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

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the Fiscal Year EndedDecember 31, 2021

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: 001-36309

INOGEN, INC.
(Exact name of registrant as specified in its charter)

Delaware	**33-0989359**
State or other jurisdiction of incorporation or organization	**I.R.S. Employer Identification No.**
301 Coromar Drive **Goleta, California**	**93117**
Address of principal executive offices	**Zip Code**

Registrant's telephone number, including area code (805) 562-0500

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 par value	**INGN**	**The NASDAQ Stock Market LLC (NASDAQ Global Select Market)**

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

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

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

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

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

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

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

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

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

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

The aggregate market value of the voting and non-voting equity held by non-affiliates of the registrant, based on the closing price of the shares of common stock on the last business day of its most recently completed second fiscal quarter, as reported on the NASDAQ Stock Market, was approximately $852.6 million.

The number of shares of the registrant's Common Stock outstanding as of February 18, 2022 was 22,735,486.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement to be filed with the Securities and Exchange Commission in connection with the registrant's 2022 Annual Meeting of Stockholders, which will be filed subsequent to the date hereof, are incorporated by reference into Part III of this Form 10-K. Such Proxy Statement will be filed with the Securities and Exchange Commission not later than 120 days following the end of the registrant's fiscal year ended December 31, 2021.

Auditor Firm Id: 34 Auditor Name: Deloitte & Touche LLP Auditor Location: Los Angeles, California, USA

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PART I

Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, that are based on our management's beliefs and assumptions and on information currently available to our management. The forward-looking statements are contained principally in the sections entitled "Business," "Risk Factors," and "Management's Discussion and Analysis of Financial Condition and Results of Operations." Forward-looking statements include, but are not limited to, statements concerning the following:

- information concerning our possible or assumed future cash flows, revenue, sources of revenue and results of operations, operating and other expenses;
- our expectations of the impact of the COVID-19 pandemic and related public health emergency (PHE) on sales, productivity, hiring, media expenditures, prescriber sales team and physician referrals, worldwide demand for oxygen therapies, and our supply chain, including supply constraints and cost inflation related to semiconductor chips used in our batteries and printed circuit boards which are components of our portable oxygen concentrators and the possibility of a future impact on our manufacturing facilities in California and Texas;
- our assessment and expectations regarding reimbursement rates, future rounds of competitive bidding, Centers for Medicare and Medicaid Services (CMS) changes associated with the COVID-19 pandemic and related PHE impacting respiratory care, CMS changes to Home Use of Oxygen national coverage determination and how those changes are implemented, and future changes in rental revenue;
- our expectations regarding regulatory approvals including the period of time during which our sales in Europe will be suspended due to delayed European Medical Device regulation approval, and government and third-party payor coverage and reimbursement;
- our ability to develop new products, improve our existing products and increase the value of our products, including the potential integration of TAV technology into our existing products;
- our expectations regarding the timing of new products and product improvement launches, as well as product features and specifications;
- market share expectations, unit sales, business strategies, financing plans, expansion of our business, competitive position, industry environment, and potential growth opportunities;
- our expectations regarding the market size, market growth and the growth potential for our business;
- our ability to grow our business and enter new markets;
- our expectations regarding the average selling prices and manufacturing costs of our products, including our expectations related to the impact of supply chain disruptions on our manufacturing costs and our ongoing efforts to reduce average unit costs for our systems;
- our expectations regarding our sales and marketing channels including expectations related to our prescriber sales team, including the expansion of the sales team and concierge service representatives and implementation of healthcare data, insights and tools through our partnership with Ashfield Healthcare, LLC (Ashfield) and its impact on clinician awareness and coverage, POC penetration, and sales team productivity;
- our expectations with respect to our European and U.S. facilities and our expectations with respect to our contract manufacturer in Europe;
- our expectations regarding tariffs being imposed by the U.S. on certain imported materials and products;
- our ability to successfully acquire and integrate companies and assets;
- our expectations regarding the impact and implementation of trade regulations on our supply chain;
- our expectations regarding excess tax benefits or deficiencies from stock-based compensation and our assessments and estimates of our effective tax rate;
- our expectations of future accounting pronouncements or changes in our accounting policies;

- our internal control environment;
- the effects of seasonal trends on our results of operations and estimated hiring plans;
- our expectation that our existing capital resources and the cash to be generated from expected product sales and rentals will be sufficient to meet our projected operating and investing requirements for at least the next twelve months; and
- the effects of competition.

Forward-looking statements include statements that are not historical facts and can be identified by terms such as “anticipates,” “believes,” “could,” “seeks,” “estimates,” “expects,” “intends,” “may,” “plans,” “potential,” “predicts,” “projects,” “should,” “will,” “would,” or similar expressions and the negatives of those terms.

Forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements. We discuss these risks in greater detail in Part I, Item 1A, “Risk Factors,” and elsewhere in this Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time-to-time. It is not possible for us to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the future events and trends discussed in this Annual Report on Form 10-K may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

The forward-looking statements made in this Annual Report on Form 10-K relate only to events as of the date on which the statements are made. Except as required by law, we assume no obligation to update these forward-looking statements, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

This Annual Report on Form 10-K also contains estimates, projections and other information concerning our industry, our business, and the markets for certain diseases, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

“Inogen,” “Inogen One,” “Inogen One G2,” “Inogen One G3,” “G4,” “G5,” “Live Life in Moments, not Minutes,” “Never Run Out of Oxygen,” “Oxygen Therapy on Your Terms,” “Oxygen.Anytime.Anywhere,” “Reclaim Your Independence,” “Intelligent Delivery Technology,” “Inogen At Home,” the Inogen design, “TIDAL ASSIST,” “TAV,” and “SIDEKICK” are registered trademarks with the United States Patent and Trademark Office of Inogen, Inc. We own a pending application for “Inogen” with the United States Patent and Trademark Office. We own trademark registrations for the mark “Inogen” in Argentina, Australia, Canada, Chile, China, Columbia, Ecuador, South Korea, Mexico, Europe (European Union Registration), the United Kingdom, Iceland, India, Israel, Japan, Kuwait, New Zealand, Norway, Paraguay, Peru, Turkey, Singapore, Switzerland, and Uruguay. We own pending applications for the mark “Inogen” in Brazil, India, Malaysia, and South Africa. We own a trademark registration for the mark “イノジェン” in Japan. We own trademark registrations for the marks “印诺真” and “艾诺根” in China. We own trademark registrations for the mark “Inogen One” in Australia, Canada, China, South Korea, Mexico, Europe (European Union Registration), and the United Kingdom. We own a trademark registration for the mark “Satellite Conserver” in Canada. We own a trademark registration for the mark “Inogen At Home” in Europe (European Union Registration) and the United Kingdom. We own trademark registrations for the mark “G4” in Europe (European Union Registration) and the United Kingdom. We own trademark registrations for the mark “G5” in Europe (European Union Registration) and the United Kingdom. We own a trademark application for the Inogen design in Bolivia. We own a trademark registration for the Inogen design in China. We own a trademark registration for the mark “إنوجن” in Saudi Arabia. Other service marks, trademarks, and trade names referred to in this Annual Report on Form 10-K are the property of their respective owners.

In this Annual Report on Form 10-K, “we,” “us” and “our” refer to Inogen, Inc. and its subsidiary.

ITEM 1. BUSINESS

General

We were incorporated in Delaware on November 27, 2001. We are a medical technology company that primarily develops, manufactures and markets innovative portable oxygen concentrators (POCs) used to deliver supplemental long-term oxygen therapy to patients suffering from chronic respiratory conditions. Traditionally, these patients have relied on stationary oxygen concentrator systems for use in the home and oxygen tanks or cylinders for mobile use, which we call the delivery model. The tanks and cylinders must be delivered regularly and have a finite amount of oxygen, which requires patients to plan activities outside of their homes around delivery schedules and a finite oxygen supply. Additionally, patients must attach long, cumbersome tubing to their stationary concentrators simply to enable mobility within their homes. Our proprietary Inogen One® systems concentrate the air around the patient to offer a single source of supplemental oxygen anytime, anywhere with a single battery and can be plugged into a power outlet as needed. We believe our Inogen One systems reduce the patient's reliance on stationary concentrators and scheduled deliveries of tanks with a finite supply of oxygen, thereby improving patient quality of life and fostering mobility.

Portable oxygen concentrators represented the fastest-growing segment of the Medicare oxygen therapy market between 2012 and 2020. Based on 2020 traditional fee-for-service Medicare data, we estimate the number of patients using portable oxygen concentrators represents approximately 21% of the total long-term oxygen therapy market (and approximately 26% of the total ambulatory long-term oxygen therapy market) in the United States, although the traditional fee-for-service Medicare data does not account for private insurance, Medicare Advantage, Medicaid and cash-pay patients in the market. We believe we were the first oxygen therapy manufacturer to employ a direct-to-consumer marketing strategy, meaning we advertise directly to patients, process their physician paperwork, and provide clinical support as needed. While other manufacturers have also begun direct-to-consumer marketing campaigns to drive patient sales, we believe we are the only manufacturer of portable oxygen concentrators that employs a direct-to-consumer rental strategy in the United States, meaning we bill Medicare or insurance on their behalf. To pursue a direct-to-consumer rental strategy, our manufacturing competitors would need to meet national accreditation and state-by-state licensing requirements and secure Medicare billing privileges, as well as compete with the home medical equipment providers who many of our manufacturing competitors sell to across their entire homecare business.

Since adopting our direct-to-consumer rental strategy in 2009, we have directly sold or rented more than 1,166,000 of our Inogen oxygen concentrators as of December 31, 2021.

We incorporated Inogen Europe Holding B.V., a Dutch limited liability company, on April 13, 2017. On May 4, 2017, Inogen Europe Holding B.V. acquired all issued and outstanding capital stock of MedSupport Systems B.V. (MedSupport) and began operating under the name Inogen Europe B.V. We merged Inogen Europe Holding B.V. and Inogen Europe B.V. on December 28, 2018. Inogen Europe B.V. is the remaining legal entity. We completed the acquisition of New Aera, Inc (New Aera) on August 9, 2019.

Our market

We consider our market to include patients that use traditional fee-for-service Medicare, commercial payors, retail sales and Veterans Administration population. While growth rates are subject to change over time, we believe that reduced reimbursement rates in connection with competitive bidding, and the enhanced Medicare billing requirements might have further contributed to growth opportunities for POCs that exceed the long-term oxygen therapy market growth rate. Since utilization of long-term oxygen therapy is strongly linked to developed nations with established government reimbursement, western Europe represents our second largest market today behind the United States.

Long-term oxygen therapy has been shown to be a cost-efficient and clinically effective means to treat hypoxemia, a condition in which patients have insufficient oxygen in the blood. Hypoxemic patients are unable to convert oxygen found in the air into the bloodstream in an efficient manner, causing organ damage and poor health. Chronic obstructive pulmonary disease, or COPD, is a leading cause of hypoxemia. Between 60% to 65% of our patient population has been diagnosed with COPD, and as COPD progresses, patients may need long-term oxygen therapy as part of their treatment. Industry sources estimate that approximately 16 million people in the United States have been diagnosed with COPD, with millions more who are unaware they have COPD. COPD is the third leading cause of death in the United States and one of the leading causes of death globally. There are an estimated 251 million individuals worldwide who have COPD, with an estimated 100 million individuals located in China. Smoking is the leading cause of COPD. However, the European Respiratory Journal published a study in July 2019 that concluded ambient air pollution was associated with lower lung function and increased COPD prevalence, based on over 300,000 individuals aged 40 to 69 years.

According to our analysis of 2020 traditional fee-for-service Medicare data, approximately 80% of U.S. long-term oxygen therapy users utilized ambulatory oxygen and the remaining approximately 20% were considered stationary, and either required oxygen twenty-four hours a day, seven days a week, or 24/7, butwere not ambulatory, or did not require oxygen 24/7 and only needed nocturnal oxygen. Clinical data has shown that ambulatory patients who use oxygen therapy 24/7, regardless of modality, have approximately two times the survival rate and spend at least 60% fewer days annually in the hospital than non-ambulatory 24/7 oxygen therapy patients. The cost of one year of long-term oxygen therapy is less than the cost of one day in the hospital.In addition, a report from the Centers for Medicare and Medicaid Services (CMS) in 2019 concluded that utilizers of oxygen therapy have lower deaths, hospitalizations, and days in the hospital than those who have a health condition that would support oxygen but do not use it.

Based on 2020 traditional fee-for-service Medicare data, we estimate that approximately 63% of the ambulatory patients rely upon the delivery model, which has the following disadvantages:

- limited flexibility outside the home, dictated by the finite oxygen supply provided by tanks and cylinders and dependence on delivery schedules;
- restricted mobility and inconvenience within the home, as patients must attach long, cumbersome tubing to a noisy stationary concentrator to move within their homes;
- products are not cleared for use on commercial aircraft and cannot plug into a vehicle outlet for extended use; and
- high costs driven by the infrastructure necessary to establish a geographically diverse distribution network to serve patients locally, as well as personnel, fuel and other costs, which have limited economies of scale and generally increase over time.

Portable oxygen concentrators were developed in response to many of the limitations associated with traditional oxygen therapy and the delivery model. Portable oxygen concentrators are designed to offer a self-replenishing, unlimited supply of oxygen that is concentrated from the surrounding air and to operate without the need for oxygen tanks or regular oxygen deliveries, enhancing patient freedom and independence. Additionally, because portable oxygen concentrators do not require the physical infrastructure and service intensity of the delivery model, we believe portable oxygen concentrators can provide long-term oxygen therapy with a lower cost structure.

We believe the following have hindered the market acceptance of portable oxygen concentrators:

- to obtain portable oxygen concentrators, patients are dependent on home medical equipment providers, which have made significant investments in the physical distribution infrastructure to support the delivery model and which we believe are therefore disincentivized to encourage adoption of portable oxygen concentrators;
- home medical equipment providers cannot easily convert their businesses to non-delivery models in oxygen due to low total reimbursement for oxygen therapy, capital expenditure constraints, investments that are spread across multiple product lines, and uncertainty around reimbursement rate changes;
- relatively low patient and physician awareness of the existence and benefits of portable oxygen concentrators as an oxygen solution instead of the traditional delivery model;
- lack of access to switch from oxygen tank or liquid deliveries to a portable oxygen concentrator using their insurance benefits due to the nature of the capped reimbursement structure; and
- constrained manufacturing costs of conventional portable oxygen concentrators, driven by home medical equipment provider preference for products that have lower upfront equipment cost.

Our solution

Our Inogen One systems provide patients who require long-term oxygen therapy with a reliable, lightweight single solution product that we believe improves quality-of-life, fosters mobility and eliminates dependence on both oxygen tanks and cylinders as well as stationary concentrators. We believe our direct-to-consumer marketing strategy increases our ability to effectively develop, design and market our Inogen One solutions, as it allows us to:

- drive patient awareness of our portable oxygen concentrators through direct marketing, thereby supporting our direct-to-consumer sales channel and creating pull through for our business-to-business channel;

- capture the manufacturer and home medical equipment provider margins on a portion of our revenue, allowing us to focus on the total cost of the solution and to invest in the development of product features instead of being constrained by the price required to attract representation from a distribution channel. For example, we have invested in features that improve patient satisfaction, product durability, reliability and longevity, which increase the cost of our hardware, but reduce the total cost of our solution by reducing our maintenance and repair cost; and
- utilize patient insights to inform our research and development efforts, allowing us to innovate based on this feedback and stay at the forefront of patient and prescriber preference.

