting period of 2.7 years.

Certain members of the Company's management elected to receive their option grants in the form of restricted stock, which contains vesting provisions. Upon election of restricted stock, the Company records a liability for the unvested portion of the grant. As the restricted stock vests, the Company reclassifies the liability into additional paid-in capital. During the first quarter of 2019, the Company modified certain previously granted performance awards where the performance condition had not been met. The modification resulted in the granting of 68,526 shares of restricted stock for which 25% was immediately vested with the remaining portion vesting over 36 months.

During 2016, the Company permitted the exercise of 79,865 stock options via nonrecourse notes. There were no exercises of stock options via nonrecourse notes in fiscal year 2018 or 2019. The nonrecourse notes were fully paid during 2019 and the related shares were issued.

The weighted average assumptions used in the Black-Scholes options pricing model are as follows:

| | Year Ended December 31, | |
|---|---|---|
| | 2019 | 2018 |
| Expected dividend yield | 0.0% | 0.0% |
| Risk free interest rate | 1.9% | 2.6% |
| Expected stock price volatility | 64.5% | 54.4% |
| Expected term (years) | 6.2 | 6.1 |

The Company assumed an average forfeiture rates of 6.73% and 8.32% for the year ended December 31, 2019 and 2018, respectively, based on historical experience with pre-vested forfeitures.

A summary of restricted stock activity for the year ended December 31, 2019 is as follows:

| | Shares | Weighted Average Grant Date Fair Value |
|---|---|---|
| **Unvested at December 31, 2018** | 399,485 | $ 1.68 |
| Granted/purchased | 86,170 | 15.52 |
| Vested | (255,742) | 4.46 |
| Canceled | - | - |
| **Unvested at December 31, 2019** | 229,913 | $ 3.76 |

Stock-based compensation expense was allocated based on the employees' and non-employees' functions as follows:

| | Year Ended December 31, | |
|---|---|---|
| | 2019 | 2018 |
| Cost of revenue | $ 187 | $ 27 |
| Research and development | 405 | 119 |
| Sales and marketing | 782 | 146 |
| General and administrative | 2,462 | 210 |
| Total | $ 3,836 | $ 502 |

**17. Income Taxes**

Net loss before income taxes is as follows:

| | Year Ended December 31, | |
|---|---|---|
| | 2019 | 2018 |
| United States | $ (50,343) | $ (42,468) |
| United Kingdom | (862) | - |
| | $ (51,205) | $ (42,468) |

The Company recorded a tax benefit of approximately $0.1 million, related to foreign net deferred income tax assets deemed more likely than not to be realized in the United Kingdom. There were no current foreign income taxes due to foreign net losses during the year ended December 31, 2019. Because the Company has historically incurred operating losses and maintains a full valuation allowance against its United States net deferred tax assets, no tax benefit or provision was recorded on its United States results in either the year ended December 31, 2019 or 2018. The reported amount of income tax benefit for both 2019 and 2018 differs from the amount that would result from applying domestic federal statutory tax rates to pretax losses primarily because of changes in the valuation allowance. There was no provision or benefit for income taxes recorded during the year ended December 31, 2018.

A reconciliation of income tax expense is computed as the statutory federal income tax rate to income taxes as reflected in the financial statement as follows:

| | Year Ended December 31, | |
|---|---|---|
| | 2019 | 2018 |
| Federal income tax benefit at statutory rate | (21.0%) | (21.0%) |
| Permanent differences | (6.7%) | 2.6% |
| Change in valuation allowance | 26.9% | 21.0% |
| Other | 0.5% | (2.6%) |
| Income tax expense | (0.3%) | 0.0% |

Significant components of the Company's net deferred tax assets are as follows:

| | December 31, | |
|---|---|---|
| | 2019 | 2018 |
| **Deferred Tax Assets** | | |
| Net operating loss carryforwards | $ 51,303 | $ 42,444 |
| Deduction of research and development costs | 5,985 | 4,239 |
| Tax credit carryforwards | 4,109 | 3,012 |
| Accrued expenses | 1,976 | 1,184 |
| Stock option expense attributed to non-ISO stock | 1,098 | 358 |
| Accrued bonus and vacation | 703 | 579 |
| Inventory valuation reserves | 280 | 154 |
| Deferred revenue | 230 | - |
| Accounts receivable allowance | 63 | 70 |
| Accrued warranty | 61 | 86 |
| Allowance for sales returns | - | 18 |
| Other temporary differences | 492 | - |
| Gross deferred tax assets | 66,300 | 52,144 |
| Less: Valuation allowance | (65,515) | (51,708) |
| Deferred tax assets after valuation allowance | 785 | 436 |
| **Deferred Tax Liabilities** | | |
| Depreciation | (593) | (366) |
| Intangible assets | (68) | - |
| Other temporary differences | (58) | (70) |
| Gross deferred tax liabilities | (719) | (436) |
| **Net Deferred Tax Assets** | $ 66 | $ - |