We believe the combination of our direct-to-consumer marketing strategy with our focus on designing and developing oxygen concentrator technology has created a best-in-class portfolio of portable oxygen concentrators. Our two most recently released portable product offerings, the Inogen One G5 and the Inogen One G4, at 4.7 and 2.8 pounds with a single battery, respectively, are among the lightest portable oxygen concentrators on the market and offer among the highest oxygen flow capacity per pound. We believe our Inogen One solutions offer the following benefits:

- *Single solution for home, ambulatory, travel (including on commercial aircraft) and nocturnal treatment* We market our Inogen One solutions as single solutions, by which we mean a patient can use our Inogen One systems as their only supplemental oxygen source with no need to also use a stationary concentrator regularly. Our compressors are specifically designed to enable our patients to run our portable oxygen concentrators 24/7, whether powered by battery or plugged into a power outlet at home or in a car while the battery is recharging.
- *Reliability*. We have an integrated engineering structure to ensure design and manufacturing engineers operate as a single team to improve product reliability throughout the product lifecycle. Additionally, with the launch of our Inogen Connect system we can address certain types of reliability issues and provide functionality improvements through our software update capabilities.
- *Effective for nocturnal use.* Our Intelligent Delivery Technology® enables our portable oxygen concentrators to provide consistent levels of oxygen during sleep despite decreased respiratory rates. As a result, patients can rely on our Inogen One portable oxygen concentrators overnight while sleeping.
- *Unparalleled flow capacity.* Our 2.8 pound Inogen One G4 has higher flow capacity than other sub-3 pound portable oxygen concentrators and our Inogen One G5 has higher flow capacity than other sub-5 pound portable oxygen concentrators.
- *User friendly features.* Our systems are designed with multiple user-friendly features, including long battery life and low noise levels in their respective weight categories.

Our Inogen One systems and Inogen At Home system

We market our current portable product offerings, the Inogen One G5 and the Inogen One G4, as single solutions for long-term oxygen therapy. This means our solutions can operate on a 24/7 basis for at least 60 months without a stationary concentrator, with minimal servicing of sieve beds, filters, and accessories. The technology in our Inogen One systems is effective for nocturnal use. Our Inogen One portable oxygen concentrators can operate reliably and cost-effectively over the long period of time needed to service long-term oxygen therapy patients without supplemental use of a stationary concentrator or a replacement portable oxygen concentrator. The following table summarizes our key product features:

	Key Product Specifications	
	Inogen One G5	**Inogen One G4**
Capacity (ml/min)	1,260	630
Weight (lbs)	4.7 (single battery)	2.8 (single battery)
	5.7 (double battery)	3.3 (double battery)
Battery run-time	Up to 6.5 hours	Up to 2.6 hours
	(single battery)	(single battery)
	Up to 13 hours	Up to 5 hours
	(double battery)	(double battery)
Technology effective for overnight use	Yes	Yes
Sound	38 dBA	40 dBA

We have focused our research and development efforts on creating solutions that we believe have overcome the reputation of portable oxygen concentrators as being limited in durability and reliability as well as unsuitable for nighttime or 24/7 use. We specifically designed our compressors for 24/7 use.

All of our Inogen One systems are equipped with Intelligent Delivery Technology, a form of pulse-dose technology from which the patient receives a bolus of oxygen upon inhalation. Pulse-dose technology was developed to extend the number of hours an oxygen tank would last and is generally used on all ambulatory long-term oxygen therapy devices. Our proprietary conserver technology utilizes differentiated triggering sensitivity to quickly detect a breath and ensure oxygen delivery within the first 400 milliseconds of inspiration, the interval when oxygen has the most effect on lung gas exchange. During periods of sleep, respiratory rates typically decrease. Our Inogen One systems actively respond to this changing physiology through the use of proprietary technology that increases bolus size. Our Intelligent Delivery Technology is designed to provide effective levels of blood oxygen saturation during sleep and all other periods of rest and activity that are substantially equivalent to continuous flow systems.

We have also launched Inogen Connect, a wireless connectivity platform for the Inogen One G4 and Inogen One G5 consisting of a front-end mobile application for use by long-term oxygen therapy users and a back-end database portal for use by homecare providers. The Inogen Connect app is compatible with Apple and Android platforms and includes patient features such as oxygen purity status, battery run time, product support functions, notification alerts, and remote software updates. We believe features of the back-end database portal such as remote troubleshooting, equipment health checks, and a location tracker will drive operational efficiencies for home oxygen providers and lower the total cost of servicing oxygen therapy patients.

The Inogen One G5, our latest portable oxygen concentrator released to market in April 2019, is among the lightest products on the market and has higher oxygen production capabilities than the other sub-5 pound portable oxygen concentrators on the market. The performance parameters around our Inogen One systems allow us to serve ambulatory long-term oxygen patients based on their clinical needs. Our products enable us to address a patient's particular clinical needs, as well as lifestyle and performance preferences.

The Inogen At Home stationary oxygen concentrator allows us to access the non-ambulatory long-term oxygen therapy patient market and serves as a backup to our Inogen One system for ambulatory patients on our rental service. At approximately 18 pounds, we believe the Inogen At Home concentrator is the lightest five liter per minute continuous flow oxygen concentrator on the market today. Additionally, the Inogen At Home product has low power consumption with worldwide electrical compatibility, which should reduce the cost of electricity for oxygen therapy patients and reduce environmental impact of the product, as well as reduce manufacturing and distribution complexities. While the Inogen One product line is clinically validated for 24/7 use, the Inogen At Home product represents a compelling solution for stationary long-term oxygen therapy patients that do not require a portable solution, which are estimated to represent approximately 20% of total long-term oxygen therapy patients in the United States based on 2020 traditional fee-for-service Medicare data.

Our direct-to-consumer business model has enabled us to design and commercialize portable oxygen concentrators that address the full suite of features and benefits critical to patient preference and retention. Our products prevent patients from having to choose between lightweight size, suitability for 24/7 use, reliability, and key features such as battery life, flow and reduced noise levels.

Domestic sales and marketing

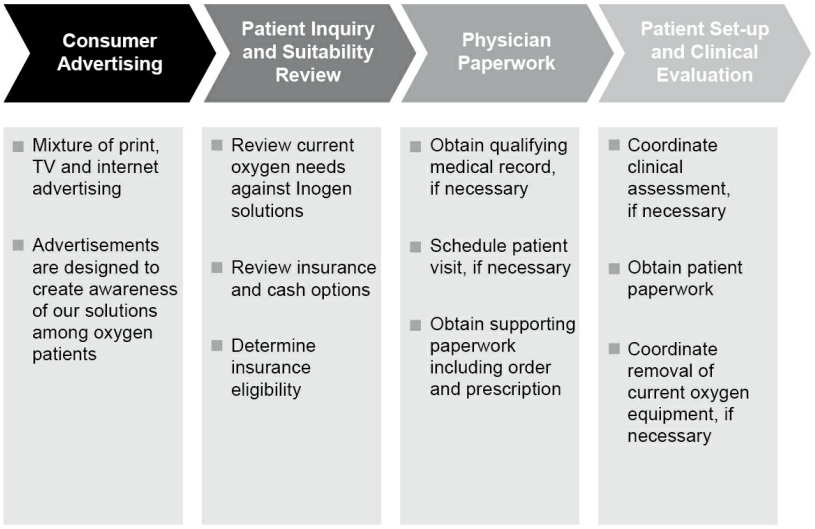
In the United States, we market and distribute our products directly to consumers through a wide variety of direct-to-consumer sales and marketing strategies including consumer advertising, an inside sales staff, and a physician referral model. Of the $278.5 million of our 2021 revenue derived from the United States, approximately 50.6% represented direct-to-consumer sales, 32.8% represented sales to traditional home medical equipment providers, distributors (including our private label partner) and resellers, and 16.6% represented direct-to-consumer rentals.

As of December 31, 2021, we employed a marketing team of 5 people, an in-house sales team of 326 people (including 292 inside sales representatives), a field-based prescriber sales team of 41 people (including 35 prescriber sales representatives), and a business-to-business sales and global support team of 25 people.

Our direct-to-consumer sales and marketing efforts are focused on generating awareness and demand for our Inogen One systems and Inogen At Home systems among patients, physicians and other clinicians, and third-party payors.

Patients who choose to use their Medicare or private insurance benefitstypically rent our systems. Those who purchase our product outright are typicallypatients who are not eligible to use their insurance benefits due to their capped rental status, prefer our Inogen One G4 and Inogen One G5 products that are not currently available for rent, prefer to own the equipment, prefer new equipment, or have an immediate need for our product that cannot be processed in time by their primary insurance carrier (e.g., an upcoming trip). Our ability to rent to Medicare patients directly, bill Medicare and other third-party payors on their behalf, and service patients in their homes requires that we hold a valid Medicare supplier number, are accredited by an independent agency approved by Medicare, and comply with the differing licensure and process requirements in the 50 states in which we serve patients.

We use a variety of direct-to-consumer marketing strategies to generate interest in our solutions among current oxygen therapy patients. After a patient contacts us, we guide them through product selection and insurance eligibility, and, if they choose to move forward, process the necessary reimbursement and physician paperwork on their behalf, as well as coordinate the shipping, instruction, and clinical setup process. In accordance with Medicare regulations, we do not initially contact patients directly and contact them only upon an inbound inquiry or upon receipt of a physician's order. The chart below describes our United States direct-to-consumer sales and rental process.



We engage in a number of other initiatives to increase awareness, demand, and orders for Inogen One systems and Inogen At Home systems. These include attendance at oxygen therapy support groups, guest speaking arrangements at trade shows, and product demonstrations, as requested. Additionally, we are targeting private payors to become an in-network provider of oxygen therapy solutions, which we expect will reduce patient co-insurance amounts associated with using our solution. We believe this will result in both increased conversion of our initial leads, as well as direct referrals from insurance companies in some cases.

To supplement the direct-to-consumer marketing model, we are also utilizing a physician referral model as a complementary sales method. Under this model, our prescriber sales organization works with physicians in the representative's territory to help physicians understand our products and the value these products provide for patients. We believe that by educating physicians on our products, we can cost-effectively supplement our direct-to-consumer sales and rentals and capture a greater number of patients earlier in the course of their oxygen therapy.

Our direct-to-consumer marketing strategies also create demand for our products among other homecare equipment providers and business partners. In addition to generating consumer demand, we believe our products can create value for our business partners by either creating a retail sale opportunity for them or by reducing the need for costly home deliveries associated with oxygen tanks.

We also sell to resellers and traditional homecare providers in the United States, Canada, Europe, the Asia-Pacific region, Latin America, the Middle East and Africa that choose to deploy our products to long-term oxygen therapy patients either through insurance reimbursement or retail. These customers market the benefits of our products to oxygen therapy patients through consumer advertising and/or retail locations or to physicians through field-based prescriber sales representatives. We believe that in addition to the marketing efforts employed by our business customers, our own direct-to-consumer marketing efforts in the United States result in patient interest that our business customers field.

Traditional homecare providers that employ the standard delivery model with oxygen tanks need to replace the oxygen tanks on a regular basis by picking up the empty oxygen tanks and delivering full oxygen tanks for the patient. The delivery model has historically necessitated that a homecare provider has a facility near the oxygen patients that it serves and that the provider has invested in personnel, trucks, etc. to facilitate routine deliveries. The cost to deliver the oxygen tanks to patients is significant for many providers in the standard delivery model. Homecare providers that have adopted Inogen products should be able to reduce the costly deliveries associated with oxygen tanks since our products generate their own oxygen and do not need to be refilled. Our business-to-business sales and marketing strategy for these customers is to raise awareness of our solutions and educate homecare providers on how our products may be able to reduce their total cost of ownership of servicing oxygen patients. As a homecare provider ourselves, we are able to help our business customers adopt a non-delivery long-term oxygen therapy model utilizing patient preferred portable oxygen concentrators. We also private label our product with a business partner that sells to traditional homecare providers. Our private label partner employs field sales representatives who call on homecare providers to showcase the benefits of our products.

Concentration of Customers

We primarily sell our products to traditional home medical equipment providers, distributors, and resellers in the United States and in foreign countries on a credit basis. We also sell our products direct-to-consumers on a primarily prepayment basis. For the year ended December 31, 2021, Medicare's service reimbursement programs represented more than 10% of our total revenue. For the year ended December 31, 2020, one single customer represented more than 10% of our total revenue, OxyGo HQ Florida, our private label distribution partner. For the year ended December 31, 2019, no single customer represented more than 10% of our total revenue. As of December 31, 2021, one single customer and Medicare each represented more than 10% of our net accounts receivable with accounts receivable balances of $5.9 million and $2.7 million, respectively. As of December 31, 2020, two customers each represented more than 10% of our net accounts receivable balance with accounts receivable balances of $8.4 million and $7.0 million.

We rent products directly to consumers for insurance reimbursement, which resulted in a customer concentration relating to Medicare's service reimbursement programs. Medicare's service reimbursement programs accounted for 81.9%, 81.5% and 81.1% of rental revenue in 2021, 2020 and 2019, respectively, and based on total revenue were 10.6%, 7.5% and 4.8% for 2021, 2020 and 2019, respectively. Accounts receivable balances relating to Medicare's service reimbursement programs (including held and unbilled receivables, net of allowances) amounted to $2.7 million or 11.0% of total net accounts receivable as of December 31, 2021 and $1.9 million or 6.3% of total accounts receivable as of December 31, 2020.

International

Approximately 22.2% of our total revenue was from outside the United States in 2021. We sell through distributors, resellers, and home medical equipment providers in certain markets within Canada, Europe, the Asia-Pacific region, Latin America, the Middle East, and Africa. To date, we have sold our products in a total of 59 countries outside the United States through distributors or directly to large "house" accounts, which include gas companies and home oxygen providers. In this case, we sell to and bill the distributor or house accounts directly, leaving the patient billing, support, and clinical setup to the local provider. As of December 31, 2021, we had 13 people located in the United States who focused on selling our products and providing service and support to distributors and house accounts worldwide and 8 in-house and contract employees and independent employees located in Europe who provided sales and customer support services to a portion of our international customers. No single international customer and no single foreign country represented more than 10% of our total revenue in 2021, 2020 or 2019.

We believe that the international oxygen therapy market is attractive for the following reasons:

- more favorable reimbursement rates in certain countries, including France and the United Kingdom, where portable oxygen concentrators receive higher reimbursement rates than in the United States;
- less developed oxygen delivery infrastructure in some countries. We believe that some countries outside the United States have less developed oxygen delivery infrastructure than in the United States. As a result, portable oxygen concentrators enable providers to reach and service patients they cannot economically reach with the delivery model; and
- an absence of reimbursement for any ambulatory long-term oxygen therapy modalities in some countries, resulting in patients bearing all of the cost of ambulatory long-term oxygen therapy and therefore becoming more involved in the selection of the modality. In Australia, for example, patients shoulder the burden of all costs associated with ambulatory long-term oxygen therapy. In these cases, they tend to choose products like portable oxygen concentrators that provide a higher level of personal freedom.

In 2017, we added a European customer support site in the Netherlands after acquiring a previous distributor, MedSupport, now operating under Inogen Europe B.V. This site offers multi-lingual customer service and sales support to improve our European customer support at lower cost. Also in support of our European operations, we produce our Inogen One G3 and Inogen One G5 concentrators and perform related repair activities using a contract manufacturer, Foxconn, located in the Czech Republic to improve our ability to service our European customers.

Order fulfillment and customer support

Our procedures are designed to enable us to package and ship a system directly to the patient in the patient's preferred configuration and we aim to do so the same day the order is received in most cases. This enables us to minimize the amount of finished goods inventory we keep on hand. Our primary logistics partner for shipments originating in the U.S. is UPS, which also provides additional services that support our direct-to-consumer oxygen therapy program. The UPS pick up service is used to retrieve products requiring repair and systems that are no longer needed by our rental patients. When necessary, we utilize a courier for white-glove service whereby the courier goes into a patient's home to remove a replacement product from the box, package the failed device and return it to us. In this manner, we are able to operate as a remote provider while maintaining the level of customer service of a local oxygen therapy provider.

We believe it is important to provide patients with quality customer support to achieve satisfaction with our products and optimal outcomes. As of December 31, 2021, we had a dedicated customer service team of 61 people who were trained on our products, a clinical support team of 23 people who were licensed nurses or respiratory therapists, a patient intake team of 36 people, a rental billing intake team of 31 people, and a dedicated billing services team of 68 people. We provide our patients with a dedicated 24/7 hotline. Via the hotline, patients have direct access to our customer service representatives who can handle product-related questions. Additionally, clinical staff is on call 24/7 and available to patients whenever either the patient or the customer service representative deems appropriate. Our rental intake staff supports patients who wish to use their rental insurance benefits to receive our products and services. Our dedicated billing services team is available to answer patient questions regarding invoicing, reimbursement, and account status during normal business hours. We receive no additional reimbursement for patient support, but we provide high-quality customer service to enhance patient comfort, satisfaction, compliance, and safety with our products.

Third-party reimbursement

Medicare and private insurance rentals represented 12.9% of our total revenue in 2021, up from 9.2% of our total revenue in 2020. The increased rental revenue as a percentage of total revenue was primarily due to increased rental patients on service, and increased reimbursement rates. In cases where we rent our long-term oxygen therapy solutions directly to patients, we bill third-party payors, such as Medicare or private insurance, for monthly rentals on behalf of our patients. We process and coordinate all physician paperwork necessary for reimbursement of our solutions. A common medical criterion for long-term oxygen therapy reimbursement is insufficient blood oxygen saturation level. Our team in sales and rental intake are trained on how to verify benefits, review medical records and process physician paperwork. Additionally, an independent internal review is performed, and our products are not deployed until after physician paperwork is processed and reimbursement eligibility is verified and communicated to the patient.

We rely significantly on reimbursement from Medicare and private payors, including Medicare Advantage plans, Medicaid and patients for our rental revenue. For the year ended December 31, 2021, approximately 81.9% of our rental revenue was derived from Medicare's traditional fee-for-service reimbursement programs. The U.S. list price for our stationary oxygen rentals Healthcare Common Procedure Coding System (HCPCS E1390) is $260 per month and the U.S. list price for our oxygen generating portable equipment (OGPE) rentals (HCPCS E1392) is $70 per month. The average Medicare reimbursement rates in former competitive bidding areas (CBAs) in the prior five years are outlined in the table below for E1390 and E1392, which are the two primary codes that we bill to Medicare and other payors for our oxygen product rentals. These rates are typically updated annually each January as they are subject to Consumer Price Index (CPI), sequestration and budget neutrality adjustments but are also subject to adjustments during the year due to legislative rulings. Competitive bidding contracts were scheduled to go into effect on January 1, 2021; however, on October 27, 2020, CMS announced that competitive bidding contracts would not be awarded for most product categories, including oxygen, due to the payment amounts not achieving the expected savings and the current COVID-19 pandemic and the related PHE. Effective April 1, 2021, rates were adjusted to remove a percentage reduction that was put in place to meet the budget neutrality requirement previously mandated by section 1834(a)(9)(D)(ii) of the Social Security Act. See the table below for average Medicare rates in former CBAs, using a simple average of rates in each CBA.

Average Medicare reimbursement rates in former CBAs	E1390	E1392
As of January 1, 2022	$ 85.31	$ 41.81
As of April 1, 2021	$ 81.25	$ 39.82
As of January 1, 2021	$ 73.88	$ 36.20
As of January 1, 2020	$ 73.98	$ 36.25
As of January 1, 2019	$ 72.92	$ 35.72
As of January 1, 2018	$ 77.03	$ 36.06

Medicare payment rates are based upon whether the beneficiary resides in former or current CBAs, or in rural or non-rural non-CBAs, or in non-contiguous states. Non-CBA payment rates are based on regional pricing, that are derived from (former) competitive bidding payment rates. In rural areas and non-contiguous states, payment rates are higher, to account for higher servicing costs in those areas. The Medicare reimbursement rates in rural areas is outlined in the table below, and include areas that are considered non-contiguous (Alaska, Hawaii, Puerto Rico, and the Virgin Islands). We estimate that approximately 18% of our patients are eligible to receive the higher reimbursement rates based on the geographic locations of our current patient population. These rates are typically updated annually each January as they are subject to the CPI, sequestration and budget neutrality adjustments, but are also subject to adjustments during the year due to legislative rulings. Effective April 1, 2021, rates were adjusted to remove a percentage reduction that was put in place to meet the budget neutrality requirement previously mandated by section 1834(a)(9)(D)(ii) of the Social Security Act. Therefore, Medicare payment rates are no longer affected by a budget neutrality adjustment, as of April 1, 2021. See the table below for average Medicare rates in rural areas, using a simple average of rates in each state.

Average Medicare reimbursement rates in rural areas	E1390	E1392
As of January 1, 2022	$ 151.15	$ 48.39
As of April 1, 2021	$ 143.48	$ 47.13
As of January 1, 2021	$ 136.84	$ 44.99
As of January 1, 2020	$ 136.71	$ 44.93
As of January 1, 2019	$ 134.71	$ 44.32
As of January 1, 2018	$ 76.31	$ 41.91

Rates in non-former CBAs that are not defined as rural are set based on the rates in former CBAs. See the table below for average Medicare rates in these non-former CBAs, non-rural areas, using a simple average of rates in each state. These rates are typically updated annually each January as they are subject to the CPI, sequestration and budget neutrality adjustments but are also subject to adjustments during the year due to legislative rulings. Effective April 1, 2021, rates were adjusted to remove a percentage reduction that was put in place to meet the budget neutrality requirement previously mandated by section 1834(a)(9)(D)(ii) of the Social Security Act. Note that the 2022 rates listed below include Coronavirus Aid, Relief, and Economic Security (CARES Act) increased rates due to the COVID-19 PHE, which may not be in place for all of 2022. If the COVID-19 PHE is declared over, the rates in these non-former CBAs, non-rural areas are expected to adjust down to the former CBA rates listed in the table above.

Average Medicare reimbursement rates in non-former CBAs, non-rural areas	E1390	E1392
As of January 1, 2022	$ 115.14	$ 43.69
As of April 1, 2021	$ 109.39	$ 42.12
As of January 1, 2021 (retroactively revised March 1, 2021)	$ 104.07	$ 40.06
As of January 1, 2020	$ 74.84	$ 36.87
As of January 1, 2019	$ 72.32	$ 35.64
As of January 1, 2018	$ 69.31	$ 38.10

There have been significant U.S. reimbursement and policy changes that impact oxygen therapy associated with the COVID-19 PHE declared by the U.S. Department of Health and Human Services (HHS) on January 31, 2020. The CARES Act allows HHS to waive certain Medicare telehealth payment requirements during the COVID-19 PHE to allow beneficiaries in all areas to receive telehealth services, including at their home, starting March 6, 2020. The Coronavirus Preparedness and Response Supplemental Appropriations Act (H.R. 6074) also granted HHS the authority to waive certain requirements with respect to telehealth services. Under this authority, CMS clarified that HHS would not conduct audits to determine whether there was a prior physician-patient relationship for telehealth claims submitted during the COVID-19 PHE. The CARES Act included the extension of the 50/50 blended rate for home medical equipment (HME) in rural and non-contiguous, non-competitively bid areas and established a new 75/25 blended rate for all other non-competitively bid areas through the duration of the COVID-19 PHE. The 75/25 blended rate was retroactive to March 6, 2020. While the duration of the current emergency is impossible to predict, the Zika virus PHE lasted approximately 360 days, and the H1N1 flu PHE lasted approximately 450 days.

The 2% Medicare sequestration benefit that has been in place since May 2020 due to the COVID-19 PHE that was set to expire December 31, 2021 has been extended by Congress until March 31, 2022. The sequestration then resumes with a 1% reduction to rates from April 1, 2022 until June 30, 2022, with the full 2% Medicare sequestration resuming starting July 1, 2022 and continuing through September 30, 2030.

On April 6, 2020, CMS published an Interim Final Rule (IFR) in the Federal Register for policy and regulatory revisions in response to the COVID-19 PHE. This IFR included that for the duration of the COVID-19 PHE, the face-to-face requirements and clinical indications of coverage for home oxygen, among other respiratory products, are waived. In addition, the Administration has issued a number of regulatory waivers to increase the flexibility in DMEPOS suppliers' ability to service patients quickly and without the normal requirements. For example, the patient's signature for proof of delivery has been waived when signatures cannot be collected during the COVID-19 PHE. In addition, CMS increased Medicare contractors' ability to waive replacement product requirements, paused the national prior authorization program for certain DMEPOS, automatically extended expiring accreditations, granted contractors the flexibility to grant appeals extensions, and medical review suspension. Both the IFR and temporary regulatory changes show significant flexibility from CMS to improve access for oxygen and other DMEPOS items during this COVID-19 PHE. These changes were retroactive to early March 2020. In August 2020, CMS resumed medical review of claims and the prior authorization program for certain DMEPOS.

CMS also issued a final rule in December 2021 (CMS-1738-P) to establish payment amounts that will be effective after the COVID-19 PHE for DMEPOS products and services covered under Medicare. We believe that Medicare rates will not change for the length of the COVID-19 PHE, except for any net change for inflation and sequestration adjustments, as outlined above.

CMS established three different fee schedule adjustment methodologies for non-CBAs after the termination of the COVID-19 PHE: (1) for non-contiguous non-CBAs; (2) for contiguous non-CBAs defined as rural areas; and (3) for non-rural non-CBAs within the contiguous United States. The final payment methodology sets the fee schedule amounts to 100% of the Medicare (competitive bid derived) rates in all non-rural areas. This will reduce Medicare rates after the PHE is over in the current areas that are considered non-rural but not covered by a former CBA, as those areas are currently receiving a 75/25 blended payment rate. The final payment methodology establishes the fee schedule amounts to a 50/50 blended payment rate, which is the same rate that is currently applicable in these areas.

In January 2021, CMS announced what the pivotal bid amounts would have been for the competitive bidding round 2021. As a reminder, the bids for oxygen were based on the HCPCS code E1390, which is for stationary oxygen, and there were 130 regions bid. The simple average of the 2018 single payment amounts for these regions for this code was $73.98. The simple average of the pivotal bid amounts for these regions for this code was $122.61, or an average increase of 65.7%. If CMS would have implemented these rate changes, the simple average payment amounts in these regions for POCs (codes E1390 and E1392) would have been $157.60, which is significantly higher than the simple average payment amounts of $110.07 and $121.07 per month being paid as of January 1, 2021 and April 1, 2021 for these regions.

CMS is required to propose future rounds of competitive bidding, which could change reimbursement rates, negatively impact the premium for POCs over other oxygen modalities, or limit beneficiary access to our technologies. At this point, CMS has not yet announced when a new round of competitive bidding will occur. Cumulatively in previous rounds of competitive bidding, we were offered contracts for a substantial majority of the CBAs and product categories for which we submitted bids. As of January 1, 2017 (when the last round of competitive bidding was in effect), we believe we had access to over 90% of the Medicare oxygen therapy market based on our analysis of the 103 CBAs that we won out of the 130 total CBAs. These 130 CBAs represented approximately 36% of the Medicare market with the remaining approximately 64% of the market not subject to competitive bidding per Medicare's data on 2018 traditional Medicare fee-for-service beneficiaries in CBAs compared to the total Medicare fee-for-service beneficiaries. As of January 1, 2019, we can choose to accept Medicare oxygen patients throughout the United States. As of July 2018, we are operating in all 50 states in the U.S. We did not sell or rent to patients in Hawaii due to the licensure requirements from inception to June 2018.

We cannot guarantee that we will be offered contracts in any subsequent rounds of competitive bidding. In all five rounds of competitive bidding in which we have participated, we have gained access to certain CBAs and been excluded from other CBAs.

In September 2021, CMS published a Decision Memo which revised the Home Use of Oxygen national coverage determination and removed the national coverage determination for Home Oxygen Use to Treat Cluster Headaches. This allows the Medicare Administrative Contractors to make coverage determinations regarding the use of home oxygen and oxygen equipment for cluster headaches. CMS also expanded patient access to oxygen and oxygen equipment in the home by allowing oxygen use for acute or short-term needs instead of limiting coverage to chronic hypoxemia, removed the requirement for alternative treatment measures before dispensing of oxygen therapy, and removed the limited list of conditions for which oxygen may be covered to respiratory-related diseases, to allow the physician flexibility to make that determination. In addition, CMS defined exercise more broadly to

include functional performance of the patient and allow more flexibility on pulse oximetry readings to account for differences in skin pigmentation. Lastly, CMS reduced provider burden by removing the oxygen certificate of medical necessity requirement. We believe these changes will expand coverage for patients who would benefit from oxygen therapy, reduce administrative burdens, and give more decision-making authority on proper patient care to the physicians. CMS issued guidance on February 10, 2022 to the Medicare Administrative Contractors detailing that the implementation date of the revised national coverage policy will be June 14, 2022. However, we do not yet have visibility on the details of how the Medicare Administrative Contractors will change their coverage determinations or the effective date of the new national coverage determinations.

Medicare revenue, including patient co-insurance and deductible obligations, represented 10.6% of our total revenue in the year ended December 31, 2021 and 7.5% in the year ended December 31, 2020.

Medicare reimbursement for oxygen rental equipment is limited to a maximum of 36 months within a 60-month service period, and the equipment remains the property of the home oxygen supplier. The supplier that billed Medicare for the 36th month of service continues to be responsible for the patient's oxygen therapy needs for months 37 through 60, and there is generally no additional reimbursement for OGPE for these later months. Medicare does not separately reimburse suppliers for oxygen tubing, cannulas and supplies that may be required for the patient. The supplier is required to keep the equipment provided in working order and in some cases, Medicare will reimburse for repair costs. At the end of the five-year useful life of the equipment, the patient may request replacement equipment and, if he or she can be re-qualified for the Medicare benefit, a new maximum 36-month payment cycle out of the next 60 months of service would begin. The supplier may not arbitrarily issue new equipment. We have analyzed the potential impact to revenue associated with patients in the capped rental period and have deferred $0 associated with the capped rental period for the years ended December 31, 2021 and December 31, 2020. Our capped patients as a percentage of total patients on service was approximately 8.0% as of December 31, 2021 and 11.7% as of December 31, 2020. The decrease in percentage of capped patients in the comparative periods was primarily due to the significant increase in new patients coming on service, which substantially exceeded the number of patients that entered the capped period. The percentage of capped patients may fluctuate over time as new patients come on service, patients come off of service before and during the capped rental period, and existing patients enter the capped rental period.

Our obligations to service Medicare patients over the rental period include supplying working equipment that meets each patient's oxygen needs pursuant to his/her doctor's prescription and supplying all disposables required for the patient to operate the equipment, including cannulas, filters, replacement batteries, carts and carry bags, as needed. If the equipment malfunctions, we must repair or replace the equipment. We determine what equipment the patient receives, and we can deploy used assets in working order as long as the prescription requirements are met. We must also procure a renewal from the patient's doctor to confirm the patient's need for continued oxygen therapy one year after the patient first receives oxygen therapy and one year after each new 36-month reimbursement period begins. The patient can choose to receive oxygen supplies and services from another supplier at any time, but the supplier may only transition the patient to another supplier in certain circumstances.

We have contracts with Medicaid, Medicare Advantage, government and private payors that qualify us as an in-network provider for these payors. As a result, patients can rent or purchase our systems at the same patient obligation as other in-network oxygen suppliers. We had 92 contracts as of December 31, 2021. Private payors typically provide reimbursement at a rate similar to Medicare allowables for in-network plans. We anticipate that private payor reimbursement levels will generally be reset in accordance with Medicare payment amounts.

We believe that we are well positioned to respond to the changing reimbursement environment because our product offerings are innovative, patient-focused and cost-effective. We have historically been able to reduce our costs through scalable manufacturing, better sourcing, continuous innovation, and reliability improvements, as well as innovations that reduce our product service costs by minimizing exchanges. As a result of design changes, supplier negotiations, bringing manufacturing and assembly largely in-house and our commitment to driving efficient manufacturing processes, we have historically reduced our overall POC system cost and intend to continue to seek ways to reduce our cost of revenue through manufacturing and design improvements.

For additional discussion of the impact of the recent Medicare reimbursement proposals, see "Risk Factors" herein.

Manufacturing and raw materials

We have been developing and refining the manufacturing of our Inogen One systems since 2004. While nearly all of our manufacturing and assembly processes were originally outsourced, assembly of the compressors, sieve beds, concentrators and certain manifolds were brought in-house in order to improve quality control and reduce cost. In support of our European sales, we use a contract manufacturer located in the Czech Republic to manufacture high volume products and perform product repairs to improve delivery to our European accounts. We expect to maintain our assembly operations for our products at our facilities in Texas and California. In 2022, we are focused on securing supply for components to make our products in spite of the higher costs of semiconductor chips, reducing the cost of our Inogen One G5 product (excluding the impact of the semiconductor chip price increases), and increasing the robustness of our supply chain as part of our efforts to reduce potential component constraints as we grow our business.