The Company's major tax jurisdictions are the United States, New Hampshire and the United Kingdom. As of December 31, 2019, the Company had federal and state net operating loss carryforwards of $218.9 million and $89.7 million, respectively, which begin to expire in 2020. Federal net operating loss carryforwards generated during or after the year ended December 31, 2018 will carryforward indefinitely. As of December 31, 2019, the Company had federal research and development tax credits carryforwards of $3.9 million which begin to expire in 2021.

Management of the Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets generated from our UK subsidiary, which are comprised principally of net operating loss carryforwards. Under the applicable accounting standards management has concluded that the Company will realize the benefit of the subsidiary's deferred tax asset.

Management of the Company has evaluated the positive and negative evidence bearing upon the realizability of its domestic deferred tax assets, which are comprised principally of net operating loss carryforwards and research and development credits. Under the applicable accounting standards, management has considered the Company's history of losses and concluded that it is more likely than not that the Company will not recognize the benefits of federal and state deferred tax assets. Accordingly, a valuation allowance of $65.5 million and $51.7 million has been established at December 31, 2019 and 2018, respectively. The valuation allowance increased $13.8 million during the year ended December 31, 2019, due primarily to net operating losses generated.

Years prior to 2016 are generally closed due to statute of limitations for purposes of taxing jurisdictions assessing additional tax; however, the tax attributes, including net operating losses and research credits, from such years can still be reviewed and reduced upon audit. Years beginning in 2016 remain open to examination for both federal and state purposes.

The Company accounts for uncertain tax positions pursuant to ASC 740, Income Taxes, which prescribes a recognition threshold and measurement process for financial statement recognition of uncertain tax positions taken or expected to be taken in a tax return. If the tax position meets this threshold, the benefit to be recognized is measured as the tax benefit having the highest likelihood of being realized upon ultimate settlement with the taxing authority. The Company recognizes interest accrued related to unrecognized tax benefits and penalties in the provision for income taxes. Management is not aware of any uncertain tax positions. As of December 31, 2019, and 2018, the Company determined that there were no liabilities associated with uncertain tax positions and no related interest and penalties. The Company's policy is to recognize interest and penalties related to income tax matters as a component of income taxes, when and if incurred.

Utilization of the net operating loss and tax credit carryforwards may be subject to a substantial annual limitation under Section 382 and 383 of the Internal Revenue Code of 1986 due to ownership change limitations that have occurred previously or that could occur in the future. These ownership changes may limit the amount of net operating loss and tax credit carryforwards that can be utilized to offset future taxable income and tax, respectively. The Company has not currently completed an evaluation of ownership changes through December 31, 2019 or 2018 to assess whether utilization of the Company's net operating loss and tax credit carryforwards would be subject to an annual limitation under Section 382 and 383. To the extent an ownership change is determined to have occurred under IRC 382 and 383, the net operating loss and credit carryforwards may be subject to limitation.

On December 22, 2017, the Tax Cuts and Jobs Act (the "TCJA") was signed into United States law. The TCJA includes a number of changes to existing tax law, including, among other things, a permanent reduction in the federal corporate income tax rate from 34% to 21%, effective as of January 1, 2018, as well as limitation of the deduction for net operating losses to 80% of annual taxable income and elimination of net operating loss carrybacks, in each case, for losses arising in taxable years beginning after December 31, 2017 (though any such net operating losses may be carried forward indefinitely). The tax rate change resulted in (i) a reduction in the gross amount of the Company's deferred tax assets recorded as of December 31, 2017, without an impact on the net amount of its deferred tax assets, which are recorded with a full valuation allowance, and (ii) no income tax expense or benefit being recognized as of the enactment date of the TCJA. The staff of the SEC issued Staff Accounting Bulletin No. 118 to address the application of accounting principles generally accepted in the United States in situations when a registrant does not have the necessary information available, prepared or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the TCJA. In connection with the analysis of the impact of the TCJA, the Company remeasured its deferred tax assets and liabilities based on the rates at which they are expected to reverse in the future, which is generally 21% for federal tax purposes. The remeasurement of the Company's deferred tax assets and liabilities was offset by a change in the valuation allowance. The Company finalized the accounting in 2018 which did not result in any adjustments.