We also use lean manufacturing practices to maximize manufacturing efficiency. We rely on third-party manufacturers to supply several components of our products. We typically enter into master service agreements for these components that specify quantity and quality requirements and delivery terms. In certain cases, these agreements can be terminated by either party upon relatively short notice. We have elected to source certain key components from single sources of supply, including our batteries, motors, valves, TAV-compatible stationary concentrators, columns, and some molded plastic components. In some cases, maintaining a single source of supply can allow us to control production costs and inventory levels and to manage component quality, but also may lead to supply availability risks and means our ability to maintain production is dependent on these single source suppliers, which may put us at an increased risk of supply disruption, as we have seen from the production halt we implemented in early January 2022 through early February 2022. In order to help mitigate against the risks related to a single source of supply, for certain components we qualify alternative suppliers and develop contingency plans for responding to disruptions. However, a continued reduction or halt in supply from one of these single-source suppliersany dual-sourced suppliers or any other limited-source suppliers with similar sub-component suppliers could limit or prevent our ability to manufacture our products or devices untilone or more sufficient replacement suppliers is found and qualified. For additional discussion of potential risks related to our manufacturing and raw materials, please see the risk factor entitled "*We obtain some of the components, subassemblies and completed products included in our products from a single source or a limited group of manufacturers or suppliers, and in some cases those components are available in only limited supplies from limited manufacturers or suppliers, and the partial or complete loss of one or more of these manufacturers or suppliers could cause significant production delays or stoppages, an inability to meet customer demand, substantial loss in revenue, and an adverse effect on our financial condition and results of operations.*"

We currently manufacture in two leased buildings in Plano, Texas and Goleta, California, that we have registered with the Food and Drug Administration (FDA), and maintain a Quality Management system for which we have obtained International Standards Organization (ISO) 13485 certification.

Our entire organization is responsible for quality management. Our Quality Assurance and Regulatory Affairs departments oversee this by tracking component, device and organization performance and by training team members outside the Quality Assurance and Regulatory Affairs departments to become competent users of our Quality Management system. By measuring component performance, communicating daily with the production group and our suppliers, and reviewing customer complaints, our Quality Assurance department, through the use of our corrective action program, drives and documents continuous performance improvement of our suppliers and internal departments. Our Regulatory Affairs department also trains internal quality auditors to audit our adherence to the Quality Management system. Our Quality Management system has been certified to ISO 13485:2016 by BSI, a Notified Body.

In 2019, 2020 and 2021, our contract manufacturer produced the vast majority of the Inogen One G3 concentrators required to support our European demand and we expect this to continue in 2022. Our contract manufacturer also began manufacturing the Inogen One G5 in January 2020 and produced the vast majority of the Inogen One G5 concentrators required to support our European demand in 2021, which we expect to continue in 2022. Lastly, our contract manufacturer began repair services for the Inogen One product line in 2020 and repaired the majority of the Inogen One concentrators for our European customers. This has allowed us to continue to expand our manufacturing and repair capacity and redirect our U.S. manufacturing activities to focus on growth in the U.S. and on our largest volume products, the Inogen One G5 and the Inogen One G4.

As of December 31, 2021, we had 280 employees in operations, manufacturing, quality assurance, manufacturing engineering and repair in the United States.

Research and development

We are committed to ongoing research and development to stay at the forefront of patient preference in the oxygen concentrator and non-invasive ventilation field. As of December 31, 2021, our research and development staff included 28 engineers and scientists with expertise in air separation, compressors, pneumatics, electronics, embedded software, mechanical design, sensor, automation, connectivity, non-invasive ventilation and manufacturing automation. Our current research and development efforts are focused primarily on increasing functionality, improving design for ease-of-use, and reducing production costs of our Inogen One systems and Inogen At Home systems, as well as developing our next-generation oxygen concentrators and non-invasive ventilators. We have leveraged our sixty-six issued patents while also have historically reduced our overall POC system cost and intend to continue to seek ways to reduce our cost of revenue through manufacturing and design improvements.

We have released six products since 2004, including our Inogen One G1 in October 2004, our Inogen One G2 in March 2010, our Inogen One G3 in September 2012, our Inogen At Home system in October 2014, our Inogen One G4 in May 2016, and our Inogen One G5 in April 2019. We also launched the Inogen Connect platform in December 2018 in our direct-to-consumer channel and in February 2019 in our domestic business-to-business channel. We launched our TAV in December 2019. Our dedication to continuous improvement has also resulted in five mid-cycle product updates and numerous incremental improvements. Development projects utilize a combination of rapid prototyping and accelerated life testing methods to ensure products are taken from concept to commercialization in a fast and capital efficient manner. We leverage our direct patient expertise to rapidly gain insight from end users and to identify areas of innovation that we believe will lead to higher-quality products and lower total cost of ownership for our products.

We continue to focus our efforts on design and functionality improvements that enhance patient quality of lifeand reduce service costs.

Competition

The long-term oxygen therapy market is a highly competitive industry.We compete with a number of manufacturers and distributors of portable oxygen concentrators, as well as providers of other long-term oxygen therapy solutions such as home delivery of oxygen tanks or cylinders, stationary concentrators, transfilling concentrators, and liquid oxygen.

Our significant manufacturing competitors are Respironics (a subsidiary of Koninklijke Philips N.V.), Invacare Corporation, Caire Medical (subsidiary of NGK Spark Plug), DeVilbiss Healthcare (a subsidiary of Drive Medical), O2 Concepts, Precision Medical, Resmed, Gas Control Equipment (subsidiary of Colfax), Nidek Medical, 3B Medical, SysMed, and Belluscura. Given the relatively straightforward regulatory path in the oxygen therapy device manufacturing market, we expect that the industry will become increasingly competitive in the future. For example, some major competitors have implemented direct-to-consumer sales models, which may increase their competitiveness and sales to patients, and we have recently seen the cost per generated lead trend higher than historical averages that may in part be due to increased competition. However, the strategies of these major competitors are currently limited to direct-to-consumer sales and do not include direct-to-consumer rentals where they would be responsible to meet national accreditation and state-by-state licensing requirements and secure Medicare billing privileges. Manufacturing companies compete for sales to providers primarily on the basis of price, quality/reliability, financing, bundling, product features, and service.

For many years, Lincare, Inc. (a subsidiary of the Linde Group), Apria Healthcare, Inc., AdaptHealth Corp., Rotech Healthcare, Inc., and Viemed Healthcare, Inc. have been among the market leaders in providing respiratory therapy products, while the remaining market is serviced by local providers. Because of reimbursement reductions, we expect more industry consolidation and volatility in ordering patterns based on how providers are restructuring their businesses and their access to capital. In addition, providers may reduce or eliminate purchases from us due to our increased focus on building out a prescriber sales team and pursuing rentals directly, which could be in competition with our providers in the United States. Respiratory therapy providers compete primarily on the basis of product features and service, rather than price, since reimbursement levels are established by Medicare and Medicaid, or by the individual determinations of private payors.

Some of our competitors are large, well-capitalized companies with greater resources than we have. Consequently, they 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, customers and third-party payors;
- established distribution networks;
- additional lines of products, and the ability to offer rebates or bundle products to offer higher discounts, lower pricing, longer warranties, financing or extended terms, other incentives to gain a competitive advantage;
- greater history in conducting research and development, manufacturing, marketing and obtaining regulatory approval for respiratory device products; and
- greater financial and human resources for product development, sales and marketing, and patent litigation.

As a result, our competitors may be able to respond more quickly and effectively than we can to new or changing opportunities, technologies, standard regulatory and reimbursement development and customer requirements or changing or uncertain business conditions or macroeconomic trends. In light of these advantages that our competitors maintain, even if our technology and direct-to-consumer distribution strategy is more effective than the technology and distribution strategy of our competitors, including those who have adopted or may in the future adopt direct-to-consumer sales models, 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 distribution strategies and as new companies enter the market with new technologies and distribution strategies. We may not be able to compete effectively against these organizations. Our ability to compete successfully and to increase our market share is dependent upon our reputation for providing responsive, professional and high-quality products and services and achieving strong customer satisfaction. Increased competition in the future could adversely affect our revenue, revenue growth rate, margins and market share.

Government regulation

Inogen One systems, Inogen At Home systems, TAV systems, and related accessories are medical devices subject to extensive and ongoing regulation by the FDA, as well as other federal and state regulatory bodies in the United States and comparable authorities in other countries. The FDA regulations govern the following activities that we perform, or that are performed on our behalf, to ensure that medical products distributed domestically or exported internationally are safe and effective for their intended uses: product design and development, pre-clinical and clinical testing, manufacturing, labeling, storage, pre-market clearance or approval, record keeping, product marketing, advertising and promotion, sales and distribution, and post-marketing surveillance.

FDA's pre-market clearance and approval requirements

Unless an exemption applies, each medical device we seek to commercially distribute in the United States will require either a prior Section 510(k) of the Food, Drug and Cosmetic Act, or 510(k) clearance, a De Novo authorization, or a pre-market approval from the FDA. 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 control needed to ensure safety and effectiveness. Devices deemed to pose lower risks are placed in either Class I or II, which requires the manufacturer to submit to the FDA a premarket notification requesting permission to commercially distribute the device. This process is generally known as 510(k) clearance. Some low-risk devices are exempted from this requirement. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously cleared 510(k) device, are placed in Class III, requiring premarket approval unless they may be marketed under a De Novo authorization from the FDA.

510(k) clearance pathway

When a 510(k) clearance is required, we must submit a premarket notification to the FDA demonstrating that our proposed device is substantially equivalent to a "predicate device" which can be a previously cleared and legally marketed 510(k) device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of a pre-market approval application. The performance goal for FDA to make a decision is within 90 FDA Days (calculated as the number of calendar days between the date the 510(k) was "accepted" by the FDA for substantive review and date of a decision, excluding the days the submission was on hold for an Additional Information request). As a practical matter, clearance often takes significantly longer. The FDA must "accept" the submission for substantive review and may require further information, including clinical data, to make a determination regarding substantial equivalence. If the FDA determines that the device, or its intended use, is not substantially equivalent to a previously-cleared device or use, the FDA will either allow the submission of a De Novo application, or place the device, or the particular use, into Class III. We obtained 510(k) clearance for the original Inogen One system on May 13, 2004. We market the Inogen One G3, Inogen One G4, and Inogen One G5 systems pursuant to the original Inogen One 510(k) clearance. We obtained 510(k) clearance for the Inogen At Home system on June 20, 2014. New Aera obtained 510(k) clearance for the TAV on December 2, 2016.

De Novo authorization pathway

The De Novo authorization pathway is a request to the FDA to classify novel devices of low to moderate risk that had automatically been placed in Class III either by virtue of receiving a "not substantially equivalent" (NSE) determination in response to a 510(k) notification or because there is no available predicate to which to claim substantial equivalence. These types of applications are referred to as "Evaluation of Automatic Class III Designation" or "De Novo." FDA review of a De Novo application may lead the FDA to authorize marketing of the device and classify it as either a Class I or II device, the latter of which can serve as a predicate device for other 510(k) premarket notification submissions.

Pre-market approval pathway

A pre-market approval application must be submitted to the FDA if the device cannot be cleared through the 510(k) or De Novo process. The pre-market approval application process is much more demanding than the 510(k) premarket notification process. A pre-market approval application must be supported by extensive data, including but not limited to technical, preclinical, clinical trials, manufacturing and labeling to demonstrate to the FDA's satisfaction reasonable evidence of safety and effectiveness of the device.

After a pre-market approval application is submitted and the FDA determines that the application is sufficiently complete to permit a substantive review, the FDA will accept the application for review. The FDA has 180 days to review an "accepted" pre-market approval application, although the review of an application generally occurs over a significantly longer period of time and can take up to several years. During this review period, the FDA may request additional information or clarification of the information already provided. Also, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA will conduct a preapproval inspection of the manufacturing facility to ensure compliance with quality system regulations.

Clinical trials

Clinical trials are almost always required to support pre-market approval and are sometimes required for 510(k) clearance. In the United States, these trials generally require submission of an application for an Investigational Device Exemption, or IDE, to the FDA. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE must be approved in advance by the FDA for a specific number of patients unless the product is deemed a non-significant risk device eligible for more abbreviated IDE requirements. Clinical trials for significant risk devices may not begin until the IDE application is approved by the FDA and the appropriate institutional review boards, or IRBs, at the clinical trial sites. We, the FDA or the IRB at each site at which a clinical trial is being performed may suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the benefits. Even if a trial is completed, the results of clinical testing may not demonstrate the safety and efficacy of the device, may be equivocal or may otherwise not be sufficient to obtain approval or clearance of the product.

Pervasive and ongoing regulation by the FDA and foreign agencies

Even after a device receives clearance or approval and is placed on the market, numerous regulatory requirements apply. These include:

- establishment registration and device listing;
- quality system regulation, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- labeling regulations and the FDA prohibitions against the promotion of products for un-cleared, unapproved or "off-label" uses, and other requirements related to promotional activities;
- medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur;
- corrections and removals 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 Federal Food, Drug and Cosmetic Act that may present a risk to health; and
- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

After a device receives 510(k) clearance, de novo clearance or a pre-market approval, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, will require a new clearance or approval. The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with a manufacturer's determination. We have modified various aspects of our Inogen One systems since receiving regulatory clearance, but we believe that new 510(k) clearances are not required for these modifications. If the FDA disagrees with our determination not to seek a new 510(k) clearance, the FDA may retroactively require us to seek 510(k) clearance or pre-market approval. The FDA could also require us to cease marketing and distribution and/or recall the modified device until 510(k) clearance or pre-market approval is obtained. Also, in these circumstances, we may be subject to significant regulatory fines and penalties.

Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions: warning letters, fines, injunctions, civil or criminal penalties, recall or seizure of our products, operating restrictions, partial suspension or total shutdown of production, refusing our request for 510(k) clearance or pre-market approval of new products, rescinding previously granted 510(k) clearances or withdrawing previously granted pre-market approvals.

As a medical device manufacturer, our manufacturing facilities are subject to periodic inspection by the FDA and certain corresponding regulatory agencies and authorities. We have been periodically audited by the FDA and found to be in substantial compliance with Good Manufacturing Practices (GMP). We have also completed surveillance and recertification audits by our notified body and found to be in substantial compliance with GMP.

International sales of medical devices are subject to foreign government regulations and registration, which may vary substantially from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA approval/clearance, and the requirements may differ. There is a trend towards harmonization of quality system standards among the European Union, United States, Canada and various other industrialized countries.

Licensure, registrations, and accreditation

In April 2009, we became an accredited Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Medicare supplier by the Accreditation Commission for Health Care for our Goleta, California facility for Home/Durable Medical Equipment Services for oxygen equipment and supplies. Our Medicare accreditation must be renewed every three years by passing an on-site inspection. Our current accreditation with Medicare is due to expire in May 2024. Several states require that durable medical equipment providers be licensed in order to sell products to patients in that state. Certain of these states require that durable medical equipment providers maintain an in-state location. Most of our state licenses are renewed on an annual or bi-annual basis. Although we believe we are in compliance with all applicable state regulations regarding licensure requirements, if we were found to be non-compliant, we could lose our licensure in that state, which could prohibit us from selling our current or future products to patients in that state. Loss of any state licensure or operating without a required state license may also impact our Medicare enrollment, which requires us to be properly licensed in every state where we bill for Medicare reimbursement. Loss or suspension of our Medicare enrollment may also affect any Medicare competitive bidding program contracts we may apply for in the future. In addition, we are subject to certain state laws regarding professional licensure. We believe that our certified clinicians are in compliance with all applicable state laws. If our clinicians were to be found non-compliant in a given state, we would need to modify our approach to providing education, clinical support and customer service in such state until compliance is achieved.

Federal anti-kickback and self-referral laws

The Federal Anti-Kickback Statute prohibits, among other things, the knowing and willful offer, payment, solicitation or receipt of any form of remuneration overtly or covertly, in cash or in kind, in return for, or to induce the:

- referral of an individual to a person for the furnishing or arranging for the furnishing of items or services reimbursable under Medicare, Medicaid or other federal healthcare programs; or
- purchase, lease, or order of, or the arrangement or recommendation of the purchasing, leasing, or ordering of any good, facility, item or service reimbursable under Medicare, Medicaid or other federal healthcare programs.

The Federal Anti-Kickback Statute applies to our arrangements with our United States sales representatives, customers and healthcare providers. Although we believe that we have structured such arrangements to comply with the Anti-Kickback Statute and other applicable laws, regulatory authorities may determine otherwise. Non-compliance with the Federal Anti-Kickback Statute can result in cancellation of our provider numbers and exclusion from Medicare, Medicaid or other federal healthcare programs, restrictions on our ability to operate in certain jurisdictions, as well as civil and criminal penalties, any of which could have an adverse effect on our business and results of operations.

Federal law also includes the Physician Self-Referral Law, commonly known as the “Stark Law,” which prohibits a physician from referring a patient to an entity with which the physician (or an immediate family member of the physician) has a financial relationship, for the furnishing of certain designated health services for which payment may be made by Medicare or Medicaid, unless an exception applies. Violation of the Stark Law could result in denial of payment, disgorgement of reimbursements received under a non-compliant arrangement, civil penalties and fees, and exclusion from Medicare, Medicaid or other federal healthcare programs. Although we believe that we have structured our provider arrangements to comply with current Stark Law requirements, regulatory authorities may determine otherwise.

Additionally, regulations issued for the Federal Anti-Kickback Statute and the Stark Law have undergone significant revisions, and it is reasonable to assume that revisions will occur in the future. While we have attempted to operate in compliance with these laws and regulations, our arrangements may ultimately be found to be not in compliance with applicable federal law.

Federal False Claims Act

The Federal False Claims Act provides, in part, that the federal government may bring a lawsuit against any person whom it believes has knowingly presented, or caused to be presented, a false or fraudulent request for payment to the federal government, or who has made a false statement or used a false record to get a claim approved. In addition, amendments in 1986 to the Federal False Claims Act have made it easier for private parties to bring “qui tam” or whistleblower lawsuits against companies. Although we believe that we are in compliance with the federal government’s laws and regulations, if we are found in violation of these laws, penalties of up to $0.024 million for each false claim, plus three times the amount of damages that the federal government sustained because of the act, can be assessed.

Civil monetary penalties law

The Federal Civil Monetary Penalties Law grants authority to the U.S. Department of Health & Human Services Office of Inspector General (OIG) to seek civil monetary penalties (CMPs) against an individual or entity based on a wide variety of conduct including violations of the Anti-Kickback Statute, Stark Law, and False Claims Act. An entity that offers to or transfers remuneration to any individual eligible for benefits under Medicare or Medicaid that such entity knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any Medicare or Medicaid payable item or service may be liable for CMPs. We sometimes offer customers various discounts and other financial incentives in connection with the sales of our products. While it is our intent to comply with all applicable laws, the federal government may find that our marketing activities violate the law. If we are found to be in non-compliance, we could be subject to CMPs of up to $0.022 million for each wrongful act, assessment of three times the amount claimed for each item or service and exclusion from Medicare, Medicaid and other federal healthcare programs. In addition, to the extent we are found to not be in compliance, we may be required to curtail or restructure our operations. Any penalties, damages, fines, exclusions, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results.

State fraud and abuse provisions

Many states have also adopted some form of anti-kickback and self-referral laws and false claims act that may apply to DMEPOS suppliers regardless of the payor source. We believe that we are in compliance with such laws. Nevertheless, a determination of liability under such laws could result in fines and penalties and restrictions on our ability to operate in these jurisdictions.

HIPAA

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, established uniform standards governing the conduct of certain electronic healthcare transactions and protecting the security and privacy of individually identifiable health information maintained or transmitted by healthcare providers, health plans and healthcare clearinghouses, which are referred to as "covered entities." Three standards have been promulgated under HIPAA's regulations: the Standards for Privacy of Individually Identifiable Health Information, which restrict the use and disclosure of certain individually identifiable health information, the Standards for Electronic Transactions, which establish standards for common healthcare transactions, such as claims information, plan eligibility, payment information and the use of electronic signatures, and the Security Standards, which require covered entities to implement and maintain certain security measures to safeguard certain electronic health information, including the adoption of administrative, physical and technical safeguards to protect such information.

In 2009, Congress passed the American Recovery and Reinvestment Act of 2009, or ARRA, which included sweeping changes to HIPAA, including an expansion of HIPAA's privacy and security standards. ARRA includes the Health Information Technology for Economic and Clinical Health, or HITECH, which, among other things, made HIPAA's privacy and security standards directly applicable to business associates of covered entities effective February 17, 2010. A business associate is a person or entity that performs certain functions or activities on behalf of a covered entity that involve the use or disclosure of protected health information in connection with recognized healthcare operations activities. As a result, business associates are now subject to significant civil and criminal penalties for failure to comply with applicable standards. Moreover, HITECH created a requirement to report certain breaches of unsecured, individually identifiable health information and imposes penalties on entities that fail to do so. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney fees and costs associated with pursuing federal civil actions. The 2013 final HITECH omnibus rule modifies the breach reporting standard in a manner that will likely make more data security incidents qualify as reportable breaches.

In addition to federal regulations issued under HIPAA, some states have enacted privacy and security statutes or regulations that, in some cases, are more stringent than those issued under HIPAA. In those cases, it may be necessary to modify our planned operations and procedures to comply with the more stringent state laws. If we fail to comply with applicable state laws and regulations, we could be subject to additional sanctions. Any liability from failure to comply with the requirements of HIPAA, HITECH or state privacy and security statutes or regulations could adversely affect our financial condition. The costs of complying with privacy and security related legal and regulatory requirements are burdensome and could have a material adverse effect on our results or operations.

Patient Protection and Affordable Care Act

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, among other things, imposed public reporting requirements on medical device manufacturers for payments or other transfers of value made by them to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. The Substance Use-Disorder Prevention that Promoted Opioid Recovery and Treatment for Patients and Communities Act enacted in 2018, extends the reporting and transparency requirements under the Physician Payments Sunshine Act to physician assistants, nurse practitioners and other mid-level practitioners, with reporting requirements going into effect in 2022 for payments made in 2021. Failure to submit required ownership and investment interest information may result in civil monetary penalties of up to an aggregate of $0.18 million per year (or up to an aggregate of $1.191 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission. Certain states also mandate implementation of compliance programs, impose restrictions on device manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to physicians and other healthcare professionals.

The Patient Protection and Affordable Care Act also requires healthcare providers to voluntarily report and return an identified Medicare or Medicaid overpayment within 60 days after identifying the overpayment. Failure to repay the overpayment within 60 days will result in the claim being considered a "false claim" and the healthcare provider will be subject to False Claims Act liability, and additional CMPs of $0.021 million for each item or service that is not reported and returned.

International regulation

International sales of medical devices are subject to foreign governmental regulations, which vary substantially from country to country. The time required to obtain clearance or approval by a foreign country may be longer or shorter than that required for FDA clearance or approval, and the requirements may be different.

The primary regulatory body in Europe is the European Commission, which has adopted numerous directives and has promulgated standards regulating the design, manufacture, clinical trials, labeling and adverse event reporting for medical devices. Devices that comply with the requirements of a relevant directive will be entitled to bear the European Conformity Marking, or CE Mark, indicating that the device conforms to the essential requirements of the applicable directives and, accordingly, can be commercially distributed throughout the member states of the European Union, and other countries that comply with or mirror these directives. The method of assessing conformity varies depending on the type and class of the product, but normally involves a combination of self-assessment by the manufacturer and a third-party assessment by a notified body, an independent and neutral institution appointed by a country to conduct the conformity assessment. This third-party assessment may consist of an audit of the manufacturer's quality system, review of technical documentation, and specific testing of the manufacturer's device. Such an assessment may be required in order for a manufacturer to commercially distribute the product throughout these countries. ISO 13485 certification is a voluntary standard. Quality systems that implement relevant harmonized standards establish the presumption of conformity with the essential requirements for a CE Mark. We have the authorization to affix the CE Mark to our oxygen therapy products and to commercialize our devices in the European Union. Our ISO 13485 certification was issued on April 21, 2005 and our EC-Certificate was issued on March 16, 2007. The final form of the European Medical Device Regulation, which will replace Europe's Medical Device Directive, entered into force on May 25, 2017 and its full application is expected to be on May 26, 2021. The Medical Device Regulation will apply in parallel with the Medical Device Directive for a transition period of three years.

Inogen has sold products in Canada since 2006 when we obtained our Medical Device License after obtaining appropriate licensure, accreditation, and meeting ISO Standard 13485. As of January 1, 2019, Health Canada implemented the Medical Device Single Audit Program (MDSAP) as the sole mechanism for manufacturers to demonstrate compliance with the quality management system requirements of the Medical Device Regulations, replacing the Canadian Medical Devices Conformity Assessment System (CMDCAS) program. Inogen has been in compliance with the MDSAP since its implementation on January 1, 2019 and believes it is still in compliance with these regulations.

In Australia, we must appoint an agent sponsor who will interact on our behalf with the Therapeutics Goods Administration (TGA). We must also prepare a technical file and declaration of conformity to essential requirements under Australian law, provide evidence of CE Marking of the device and submit this information via our agent sponsor to the TGA in a Medical Device Application. On June 4, 2007, we received our Certificate for Inclusion of a Medical Device in Australia.

U.S. Foreign Corrupt Practices Act

Also, the U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws generally prohibit companies and their intermediaries from making improper payments to foreign officials. We cannot assure you that our internal control policies and procedures will protect us from reckless or negligent acts committed by our employees, manufacturers, distributors, partners, collaborators or agents. Violations of these laws, or allegations of such violations, could result in legal fees, fines, penalties or prosecution and have a negative impact on our business, results of operations and reputation.

Intellectual property

We believe that to maintain a competitive advantage, we must develop and preserve the proprietary aspect of our technologies. We rely on a combination of patent, trademark, trade secret and other intellectual property laws, non-disclosure agreements and other measures to protect our proprietary rights. Currently, we require our employees, public accountants, consultants and advisors to execute non-disclosure agreements in connection with their employment, consulting or advisory relationships with us, where appropriate. We also require our employees, consultants and advisors with whom we expect to work on our current or future products to agree to disclose and assign to us all inventions conceived during the workday, developed using our property or related to our business. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to copy aspects of our Inogen One, Inogen At Home, or non-invasive ventilation systems, sell counterfeit versions of our products, or obtain and use information that we regard as proprietary.

Patents

As of December 31, 2021, we had twenty-seven pending patent applications and sixty-six issued patents relating to the design and construction of our respiratory devices. We anticipate it could take several years for the most recent of these patent applications to result in issued patents, if successful.

The 2019 acquisition of New Aera added a significant number of issued and pending patent applications to Inogen's portfolio. The additional patents and patent filings include U.S. and international pending and issued patents. The combined portfolio of Inogen and New Aera include several categories.

Our patent portfolio contains four principal categories of patents and patent applications. One such category includes patents and patent applications directed to system and component designs that may be incorporated into Inogen's oxygen therapy product line which includes the Inogen One G3, Inogen One G4, Inogen One G5, and the Inogen At Home oxygen concentrators. For example, U.S. patents 9,592,360 and 10,786,644 are directed to the Inogen One G3 design, U.S. patent 10,695,520 is directed to the design of the Inogen One G4, and U.S. patents 9,283,346, 10,004,869 and 10,869,986 are directed towards the Inogen at Home stationary oxygen concentrator. This category of patents expires in 2031 or later and may serve to deter competitors from reverse engineering or copying our design elements.

The second category of patents and patent applications within our portfolio pertains to operating features and design techniques. For example, U.S. patents 8,702,841; 9,220,864; and 9,283,346 are directed towards design features of the Inogen One G3, Inogen One G4, and Inogen at Home products. This category of patents expires in 2031 or later (without taking into account any patent term adjustments). These features and designs are developed to facilitate the design, manufacturing, and usefulness of our products. These patents may prevent competitors from achieving the same levels of optimization as found in our products.

A third category of patents and patent applications relates to system designs that may be directed to products in both oxygen and ventilation product categories. One example of a patent in this category is U.S. patent 9,907,926, which is directed to an oxygen concentrator for mechanical ventilation. This category of patents expires in 2023 or later (without taking into account any patent term adjustments). Patents and patent applications in this category and others may facilitate the design and development of future respiratory products that can serve patients in need of supplemental oxygen and or mechanical ventilation therapies.

The fourth category of patents and patent applications is directed to the TAV and related products. For example, U.S. patent 10,384,028 is directed to the nasal interface of the TAV. Another example of a patent in this category is U.S. patent D851,767 which is directed to the design of the TAV. This category of patents expires in 2034 or later.

Trademarks

"Inogen," "Inogen One," "Inogen One G2," "Inogen One G3," "G4," "G5," "Live Life in Moments, not Minutes," "Never Run Out of Oxygen," "Oxygen Therapy on Your Terms," "Oxygen.Anytime.Anywhere," "Reclaim Your Independence," "Intelligent Delivery Technology," "Inogen At Home," the Inogen design, "TIDAL ASSIST," "TAV," and "SIDEKICK" are registered trademarks with the United States Patent and Trademark Office of Inogen, Inc. We own a pending application for "Inogen" with the United States Patent and Trademark Office. We own trademark registrations for the mark "Inogen" in Argentina, Australia, Canada, Chile, China, Columbia, Ecuador, South Korea, Mexico, Europe (European Union registration), the United Kingdom, Iceland, India, Israel, Japan, Kuwait, New Zealand, Norway, Paraguay, Peru, Turkey, Singapore, Switzerland, and Uruguay. We own pending applications for the mark "Inogen" in Brazil, India, Malaysia, and South Africa. We own a trademark registration for the mark "イノジェン" in Japan. We own trademark registrations for the marks "印诺真" and "艾诺根" in China. We own trademark registrations for the mark "Inogen One" in Australia, Canada, China, South Korea, Mexico, Europe (European Union registration), and the United Kingdom. We own a trademark registration for the mark "Satellite Conserver" in Canada. We own a trademark registration for the mark "Inogen At Home" in Europe (European Union Registration) and the United Kingdom. We own trademark registrations for the mark "G4" in Europe (European Union registration) and the United Kingdom. We own trademark registrations for the mark "G5" in Europe (European Union Registration) and the United Kingdom. We own a trademark application for the Inogen design in Bolivia. We own a trademark registration for the Inogen design in China. We own a trademark registration for the mark "إنوجن" in Saudi Arabia. Other service marks, trademarks, and trade names referred to in this Annual Report on Form 10-K are the property of their respective owners.

Human capital

At Inogen, we believe our employees are critical to our success and our ability to focus on product quality, continuous improvement, and outstanding customer satisfaction. The unique demands of our industry, together with the challenges of running an enterprise focused on the development, manufacture and commercialization of innovative products, require talent that is highly educated and/or has significant industry experience. Additionally, for certain key functions, we require specific expertise to oversee and conduct research and development activities and complex manufacturing requirements for our products. We seek the best people we can find and support them to be productive and engaged. We strive to ensure our measures of safety, remuneration and employee engagement are competitive with those of leading companies in our industry.

Employees

As of December 31, 2021, we had 1,021 full and part-time employees worldwide, consisting of 517 employees in sales, marketing, clinical and client services, 280 employees in operations, manufacturing, quality assurance, manufacturing engineering, and repair, 196 employees in general administration and 28 employees in research and development. In addition, we had 97 temporary workers as of December 31, 2021, primarily in operations, to support spikes in demand. None of our employees are represented by a collective bargaining agreement and we believe that our employee relations are good.

Employee culture

Inogen strives to instill a culture that values honesty and ethics, which is why integrity is one of Inogen's five core values. We expect our employees to honor commitments and take ownership of mistakes and we expect our employees to always do the right thing not the easy thing. In addition, Inogen values self-responsibility, open communication, continuous improvement and service, which are all important components of our culture. All of our directors, officers, and employees are guided by our Code of Ethics and Conduct, which is published on the Investor Relations section of Inogen's website at: *http://investor.inogen.com/*. The Code of Ethics and Conduct summarizes the compliance and ethical standards we expect of our employees and directors, the procedures for a suspected breach, and the consequences of any substantiated breach. The Code of Ethics and Conduct also constitutes Inogen's Code of Ethics and Conduct under US law and the NASDAQ exchange's listing standards. It deals with conflicts of interest, confidential information, fair dealing with customers, suppliers, competitors, and healthcare professionals, and compliance with financial reporting, insider trading, and other financial market regulation. In addition, we believe our commitment to environmental, social, and governance (ESG) initiatives is important to our customers, patients, employees, suppliers, and investors, and shows our commitment towards improved global health. Our ESG strategy is grounded in business sustainability, our Code of Ethics and Conduct, and our core values.