**18. 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 because including them would have had an anti-dilutive effect:

| | Year Ended December 31, | |
|---|---|---|
| | 2019 | 2018 |
| Options to purchase common stock | 1,030,148 | 786,989 |
| Warrants to purchase common stock | 182,076 | 230,295 |
| Unvested restricted stock | 229,913 | 399,485 |
| | 1,442,137 | 1,416,769 |

**19. Related Party Transactions**

As described in Note 12, "Redeemable Convertible Preferred Stock", the Company issued Series A, B, C and D preferred stock to private investors. Certain executive officers of the Company are owners/investors in certain venture funds who purchased Series A, B, C and D preferred stock. The total amount of preferred stock purchased by related party organizations as of November 16, 2018 was $33.2 million. In connection with the Company's public offering in November 2018, all outstanding redeemable convertible preferred stock converted to common stock on a one-to-one basis.

The Company has two investors that are vendors of the Company. The total amount billed from these vendors during the year was less than $0.1 million and $1.2 million in 2019 and 2018, respectively. The accounts payable balance for these vendors was $0.5 million as of December 31, 2018, and there was no outstanding balances for these vendors at December 31, 2019.

In addition, the Company sells its products to a hospital customer who is an affiliate of a current stockholder. The total amount billed to this customer during the year was $1.4 million and $2.2 million in 2019 and 2018, respectively. The accounts receivable balance for this customer was $0.2 million and $0.1 million as of December 31, 2019 and 2018, respectively. All transactions are at arms' length and occur at published list prices.

**20. Employee Benefit Plan**

The Company has a 401(k) retirement plan (the "401(k) Plan") for the benefit of eligible employees, as defined. Each participant may elect to contribute up to 100% of his or her compensation to the 401(k) Plan each year, subject to certain Internal Revenue Service limitations. The Company matches employee contributions at a rate of 50% of the first 4% of employee contributions. The employer match is capped at $1,000 per year for employees with annual earnings less than $50,000 and $500 per year for employees with annual earnings greater than $50,000. The Company contributed $0.1 million in both the years ended December 31, 2019 and 2018.

**21. Selected Quarterly Financial Data (Unaudited)**

The following table sets forth our unaudited quarterly operating results for each of the Company's quarters in the years ended December 31, 2019 and 2018. In the opinion of management, the quarterly financial information reflects all necessary adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of this data.

| | 2019 Quarters | | | | 2019 |
|---|---|---|---|---|---|
| | First Quarter | Second Quarter | Third Quarter | Fourth Quarter | Year |
| Revenue | $ 12,299 | $ 11,986 | $ 10,809 | $ 13,010 | $ 48,104 |
| Cost of revenue | 7,120 | 6,527 | 5,999 | 7,147 | 26,793 |
| Gross profit | 5,179 | 5,459 | 4,810 | 5,863 | 21,311 |
| Operating expenses: | | | | | |
| Research and development | 3,273 | 3,167 | 3,280 | 3,656 | 13,376 |
| Sales and marketing | 9,161 | 9,432 | 9,193 | 9,903 | 37,689 |
| General and administrative | 4,879 | 4,532 | 3,978 | 5,021 | 18,410 |
| Total operating expenses | 17,313 | 17,131 | 16,451 | 18,580 | 69,475 |
| Loss from operations | (12,134) | (11,672) | (11,641) | (12,717) | (48,164) |
| Other expenses, net | (830) | (1,208) | (1,124) | 121 | (3,041) |
| Net loss before income taxes | (12,964) | (12,880) | (12,765) | (12,596) | (51,205) |
| Benefit for income taxes | - | - | - | (146) | (146) |
| Net loss | $ (12,964) | $ (12,880) | $ (12,765) | $ (12,450) | $ (51,059) |

| | 2018 Quarters | | | | 2018 |
|---|---|---|---|---|---|
| | First Quarter | Second Quarter | Third Quarter | Fourth Quarter | Year |
| Revenue | $ 10,739 | $ 10,563 | $ 9,389 | $ 11,686 | $ 42,377 |
| Cost of revenue | 6,494 | 6,469 | 5,774 | 6,868 | 25,605 |
| Gross profit | 4,245 | 4,094 | 3,615 | 4,818 | 16,772 |
| Operating expenses: | | | | | |
| Research and development | 2,225 | 2,081 | 1,768 | 2,697 | 8,771 |
| Sales and marketing | 8,051 | 8,525 | 7,755 | 9,596 | 33,927 |
| General and administrative | 2,382 | 2,603 | 2,804 | 3,397 | 11,186 |
| Loss on disposal of fixed assets | 3 | 39 | 17 | 62 | 121 |
| Total operating expenses | 12,661 | 13,248 | 12,344 | 15,752 | 54,005 |
| Loss from operations | (8,416) | (9,154) | (8,729) | (10,934) | (37,233) |
| Other expense, net | (489) | (2,073) | (730) | (1,943) | (5,235) |
| Net loss | $ (8,905) | $ (11,227) | $ (9,459) | $ (12,877) | $ (42,468) |

# DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

As of December 31, 2019, Vapotherm, Inc. (the "Company") has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act").

## Description of Capital Stock

The following description of the Company's capital stock is a summary and does not purport to be complete. It is subject to and qualified in its entirety by reference to the Company's Tenth Amended and Restated Certificate of Incorporation (the "Certificate of Incorporation") and Amended and Restated By-Laws (the "By-Laws"), each of which is incorporated by reference as an exhibit to this Annual Report on Form 10-K. The Company encourages you to read the Certificate of Incorporation, the By-Laws, and the applicable provisions of the Delaware General Corporation Law for additional information.

### Authorized Capital Shares

The Certificate of Incorporation authorizes the issuance of 175,000,000 shares of common stock, $0.001 par value per share ("Common Stock"), and 25,000,000 shares of preferred stock, $0.001 par value per share ("Preferred Stock"). As of December 31, 2019, we had 20,851,531 shares of Common Stock outstanding. As of December 31, 2019, there are no shares of Preferred Stock outstanding.

### Voting Rights

Holders of the Company's Common Stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. An election of directors by the Company's stockholders shall be determined by a plurality of the votes cast by the stockholders entitled to vote on the election.

### Dividend Rights

Holders of Common Stock are entitled to receive proportionately any dividends as may be declared by the Company's board of directors, subject to any preferential dividend rights of any series of Preferred Stock that we may designate and issue in the future.

### Liquidation Rights

In the event of the Company's liquidation or dissolution, the holders of Common Stock are entitled to receive proportionately the Company's net assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any outstanding Preferred Stock.

### Other Rights and Preferences

The Common Stock has no redemption provisions or preemptive, conversion or exchange rights. No shares of any class of the Company's capital stock are subject to any sinking fund provisions, restrictions on the alienability of securities to be registered, calls, assessments by, or liabilities of the Company.

### Certain Provisions of the Certificate of Incorporation, By-Laws, and Delaware Law

Certain provisions of the Certificate of Incorporation and By-Laws may be deemed to have an anti-takeover effect and may prevent, delay, or defer a tender offer or takeover attempt, including:

*Section 203 of the Delaware General Corporation Law*

The Company is subject to the provisions of Section 203 of the Delaware General Corporation Law ("DGCL"). In general, Section 203 prohibits a publicly-held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. A "business combination" includes, among other things, a merger, asset or stock sale or other transaction resulting in a financial benefit to the interested stockholder. An "interested stockholder" is a person who, together with affiliates and associates, owns, or did own within three years prior to the determination of interested stockholder status, 15% or more of the corporation's voting stock.

Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions: before the stockholder became interested, the corporation's board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder; upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances; or at or after the time the stockholder became interested, the business combination was approved by the board of directors of the corporation and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

A Delaware corporation may "opt out" of these provisions with an express provision in its original certificate of incorporation or an express provision in its certificate of incorporation or by-laws resulting from a stockholders' amendment approved by at least a majority of the outstanding voting shares. The Company has not opted out of these provisions. As a result, mergers or other takeover or change in control attempts of the Company may be discouraged or prevented.

*Anti-Takeover Effects of the Company's Certificate of Incorporation and By-Laws*

The Company's Certificate of Incorporation and By-Laws contain certain provisions that are intended to enhance the likelihood of continuity and stability in the composition of the board of directors but which may have the effect of delaying, deferring or preventing a future takeover or change in control of the Company unless such takeover or change in control is approved by the board of directors.

These provisions include:

*Classified board*. The Company's Certificate of Incorporation provides that the Company's board of directors be divided into three classes of directors, with the classes as nearly equal in number as possible. As a result, approximately one-third of the board of directors will be elected each year. The classification of directors has the effect of making it more difficult for stockholders to change the composition of the Company's board of directors. The Company's Certificate of Incorporation also provides that, subject to any rights of holders of Preferred Stock to elect additional directors under specified circumstances, the number of directors will be fixed exclusively pursuant to a resolution adopted by the board of directors. The Company's board of directors currently has eight members.