Talent acquisition and development

Inogen employees have specific career and development pathways, which are designed in consultation with the employee's operational management and human resources. We encourage employees to take advantage of learning opportunities and we provide financial support through a tuition reimbursement program to help employees complete their college education and be prepared for higher level positions. As part of our commitment to career development and learning, we perform an annual affirmative action review by job role, and we have a policy to address identified pay or promotion discrepancies that are not based on experience or skill.

Diversity, equity and inclusion

Diversity, equity and inclusion are essential elements of Inogen's business practices. We are committed to creating and maintaining a workplace in which all employees have an opportunity to participate and contribute to the success of the business and are valued for their skills, experience, and unique perspectives. The collective sum of the individual differences, life experiences, knowledge, inventiveness, innovation, self-expression, unique capabilities and talent that employees invest in their work represents a significant part of our culture as well as our reputation and achievements. We embrace employees' diversity of background, experience, culture, and other characteristics that make employees unique. All employees are expected to exhibit conduct that reflects inclusion during work, at work functions on or off the work site, and at all other company-sponsored and participative events.

Inogen is committed to compliance with all applicable federal and state laws prohibiting discrimination in employment and, therefore, does not discriminate against its employees or applicants based on any legally-recognized "protected class". Consistent with the Americans with Disabilities Act and similar state and local laws, we work with qualified employees and applicants with disabilities in order to identify and provide reasonable accommodations that can enable them to perform their jobs. Inogen's equal employment opportunity philosophy applies to all aspects of employment with Inogen including recruiting, hiring, job assignment, training, promotion, job benefits, compensation, discipline, and dismissal. Inogen has implemented policies, procedures, and trainings to ensure that any reports of potential discrimination or harassment are appropriately investigated and corrected.

Health and safety

Our approach to health and safety uses both our management systems and our quality culture to minimize workplace incidents and maximize the care taken for employees who suffer from a workplace incident, per our health and safety policy. Inogen also has a corporate wellness program to promote improved physical and emotional wellbeing. In response to the COVID-19 pandemic and related PHE and as part of our commitment to work to ensure the safety and well-being of our employees, our employees who are able and choose to work from home have done so since mid-March 2020. For employees returning to the workplace and the field, we have also taken additional safety measures, including implementing occupancy limits, restricting business travel, providing and requiring the use of personal protective equipment, temperature screening and COVID-19 testing or vaccination records to access our workplaces.

Environmental matters

Our research and development and manufacturing processes involve the controlled use of hazardous materials, including flammables, toxics, and corrosives. Our research and manufacturing operations produce hazardous chemical waste products. We seek to comply with applicable laws regarding the handling and disposal of such materials. Given the small volume of such materials used or generated at our facilities, we do not expect our compliance efforts to have a material effect on our capital expenditures, earnings, and competitive position. However, we cannot eliminate the risk of accidental contamination or discharge and any resultant injury from these materials. We do not currently maintain separate environmental liability coverage and any such contamination or discharge could result in significant cost to us in penalties, damages, and suspension of our operations.

Climate change

As a global respiratory therapy and medical device company, Inogen recognizes that greenhouse gas (GHG) emissions affect our climate and pose a serious challenge to the environment—and ultimately to the global economy. We believe that everyone shares responsibility to improve energy efficiency and to reduce GHG emissions in the atmosphere. Inogen supports global and national efforts to mitigate the impact of climate change. Inogen is committed to complying with all applicable laws and regulations that help reduce GHG and encouraging market adoption of low GHG emission technologies. Our position on climate change policy is guided by five principles:

1. We believe that any global or national strategy to address climate change must be environmentally sustainable and economically viable.
2. We believe that any climate change policy should be technology-neutral and designed to encourage private sector innovation and investment so that emissions reductions can be achieved in the most efficient manner possible.
3. We believe that any global or national strategy to address climate change must be developed with input from stakeholder communication, including the public and private sectors, non-governmental organizations, academia, and investors.
4. We believe that any policy to regulate GHG emissions should provide a clear, stable framework that enables the private sector to invest accordingly, and that minimizes the market imbalances that can result from policies applied unequally within or among nations.
5. We believe that any policy to regulate GHG emissions should fairly account for companies that have already taken voluntary steps to reduce their GHG emissions.

Inogen is a responsible corporate citizen that has done business in 59 countries and territories around the world. Our business success and our environmental stewardship both depend on the efficiency of our global distribution network. Our long-term GHG reduction strategy is to optimize the processes that consume non-renewable resources within this network. We also recognize that, as a critical component of our customers' supply chains, Inogen plays an important role in helping them operate in a more environmentally sustainable way.

Backlog

We run our operations on a just-in-time basis; however, the volatility of order intake may result in periods when incoming orders exceed our capacity. We do not currently have a backlog of orders that could not be fulfilled in our ordinary course of business. Further, our customers can change or cancel orders with limited or no penalty and limited advance notice prior to shipment.

Geographic information

During the years ended December 31, 2021, 2020, and 2019, substantially all of our long-lived assets were located within the United States. See Note 2 to our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional information related to our U.S. and non-U.S. revenue.

Seasonality

We believe our sales may be impacted by seasonal factors. For example, we typically experience higher total sales in the second and third quarters, as a result of consumers traveling and vacationing during warmer weather in the spring and summer months, but this may vary year-over-year. In particular, due to the COVID-19 pandemic and related PHE, we have seen and expect to continue to see a disruption in our normal seasonal trends due to the mandates and behaviors emanating from the COVID-19 pandemic and related PHE, including shelter-in-place orders, reduced travel, and lower consumer confidence, and we did not see the typical seasonal increases in direct-to-consumer sales in 2020 that we have seen in prior years, although a partial return to normal seasonal trends was seen in 2021. Additionally, as more home medical equipment (HME) providers adopt portable oxygen concentrators in their businesses, we expect our historical seasonality in the domestic business-to-business channel could change as well, which was previously influenced mainly by consumer buying patterns. Direct-to-consumer sales seasonality may also be impacted by the number of sales representatives and the amount of marketing spend in each quarter. For the years ended December 31, 2021, 2020, and 2019, the sales revenue in the second quarter accounted for 29.0%, 23.4% and 28.1%, respectively, and the sales revenue in the third quarter accounted for 26.0%, 23.8% and 25.4%, respectively, of our total sales revenue.

Corporate and available information

We were incorporated in Delaware in November 2001. Our principal executive offices are located at 301 Coromar Drive, Goleta, California 93117. Our telephone number is (805) 562-0500. Our website address is *www.inogen.com.* We make available on our website, free of charge, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and any amendments to those reports, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission, or SEC. Our SEC reports can be accessed through the investor relations page of our website located at *http://investor.inogen.com*. The SEC also maintains a website that contains our SEC filings. The address of the site is *www.sec.gov*.

We webcast our earnings calls and certain events we participate in or host with members of the investment community on our investor relations page of our website. In addition, we use our website *http://investor.inogen.com* as a means of disclosing information about our company, our products, our planned financial and other announcements, our attendance at upcoming investor conferences, and other matters. It is possible that the information we post on our website could be deemed material information. We may use our website to comply with our disclosure obligations under Regulation FD. Therefore, investors should monitor our website in addition to following our press releases, SEC filings, public conference calls, and webcasts. Corporate governance information, including our board committee charters, code of ethics, and corporate governance principles, is also available on our investor relations page of our website located at *http://investor.inogen.com*. The contents of our website are not incorporated by reference into this Annual Report on Form 10-K or in any other report or document we file with the SEC, and any references to our website are intended to be inactive textual references only.

Information about our executive officers

The following table identifies certain information about our executive officers as of February 18, 2022.

Name	Age	Position
Nabil Shabshab	56	Chief Executive Officer, President, and Director
Michael Sergesketter	62	Executive Vice President, Finance, Chief Financial Officer, and Corporate Treasurer
Bart Sanford	56	Executive Vice President, Operations
Stanislav Glezer	49	Executive Vice President, Chief Technology Officer
George Parr	51	Executive Vice President, Chief Commercial Officer
Jason Somer	54	Executive Vice President, General Counsel and Corporate Secretary

Nabil Shabshab has served as our President, Chief Executive Officer, and as a director since February 2021. Previously, Mr. Shabshab served as Worldwide President of Diabetes Care and Digital Health at Becton Dickinson and Company from August 2017 until January 2021 and served as its Chief Marketing Officer and Executive Vice President of Strategic Planning from August 2011 until May 2017. Previously, from 2006 to 2010, Mr. Shabshab served as EVP, Global Portfolio, Chief Marketing Officer and Head of RD&E of Diversey, Inc., a cleaning and sanitation solutions company. Prior to that, from 2004 to 2006, Mr. Shabshab served as Principal of The Zyman Group, a marketing consulting firm. From 2002 to 2004, Mr. Shabshab served as Vice President, Client Solutions and Consulting, of Symphony IRI, a consumer marketing firm. Prior to that, Mr. Shabshab served in various sales and marketing roles in consumer goods companies. Mr. Shabshab holds an MBA from Northwestern University Kellogg School of Management and a B.S. in Computer Sciences from American Lebanese University. The board of directors believes that Mr. Shabshab's extensive industry experience qualifies him to serve on our board of directors.

Michael Sergesketter has served as our Executive Vice President, Chief Financial Officer since December 2021. Mr. Sergesketter most recently served as CFO of Kimball Electronics, Inc. Mr. Sergesketter brings over forty years of finance experience in the manufacturing services industry. He brings expertise working across business functions, including with the CEO and Board of Directors, Audit Committee and Compensation and Governance Committee. As part of his role as the CFO of Kimball Electronics, Inc. following its spin-off in 2014 and through June 2021, Mr. Sergesketter led the transformation of the finance and reporting functions to support the newly formed public company, helping to formulate and execute on the strategy that led to global expansion. During his tenure at Kimball Electronics and its predecessors, Mr. Sergesketter had the responsibility for a number of critical finance functions, including SEC reporting, Treasury, Investor Relations, Tax, Financial Planning & Analysis, Internal Audit while playing a leading role in various M&A transactions in the U.S. and abroad.

Bart Sanford has served as our Executive Vice President, Operations since September 2018. From April 2017 to September 2018, Mr. Sanford was Senior Vice President, Operations, at Cepheid Inc., a molecular diagnostics company. From October 2010 to March 2017, Mr. Sanford was Vice President, Global Operations, at Molecular Devices, LLC, a life sciences company. From January 2009 to September 2010, Mr. Sanford was a Corporate Director at Danaher Corporation, a medical device company. From March 2000 to December 2008, Mr. Sanford held various positions at Fluke Corporation, an industrial test product company, including plant manager, manufacturing manager and materials manager. Mr. Sanford received an MBA from Central Michigan University and a Bachelor of Arts degree in Logistics, Materials and Supply Chain Management from Michigan State University.

Dr. Stanislav Glezer has served as our Executive Vice President, Chief Technology Officer since October 2021, responsible for R&D and Engineering, Medical Affairs, and Regulatory Affairs. Dr. Glezer has also served as our Executive Vice President and Chief Medical Officer from June 2021 to October 2021. Previously, Dr. Glezer was with Becton, Dickinson and Company, a global medical technology company where he served as the Worldwide Vice President of Medical Affairs for Diabetes Care since September 2018 with Business Development responsibilities added under him since January 2021. Prior to joining Becton Dickinson, Dr. Glezer served as the Chief Medical Officer at Adocia S.A. a biotechnology company, from 2017 to 2018. From 2016 to 2017, Dr. Glezer served as Vice President of Global Medical Affairs at Novo Nordisk, Inc., a healthcare company. Earlier, Dr. Glezer served in a number of roles of progressively increasing seniority, including, Global Project Head for the largest late-stage pipeline asset, Vice President of Evidence and Value & Access, Vice President of Medical Affairs, and Senior Director of Medical Strategy & Operations, for Sanofi S.A., a multinational pharmaceutical company, from 2001 to 2015. Dr Glezer holds a doctor of medicine from Moscow State University of Medicine and Dentistry and a MBA from California Coast University.

George Parr has served as our Executive Vice President and Chief Commercial Officer since April 2021. Most recently, Mr. Parr served as Executive Vice President & Chief Marketing Officer at Becton Dickinson and Company, a leading medical technology company, from November 2017 through January 2020. Previously, from 2014 to 2017, Mr. Parr served as Senior Vice President & Chief Marketing Officer at SIRVA Worldwide Relocation & Moving, a moving industry company. Prior to that, from 2006 to 2013, Mr. Parr served at Diversey, Inc., a cleaning and hygiene solutions company, as Senior Vice President & Chief Marketing Officer from 2010 to 2013 and Worldwide General Manager, Kitchen Hygiene & Fabric Care from 2006 to 2010. Prior to that, Mr. Parr served in various managing roles in consumer goods companies. Mr. Parr holds a MBA from DePaul University and a B.S. in Accounting from LaSalle University.

Jason Somer has served as our Executive Vice President and General Counsel and Secretary since July 2021. Most recently, Mr. Somer served as head Legal Counsel at Invoca, Inc., a SaaS analytics company. Prior to his time at Invoca, Mr. Somer served as Associate General Counsel at Sunniva, Inc., and as General Counsel and Corporate Secretary for Innova Gaming Group, a gaming company. Prior to joining Innova, Mr. Somer served as the Senior Vice President of Business Development and General Counsel at Sunora Energy Solutions, a solar energy development company. Mr. Somer also previously served as the Vice President of Special Projects and the Senior Global Counsel at Suntech Power, a Shanghai-based solar energy technology company. Prior to joining Suntech Power, Mr. Somer served as Director of Legal Affairs & Business Development at Ironport Systems, Inc. and as Associate General Counsel and a Business Development Director of Neoforma, Inc. Mr. Somer joined Neoforma from Morrison & Foerster where he was a corporate/securities associate based in New York. Mr. Somer holds a L.L.M. from Boston University, a L.L.B from the University of British Columbia School of Law, and a B.Sc. from the University of Western Ontario in Biology/Pharmacology.

ITEM 1A. RISK FACTORS

We operate in a rapidly changing environment that involves numerous uncertainties and risks. In addition to the other information included in this Annual Report on Form 10-K, the following risks and uncertainties may have a material and adverse effect on our business, financial condition, results of operations, or stock price. You should consider these risks and uncertainties carefully, together with all of the other information included or incorporated by reference in this Annual Report on Form 10-K. The risks and uncertainties described below may not be the only ones we face. If any of the risks or uncertainties we face were to occur, the trading price of our securities could decline, and you may lose all or part of your investment. This Annual Report on Form 10-K also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this report.

Risk factors include, but are not limited to, statements concerning the following:

Risks related to our business and strategy:

- the intense international, national, regional and local competition we face in our industry;
- our dependence on a limited number of customers for a significant portion of our sales revenue;
- our reliance on a single source or a limited group of manufacturers or suppliers;
- the lack of long-term supply contracts with many of our third-party suppliers;
- the possibility our manufacturing facilities could become unavailable or inoperable and other potential manufacturing problems or delays;
- our reliance upon a third-party contract manufacturer for certain manufacturing and repair operations;
- the need to continue to enhance our existing products and develop and market new products;
- risks associated with public health threats and epidemics, including the COVID-19 pandemic and related public health emergency (PHE);
- the competitive bidding process or other reimbursement policy changes under Medicare or other third-party payors, including recently enacted and potential future changes in the reimbursement rates or payment methodologies under Medicare, Medicaid and other government programs;
- healthcare reform measures;
- the complex and lengthy reimbursement process we depend upon for a significant portion of our revenue;
- potential failure to maintain or obtain new private payor contracts and future reductions in reimbursement rates from private payors;
- our ability to hire and retain highly qualified individuals;
- our ability to manage our anticipated growth effectively;
- potential acquisitions of, or investments in, other companies;
- our international sales and manufacturing activities;
- warranty or product liability claims or other litigation;
- increases in our operating costs;
- our dependence on the services of our senior executives and other key technical personnel;
- variance in our financial condition and results of operations; and
- the market opportunities for our products.

Risks related to the regulatory environment:

- extensive federal, state, and international regulations related to our business by numerous government agencies, including the U.S. Food and Drug Administration, or FDA and the European Medical Devices regulation;
- the potential need to seek additional clearances or approvals for our products; and
- potential FDA, state, or international regulatory enforcement action.

Risks related to our intellectual property:

- our ability to secure and maintain patent or other intellectual property protection for the intellectual property used in our products;
- the possibility that any of our patents may be challenged, invalidated, circumvented or rendered unenforceable; and
- patent and other intellectual property litigation if our products infringe or appear to infringe the intellectual property rights of others.

Risks related to being a public company:

- increased costs as a result of operating as a public company and the substantial time our management will be required to devote to compliance initiatives and corporate governance practices; and
- our ability to maintain effective internal controls.

Risks related to our common stock:

- the volatility of the trading price of our common stock;
- the publication of research reports by securities or industry analysts;
- potential sales of a large number of shares of our common stock;
- anti-takeover provisions in our charter documents and under Delaware law; and
- our intention not to pay dividends for the foreseeable future.

Risks related to our business and strategy

We face intense international, national, regional and local competition and if we are unable to compete successfully, it could have an adverse effect on our revenue, revenue growth rate, if any, and market share.

The long-term oxygen therapy market is a highly competitive industry. We compete with a number of manufacturers and distributors of portable oxygen concentrators (POCs), as well as providers of other long-term oxygen therapy solutions such as home delivery of oxygen tanks or cylinders, stationary concentrators, transfilling concentrators, and liquid oxygen.

Our significant manufacturing competitors are Respironics (a subsidiary of Koninklijke Philips N.V.), Invacare Corporation, Caire Medical (subsidiary of NGK Spark Plug), DeVilbiss Healthcare (a subsidiary of Drive Medical), O2 Concepts, Precision Medical, Resmed, Gas Control Equipment (subsidiary of Colfax), Nidek Medical, 3B Medical, SysMed, and Belluscura. Given the relatively straightforward regulatory path in the oxygen therapy device manufacturing market, we expect that the industry will become increasingly competitive in the future. For example, some major competitors have implemented direct-to-consumer sales models, which may increase their competitiveness and sales to patients, and we have recently seen the cost per generated lead trend higher than historical averages that may in part be due to increased competition. However, the strategies of these major competitors are currently limited to direct-to-consumer sales and do not include direct-to-consumer rentals where they would be responsible to meet national accreditation and state-by-state licensing requirements and secure Medicare billing privileges. Manufacturing companies compete for sales to providers primarily on the basis of price, quality/reliability, financing, bundling, product features, and service.

For many years, Lincare, Inc. (a subsidiary of the Linde Group), Apria Healthcare, Inc., AdaptHealth Corp., Rotech Healthcare, Inc., and Viemed Healthcare, Inc. have been among the market leaders in providing respiratory therapy products, while the remaining market is serviced by local providers. Because of reimbursement reductions, we expect more industry consolidation and volatility in ordering patterns based on how providers are restructuring their businesses and their access to capital. In addition, providers may reduce or eliminate purchases from us due to our increased focus on building out a prescriber sales team and pursuing rentals directly, which could be in competition with our providers in the United States. Respiratory therapy providers compete primarily on the basis of product features and service, rather than price, since reimbursement levels are established by Medicare and Medicaid, or by the individual determinations of private payors.

Some of our competitors are large, well-capitalized companies with greater resources than we have. Consequently, they 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, customers and third-party payors;
- established distribution networks;
- additional lines of products, and the ability to offer rebates or bundle products to offer higher discounts, lower pricing, longer warranties, financing or extended terms, other incentives to gain a competitive advantage;
- greater history in conducting research and development, manufacturing, marketing and obtaining regulatory approval for respiratory device products; and
- greater financial and human resources for product development, sales and marketing, and patent litigation.

As a result, our competitors may be able to respond more quickly and effectively than we can to new or changing opportunities, technologies, standard regulatory and reimbursement development and customer requirements or changing or uncertain business conditions or macroeconomic trends, including supply chain challenges. In light of these advantages that our competitors maintain, even if our technology and direct-to-consumer distribution strategy is more effective than the technology and distribution strategy of our competitors, including those who have adopted or may in the future adopt direct-to-consumer sales models, 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 distribution strategies and as new companies enter the market with new technologies and distribution strategies. We may not be able to compete effectively against these organizations. Our ability to compete successfully and to increase our market share is dependent upon our reputation for providing responsive, professional and high-quality products and services and achieving strong customer satisfaction. Increased competition in the future could adversely affect our revenue, revenue growth rate, margins and market share.

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

We receive a significant amount of our sales revenue from a limited number of customers, including distributors, HME providers, our private label partner, resellers, and charitable organizations. For the years ended December 31, 2021, 2020, and 2019, sales revenue to our top 10 customers accounted for approximately 27.4%, 29.0% and 33.5%, respectively, of our total revenue. The Medicare service reimbursement programs represented more than 10% of our total revenue for the year ended December 31, 2021. One single customer represented more than 10% of our total revenue for the year ended December 31, 2020 and no single customer represented more than 10% of our total revenue for year ended December 31, 2019. We expect that sales to relatively few customers will continue to account for a significant percentage of our total revenue in future periods. Our future success will significantly depend upon the timing and volume of business from our largest customers and the financial and operational success of these customers. However, we can provide no assurance that any of these customers or any of our other customers will continue to purchase our products at current levels, pricing, or at all, and our revenue could fluctuate significantly due to changes in customer order levels, economic conditions, the adoption of competitive products, or the loss of, reduction of business with, or less favorable terms with any of our largest customers. For example, we have previously experienced a decline in sales to one large national homecare provider who purchased through our private label partner. We have also experienced a decline in sales from other home medical equipment providers and these providers have communicated to us that they continue to be subject to capital constraints. Moreover, in the second quarter of 2020 and continuing through the first quarter of 2021, we experienced a decline in total sales to business-to-business customers worldwide, which we believe was primarily due to the COVID-19 pandemic and related PHE. If we were to lose one of our key customers or have a key customer significantly reduce its volume of business with us, such as we previously experienced with the large national homecare provider, our revenue may be materially reduced and there would be an adverse effect on our business, financial condition and results of operations.

We obtain some of the components, subassemblies and completed products included in our products from a single source or a limited group of manufacturers or suppliers, and in some cases those components are available in only limited supplies from limited manufacturers or suppliers, and the partial or complete loss of one or more of these manufacturers or suppliers could cause significant production delays or stoppages, an inability to meet customer demand, substantial loss in revenue, and an adverse effect on our financial condition and results of operations.

We utilize single-source suppliers for some of the components and subassemblies we use in our Inogen One systems, our Inogen At Home systems, and our Tidal Assist® Ventilator (TAV®). For example, we have elected to source certain key components from single sources of supply, including our batteries, motors, valves, TAV-compatible stationary concentrators, columns, and some molded plastic components. Many of our products also utilize components that are available from a limited number of suppliers. Our dependence on single-source or limited-source suppliers of components may expose us to several risks, including, among other things:

- our suppliers or their component sub-suppliers may be unable to meet demands due to global supply chain disruptions;
- we may experience delays in delivery by our suppliers due to customs clearing delays, shipping delays, scarcity of raw materials and components or changes in demand from us or their other customers;
- our suppliers may be unable to meet demands due to the effect of exposure to infectious diseases, epidemics or other public health emergencies, including the COVID-19 pandemic and related PHE;
- we may not be able to find new or alternative components, even at elevated prices, or reconfigure our system and manufacturing processes in a timely manner if the necessary components become unavailable, which could lead to a production slowdown or temporary stoppage;
- 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;
- 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 performance or safety of our products, cause delays in supplying of our products to our customers, or result in regulatory enforcement against us or our suppliers;
- newly identified suppliers may not qualify under the stringent quality regulatory standards to which our business is subject, which could inhibit their ability to fulfill our orders and meet our requirements;
- 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 be subject to price fluctuations due to a lack of long-term supply arrangements for key components or changes in import tariffs, trade restrictions or barriers or other government actions that impact our ability to obtain such components;
- we or our suppliers may lose access to critical services, tools, moldings, and components, resulting in an interruption in the manufacture, assembly and shipment of our systems;
- 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; and
- our suppliers may wish to discontinue supplying components or services to us.

We have experienced supply problems with one or more of our suppliers and may again experience problems in the future. For example, we have seen supply chain disruptions in 2021 and the first quarter of 2022 and expect to continue to see these disruptions through 2022, primarily associated with semiconductor chips used in our batteries and printed circuit boards, which are components of our portable oxygen concentrators. This semiconductor chip shortage is being experienced across many industries, placing additional pressure on existing supplies. While we have taken steps to attempt to mitigate the impact of this supply shortage, it has had and will likely continue to have an increased negative impact on our ability to manufacture products (including with respect to the production halt discussed below) as these chips are used across all of our portable oxygen concentrators in our batteries and printed circuit boards. We are continuing to focus our mitigation efforts on product redesign, seeking increased commitments on shipment dates from our regular suppliers, canvassing the open market for supplies, and using the price increase we implemented on September 1, 2021 to help offset some of the increased costs, but in spite of these efforts we have been supply constrained and with these components facing extremely high demand, we expect continued challenges in terms of supply constraint and pricing inflation moving forward.

The inflated costs related to the supply shortage negatively impacted our cost of goods sold in the third and fourth quarter of 2021, and we expect this to have an increased impact on our material costs in 2022. Even though we paid significant costs in the third and fourth quarters of 2021 associated with these chips, most of these costs increased our prepaid expense and inventory given that these components were either not yet delivered or not yet sold in finished products during the period. We believe based on our assessment and industry feedback that these supply shortages may continue through 2022. In addition to the semiconductor chip limitations, we are continuing to see supply chain constraints for other components used in our products. As a result of the semiconductor chip shortages, we temporarily suspended manufacturing operations at our Texas and California locations from January 3, 2022 to February 7, 2022 and Foxconn, our Czech Republic-based OEM, suspended manufacturing due to the same supply constraints from January 3, 2022 to February 9, 2022. While we were able to resume manufacturing operations, we are still seeing challenges in terms of availability of supply and we believe the supply shortage continues to represent an increased risk to the business in 2022, and we may suspend manufacturing again in the future due to these shortages.

In addition, we have seen supply chain challenges tied to the COVID-19 pandemic and related PHE in printed circuit boards, corrugated boxes, aluminum machined parts, plastic molded parts, and batteries. While we have been able to coordinate with our suppliers to minimize disruption to our business related to these components, we may not be able to do so in the future and may be required to further slowdown or temporarily halt production. We may also face similar situations in the future and we may not be able to quickly establish additional or replacement suppliers, particularly for our single source components or subassemblies, and may experience similar delays in manufacturing. Any interruption or delay in the supply of components or subassemblies, or our inability to obtain components or subassemblies from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and cause them to cancel orders or switch to competitive products.

Recently, the FDA released guidance that requires manufacturers of certain medical devices, including ventilation-related products under product code CAW, among others, to notify FDA of a permanent discontinuance or interruption in manufacturing of an applicable device under Section 506J of the Federal Food, Drug, and Cosmetic Act during the COVID-19 PHE. To the extent we experience an interruption in our manufacturing during the COVID-19 PHE that falls within the scope of this guidance, we would be required to notify FDA. This and other regulatory requirements could increase the cost of our operations and compliance.

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, we may be required to perform due diligence to determine 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 requirements could adversely affect the sourcing, availability, and pricing of minerals used in the manufacture of our products. In addition, we have incurred 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 fail to comply with the applicable regulations, we could be required to pay civil penalties, face criminal prosecution and, in some cases, be prohibited from distributing our products in commerce until the products or component substances are brought into compliance. If we are unable to satisfy commercial demand for our products 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 and disruption. In some cases, we would need to change the components or subassemblies if we sourced them from an alternative supplier. This, in turn, could constitute a material modification or require a redesign of our products and, potentially, require additional FDA clearance or approval before we could use any materially modified or redesigned product with new components or subassemblies, thereby causing further costs and delays that could adversely affect our business, financial condition and results of operations.

If we are unable to continue to enhance our existing products, develop or acquire and market our products that respond to customer needs and preferences and achieve market acceptance, we may experience a decrease in demand for our products and our business could suffer.

We may not be able to compete as effectively with our competitors and ultimately satisfy the needs and preferences of our customers unless we can continue to enhance existing products, acquire companies with new or different products, sell our existing products, and develop new innovative products ourselves. Product development requires significant financial, technological and other resources. While we expended $16.6 million, $14.1 million and $9.4 million for the years ended December 31, 2021, 2020, and 2019, respectively, in research and development efforts, we cannot assure that this level of investment will be sufficient to maintain a competitive advantage in product innovation, which could cause our business to suffer. We also plan to incorporate the TAV technology acquired from the New Aera acquisition directly into our oxygen concentrators, with minimal expected sales of the TAV product in its current configuration.

Product improvements and new product introductions also require significant planning, design, development, patent protection, and testing at the technological, product, and manufacturing process levels and we may not be able to timely develop product improvements or new products or obtain necessary patent protection and regulatory clearances or approvals for such product improvements or new products in a timely manner, or at all. Our competitors' new products may enter the market before our new products reach the market, be more effective with more features, obtain better market acceptance, or render our products obsolete. Any new products that we develop or acquire may not receive market acceptance or otherwise generate any meaningful sales or profits for us relative to our expectations based on, among other things, existing and anticipated investments in manufacturing capacity and commitments to fund advertising, marketing, promotional programs and research and development. In addition, if we are unable to seek and obtain regulatory approval or adequate coverage and reimbursement for any new products that we develop or introduce, in a timely manner or at all, we may realize lower revenue than expected or even no revenue at all from these products. As a result, our business, financial condition and results of operations could be materially harmed.

We are subject to risks associated with public health threats and epidemics, including the COVID-19 pandemic and related PHE.

Public health outbreaks, epidemics, pandemics of contagious or infectious diseases, such as COVID-19, may significantly disrupt our business. Such outbreaks pose the risk that we or our employees, contractors, suppliers, or other partners may be prevented from conducting business activities for an indefinite period of time due to spread of the disease, or due to shutdowns that may be requested or mandated by federal, state and local governmental authorities. Business disruptions could include disruptions or restrictions on our ability to travel, as well as temporary closures of our facilities or the facilities of our contractors, suppliers, and other partners. For example, total business-to-business demand declined in the second quarter of 2020 continuing through the first quarter of 2021 due to physician offices limiting patient interactions for COPD patient referrals, HME providers minimizing patient interactions in response to the COVID-19 pandemic and related PHE which includes replacing existing oxygen patient setups with POCs and temporary reduced operating capacity of certain respiratory assessment centers and continued delays in certain European markets due to the COVID-19 pandemic and related PHE. While it is not possible at this time to estimate the overall impact that the COVID-19 pandemic and related PHE could have on our business, the continued spread of COVID-19, both across the United States and through much of the world, and the measures taken by the governments and local authorities of affected regions has adversely affected our operating results and could cause or contribute to, among other things: significant volatility or reductions in demand for our products; delays in our product development pipeline; delays in obtaining regulatory clearances or approvals to market our products in certain jurisdictions; failure of third parties on which we rely to meet their obligations to us, or significant disruptions in their ability to do so; and our inability to meet our customers' needs due to disruptions to our operations or the operations of our contractors, suppliers, other partners or customers including disruptions to production, development, manufacturing, administrative and supply operations and arrangements. In addition, new variants of COVID-19 could prove to be deadlier or more transmittable, or the developed vaccines may be ineffective versus these new variants, which could negatively impact our business and financial results.

In addition, we have strived to follow recommended actions of government and health authorities to protect the health and safety of our employees and community, while working to ensure the sustainability of our business operations as this unprecedented situation continues to evolve. Employees whose tasks can be done offsite have been allowed to work from home and most of our total personnel continue to work from home. While we have worked closely with local and national officials and have thus far been able to keep our manufacturing facilities open due to the essential nature of our products, there can be no assurance that we will be able to keep such facilities open indefinitely during the COVID-19 pandemic and related PHE. We have thus far been able to keep our contract manufacturer capability and capacity available but there can be no assurance that we will be able to keep such facilities open indefinitely during COVID-19 pandemic and related PHE. We continue to evaluate the impact COVID-19 may have on our ability to effectively conduct our business operations as planned to mitigate risk to our employees and customers while taking into account regulatory, institutional, and government guidance and policies, but there can be no assurance that we will be able to avoid part or all of any impact from the spread of COVID-19 or its consequences.