*Action by written consent; special meetings of stockholders*. The Company's Certificate of Incorporation provides that stockholder action can be taken only at an annual or special meeting of stockholders and cannot be taken by written consent in lieu of a meeting. The Company's Certificate of Incorporation and By-Laws also provide that, except as otherwise required by law, special meetings of the stockholders can only be called pursuant to a resolution adopted by a majority of the board of directors. Except as described above, stockholders are not permitted to call a special meeting or to require the Company's board of directors to call a special meeting.

*Removal of directors*. The Company's Certificate of Incorporation provides that its directors may be removed only for cause by the affirmative vote of at least 75% of the voting power of the outstanding shares of capital stock, voting together as a single class. This requirement of a supermajority vote to remove directors could enable a minority of the Company's stockholders to prevent a change in the composition of the board of directors.

*Advance notice procedures*. The Company's By-Laws have an advance notice procedure for stockholder proposals to be brought before an annual meeting of its stockholders, including proposed nominations of persons for election to the board of directors. Stockholders at an annual meeting are only be able to consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of the board of directors or by a stockholder who was a stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has given the Company's Secretary timely written notice, in proper form, of the stockholder's intention to bring that business before the meeting. Although the By-Laws do not give the Company's board of directors the power to approve or disapprove stockholder nominations of candidates or proposals regarding other business to be conducted at a special or annual meeting, the By-Laws may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed or may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect its own slate of directors or otherwise attempting to obtain control of the Company.

*Supermajority approval requirements*. The DGCL generally provides that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation's certificate of incorporation or by-laws, unless either a corporation's certificate of incorporation or by-laws requires a greater percentage. The Company's Certificate of Incorporation and By-Laws provide that the affirmative vote of holders of at least 75% of the total votes eligible to be cast in the election of directors will be required to amend, alter, change or repeal specified provisions. This requirement of a supermajority vote to approve amendments to the Company's Certificate of Incorporation and By-Laws could enable a minority of its stockholders to exercise veto power over any such amendments.

*Authorized but unissued shares*. The Company's authorized but unissued shares of Common Stock and Preferred Stock are available for future issuance without stockholder approval. These additional shares may be utilized for a variety of corporate purposes, including future public offerings to raise additional capital, corporate acquisitions and employee benefit plans. The existence of authorized but unissued shares of Common Stock and Preferred Stock could render more difficult or discourage an attempt to obtain control of a majority of the Company's Common Stock by means of a proxy contest, tender offer, merger or otherwise.

*Exclusive forum*. The Company's Certificate of Incorporation requires, to the fullest extent permitted by law, that derivative actions brought in the name of the Company, actions against directors, officers and employees for breach of a fiduciary duty and other similar actions may be brought only in specified courts in the State of Delaware. Although the Company believes this provision beneficially provides increased consistency in the application of Delaware law in the types of lawsuits to which it applies, such provision may have the effect of discouraging lawsuits against the Company's directors and officers.

**Transfer Agent and Registrar**

The transfer agent and registrar for the Company's Common Stock is American Stock Transfer & Trust Company, LLC.

**Listing**

The Company's Common Stock is listed on the New York Stock Exchange under the symbol "VAPO."

**Exhibit 23.1**

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We have issued our report dated March 4, 2020, with the respect to the consolidated financial statements included in the Annual Report of Vapotherm, Inc. on Form 10-K for the year ended December 31, 2019. We consent to the incorporation by reference of the said report in the Registration Statement of Vapotherm, Inc. on Form S-3 (File No. 333-235657) and on Form S-8 (File No. 333-229327).

/s/ GRANT THORNTON LLP

Boston, Massachusetts
March 4, 2020

**Exhibit 31.1**

**CERTIFICATION**

I, Joseph Army, certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2019 of Vapotherm, 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(s) 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 4, 2020

By: /s/ JOSEPH ARMY

Joseph Army
*President, Chief Executive Officer and Director*
*(principal executive officer)*

**Exhibit 31.2**

**CERTIFICATION**

I, John Landry, certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2019 of Vapotherm, 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(s) 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 4, 2020

By: /s/ JOHN LANDRY

John Landry
*Chief Financial Officer*
*(principal financial officer and principal accounting officer)*

**Exhibit 32.1**

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

In connection with the Annual Report of Vapotherm, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; 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 4, 2020

By: /s/ Joseph Army

Joseph Army
*President, Chief Executive Officer and Director*
*(principal executive officer)*

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

**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 of Vapotherm, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; 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 4, 2020

By: /s/ JOHN LANDRY

John Landry
*Chief Financial Officer*
*(principal financial officer and principal accounting officer)*

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.