The COVID-19 pandemic and related PHE continues to rapidly evolve. The COVID-19 pandemic and related PHE has already adversely affected our financial results and the extent to which COVID-19 ultimately impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions, the effectiveness of actions taken in the United States and other countries to contain and treat the disease and to address its impact, including on financial markets or otherwise, and how quickly and to what extent normal economic and operating conditions can resume if and when the COVID-19 pandemic and related PHE subsides. While the extent of the impact of the COVID-19 pandemic and related PHE on our business and financial results is uncertain, we have already been negatively impacted and a continued and prolonged public health crisis could have a further material negative impact on our business, financial condition and results of operations. Even after the COVID-19 pandemic and related PHE has subsided, we may continue to experience materially adverse impacts on our financial condition and our results of operations and many of our known risks described in this Annual Report on Form 10-K may be heightened.

While we have received funding from programs enacted under the CARES Act, due to the enactment of the CARES Act and related legislation, there is still a high degree of uncertainty surrounding their implementation, and the COVID-19 pandemic and related PHE continues to evolve. HHS is still issuing additional guidance to providers and suppliers regarding the terms and conditions associated with the implementation of the CARES Act Provider Relief Fund. The federal government may consider additional stimulus and relief efforts, but we are unable to predict whether additional stimulus measures will be enacted or their impact. There can be no assurance as to the total amount of financial and other types of assistance we will receive under the CARES Act or future legislation, if any, and it is difficult to predict the impact of such legislation on our operations. Further, there can be no assurance that the terms of provider relief funding or other programs will not change in ways that affect our funding or eligibility to participate. We will continue to assess the potential impact of the COVID-19 pandemic and related PHE and government responses to the pandemic on our business, results of operations, financial condition and cash flows.

We do not have long-term supply contracts with many of 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 many of these third-party suppliers. Many of our 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. We do not maintain large volumes of inventory from most of these suppliers. For example, our batteries are sourced from a single source supplier, and sub-components of the battery are also sourced from single source suppliers. While our printed circuit boards are sourced from dual sources, the sub-components of these boards are sourced from single source suppliers. We are experiencing limited availability of certain semiconductor chip components for our Inogen One portable oxygen concentrators in both its batteries and printed circuit boards, and we do not have long-term supply contracts that would guarantee our supply during these periods of higher demand and lower availability of these sub-components. This has led to orders not being filled in a timely manner and a temporary production halt in the first quarter of 2022 and is expected to lead to increased costs for components and limited supply availability through 2022. Therefore, we expect to be unable to fully meet customer demand for our products during the first quarter of 2022 and we expect these supply constraints to continue through 2022. For additional discussion of potential risks related to our inability to source components of our products, please see the risk factor entitled "*We obtain some of the components, subassemblies and completed products included in our products from a single source or a limited group of manufacturers or suppliers, and in some cases those components are available in only limited supplies from limited manufacturers or suppliers, and the partial or complete loss of one or more of these manufacturers or suppliers could cause significant production delays or stoppages, an inability to meet customer demand, substantial loss in revenue, and an adverse effect on our financial condition and results of operations.*"

We may also be affected by other supply limitations during the COVID-19 pandemic and related PHE that could affect our ability to fulfill orders. If we inaccurately forecast demand or fail to place orders timely enough relative to fluctuating lead time requirements for components or subassemblies, our ability to manufacture and commercialize our products could be delayed and our competitive position and reputation could be harmed. In addition, if we fail to effectively manage our relationships with these suppliers or if our suppliers, in the near term or the long term, are not able to supply sufficient quantities of components or subassemblies needed for our products due to the COVID-19 pandemic and related PHE, we may be required to change suppliers or, if we are unable to find alternative suppliers in a timely manner, we may be required to further slowdown or temporarily halt production which would adversely impact our business, financial condition and results of operations.

A significant majority of our rental patients who use our product have health coverage under the Medicare program, and recently enacted and future changes in the reimbursement rates or payment methodologies under Medicare, Medicaid and other government programs have affected and could continue to materially and adversely affect our business and operating results.

As a provider of oxygen equipment rentals, we depend heavily on Medicare reimbursement as a result of the higher proportion of elderly persons suffering from chronic long-term respiratory conditions. Medicare Part B, or Supplementary Medical Insurance Benefits, provides coverage to eligible beneficiaries that include items of durable medical equipment for use in the home, such as oxygen equipment and other respiratory devices. There are increasing pressures on Medicare to control healthcare costs and to reduce or limit reimbursement rates for home medical products.

Legislation, including the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the Deficit Reduction Act of 2005, the Medicare Improvements for Patients and Providers Act of 2008, and the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, contain provisions that directly impact reimbursement for the durable medical equipment products provided by us:

- The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 significantly reduced reimbursement for inhalation drug therapies beginning in 2005, reduced payment amounts for certain durable medical equipment, including oxygen, beginning in 2005, froze payment amounts for other covered HME items through 2008, established a competitive bidding program for home medical equipment and implemented quality standards and accreditation requirements for durable medical equipment suppliers.

- The Deficit Reduction Act of 2005 limited the total number of continuous rental months for which Medicare will pay for oxygen equipment to 36 months, after which time there is generally no additional reimbursement to the supplier (other than for periodic, in-home maintenance and servicing). The Deficit Reduction Act of 2005 also provided that title of the equipment would transfer to the beneficiary, which was later repealed by the Medicare Improvements for Patients and Providers Act of 2008. For purposes of the rental cap, the Deficit Reduction Act of 2005 provided for a new 36-month rental period that began January 1, 2006 for all oxygen equipment. After the 36th continuous month during which payment is made for the oxygen equipment, the supplier is generally required to continue to furnish the equipment during the period of medical need for the remainder of the useful lifetime of the equipment, provided there are no breaks in service due to medical necessity that exceed 60 days. The reasonable useful lifetime for our portable oxygen equipment is 60 months. After 60 months, if the patient requests, and the patient meets Medicare coverage criteria, the rental cycle starts over and a new 36-month rental period begins. There are no limits on the number of 60-month cycles over which a Medicare patient may receive benefits and an oxygen therapy provider may receive reimbursement, so long as such equipment continues to be medically necessary for the patient. We anticipate that the Deficit Reduction Act of 2005 oxygen payment rules will continue to negatively affect our net revenue on an ongoing basis, as each month additional customers reach the capped rental period in month thirty-seven, resulting in potentially two or more years without rental income from these customers while we continue to incur customer service and maintenance costs. Our capped patients as a percentage of total patients on service was approximately 8.0% as of December 31, 2021 and 11.7% as of December 31, 2020. The percentage of capped patients may fluctuate over time as new patients come on service, patients come off of service before and during the capped rental period, and existing patients enter the capped rental period. We cannot predict the potential impact to rental revenues in future periods associated with patients in the capped rental period.
- The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, includes, among other things, face-to-face physician encounter requirements for certain durable medical equipment and home health services, and a requirement that by 2016, the competitive bidding process must be nationalized or prices in non-competitive bidding areas must be adjusted to match competitive bidding prices.
- There have been significant U.S. reimbursement and policy changes associated with the COVID-19 PHE that impact oxygen therapy and other durable medical equipment. The CARES Act allows HHS to waive certain Medicare telehealth payment requirements during the COVID-19 PHE declared by HHS on January 31, 2020 to allow beneficiaries in all areas to receive telehealth services, including at their home, starting March 6, 2020. The Coronavirus Preparedness and Response Supplemental Appropriations Act (H.R. 6074) also granted HHS the authority to waive certain requirements with respect to telehealth services. Under this authority, CMS clarified that HHS would not conduct audits to determine whether there was a prior physician-patient relationship for telehealth claims submitted during the COVID-19 PHE. The CARES Act, passed on March 27, 2020 included the extension of the 50/50 blended rate for HME in rural and non-contiguous, non-competitively bid areas and established a new 75/25 blended rate for all other non-competitively bid areas through the duration of the COVID-19 PHE. The 75/25 blended rate was retroactive to March 6, 2020. While the duration of the current emergency is impossible to predict, the Zika virus PHE lasted approximately 360 days, and the H1N1 flu PHE lasted approximately 450 days.
- In May 2020, Congress eliminated the 2% Medicare sequestration payment reduction that applies to all Medicare providers and suppliers, due to the COVID-19 PHE, and Congress has extended it until March 31, 2022. The sequestration payment reduction resumes with a 1% reduction to rates from April 1, 2022 until June 30, 2022, with the full 2% Medicare sequestration resuming on July 1, 2022.
- In addition, the CARES Act established a provider relief fund of $100 billion for Medicare providers and suppliers to prevent, prepare for, and respond to the COVID-19 PHE, and as a Medicare supplier we also received funds of $6.2 million in the second quarter of 2020. The Paycheck Protection Program and Heath Care Enhancement Act was also signed into law on April 24, 2020 and provides additional funding of $484 billion to programs enacted under the CARES Act. Of the $484 billion, $75 billion is additional funding for healthcare providers to reimburse healthcare related expenses and lost revenues attributable to COVID-19 PHE, which is in addition to the $100 billion approved in the CARES Act.
- On April 6, 2020, CMS issued an Interim Final Rule (IFR) in the Federal Register for policy and regulatory revisions in response to the COVID-19 PHE. This IFR included that for the duration of the COVID-19 PHE, the face-to-face requirements and clinical indications of coverage for home oxygen, among other respiratory products, will be waived.

- The Trump administration also issued a number of regulatory waivers to increase the flexibility in durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) suppliers' ability to service patients quickly and without the normal requirements. For example, the patient signature for proof of delivery for DMEPOS is waived when signatures cannot be collected during the COVID-19 PHE for dates of services within the PHE. In addition, CMS increased Medicare contractors' ability to waive replacement product requirements, paused the national prior authorization program for certain DMEPOS, automatically extended expiring accreditations, granted contractors the flexibility to grant appeals extensions, and suspended medical review of claims. Both the IFR and temporary regulatory changes show significant flexibility from CMS to improve access for oxygen and other DMEPOS items during this COVID-19 PHE. These changes were retroactive to early March 2020. In August 2020, CMS resumed medical review of claims and the prior authorization program for certain DMEPOS.
- CMS also issued a final rule in December 2021 (CMS-1738-P) to establish payment amounts that will be effective after the COVID-19 PHE for DMEPOS products and services covered under Medicare. We believe that Medicare rates will not change for the length of the COVID-19 PHE, except for any net change for inflation and sequestration, as outlined above.

  CMS established three different fee schedule adjustment methodologies for non-CBAs after the termination of the COVID-19 PHE: (1) for non-contiguous non-CBAs; (2) for contiguous non-CBAs defined as rural areas; and (3) for non-rural non-CBAs within the contiguous United States. Payment methodologies (1) and (2) contemplate utilizing the 50/50 blended rates as a permanent construct, but payment methodology (3) contemplates setting the fee schedule amounts to 100% of the Medicare rates that are based upon (former) competitive bid rates. This will reduce Medicare rates after the PHE is over in the current areas that are considered non-rural but not covered by a former CBA, as those areas are currently receiving a 75/25 blended reimbursement rate.
- In January 2021, CMS announced, for informational purposes only, the payment amounts that would have been effective for the competitive bidding round 2021 as part of its effort to increase transparency into the DMEPOS Competitive Bidding Program. As a reminder, the bids for oxygen were based on the HCPCS code E1390, which is for stationary oxygen, and there were 130 regions bid. The simple average of the 2018 payment amounts for these regions for this code was $73.98. The simple average of the payment amounts for these regions for this code was $122.61, or an average increase of 65.7%. If CMS were to have implemented these rate changes, the simple average payment amounts in these regions for POCs (codes E1390 and E1392) would have been $157.60, which is significantly higher than the simple average payment amounts of $110.07 and $121.07 per month being paid as of January 1, 2021 and April 1, 2021 for these regions.
- In September 2021, CMS published a Decision Memo which revised the Home Use of Oxygen national coverage determination and removed the national coverage determination for Home Oxygen Use to Treat Cluster Headaches. This will allow the Medicare Administrative Contractors to make coverage determinations regarding the use of home oxygen and oxygen equipment for cluster headaches. CMS also expanded patient access to oxygen and oxygen equipment in the home by allowing oxygen use for acute or short-term needs instead of limiting coverage to chronic hypoxemia, removed the requirements for alternative treatment measures before dispensing of oxygen therapy, and removed the limited list of conditions for which oxygen may be covered to respiratory-related diseases, to allow the physician flexibility to make that determination. In addition, CMS defined exercise more broadly to include functional performance of the patient and allow more flexibility on pulse oximetry readings to account for differences in skin pigmentation. Lastly, CMS reduced provider burden by removing the oxygen certificate of medical necessity requirement. We believe these changes will expand coverage for patients who would benefit from oxygen therapy, reduce administrative burdens, and give more decision-making authority on proper patient care to the physicians. CMS has announced that the implementation date for the revised national coverage determination will be June 14, 2022. However, we do not yet have visibility on the details of how the Medicare Administrative Contractors will change their coverage determinations.

These legislative provisions have had and may continue to have a material and/or adverse effect on our business, financial condition and results of operations.

The HHS Office of Inspector General (OIG) has recommended that states review Medicaid reimbursement for durable medical equipment (DME) and supplies. The OIG cites an earlier report estimating that four states (California, Minnesota, New York, and Ohio) could have saved more than $18.1 million on selected DME items if their Medicaid prices were comparable to those under round one of the Medicare competitive bidding program. Since issuing those reports, the OIG identified $12 million in additional savings that the four states could have obtained on the selected items by using pricing similar to the Medicare round two competitive bidding and national mail-order programs. In light of varying Medicaid provider rates for DME and the potential for lower spending, the OIG recommends that CMS (1) seek legislative authority to limit state Medicaid DME reimbursement rates to Medicare program rates, and (2) encourage further reduction of Medicaid reimbursement rates through competitive bidding or manufacturer rebates (the OIG did not determine the cost of implementing a rebate or competitive bidding program in each state). This was effective beginning January 1, 2018.

Due to budgetary shortfalls, many states are considering, or have enacted, cuts to their Medicaid programs. In addition, many private payors reimburse at a percentage of the Medicare rates. Medicare, Medicaid and private payor reimbursement rate cuts have included, or may include elimination or reduction of coverage for our products, amounts eligible for payment under co-insurance arrangements, or payment rates for covered items. Continued state budgetary pressures could lead to further reductions in funding for the reimbursement for our products which, in turn, would adversely affect our business, financial condition and results of operations.

The competitive bidding process or other reimbursement policy changes under Medicare or other third-party payors could negatively affect our business and financial condition.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 requires the Secretary of HHS to establish and implement programs under which competitive acquisition areas are established throughout the United States for purposes of awarding contracts for the furnishing of competitively priced items of durable medical equipment, including oxygen equipment.

We rely significantly on reimbursement from Medicare and private payors, including Medicare Advantage plans, Medicaid and patients for our rental revenue. For the year ended December 31, 2021, approximately 81.9% of our rental revenue was derived from Medicare's traditional fee-for-service reimbursement programs.

The U.S. list price for our stationary oxygen rentals Healthcare Common Procedure Coding System (HCPCS E1390) is $260 per month and the U.S. list price for our oxygen generating portable equipment (OGPE) rentals (HCPCS E1392) is $70 per month. The average Medicare reimbursement rates in former competitive bidding areas (CBAs) in the prior five years are outlined in the table below for E1390 and E1392, which are the two primary codes that we bill to Medicare and other payors for our oxygen product rentals. These rates are typically updated annually each January as they are subject to Consumer Price Index (CPI) and sequestration adjustments, but can also be subject to adjustments during the year due to legislative rulings. Competitive bidding contracts were scheduled to go into effect on January 1, 2021; however, on October 27, 2020, CMS announced that competitive bidding contracts would not be awarded for most product categories, including oxygen, due to the payment amounts not achieving the expected savings and the current COVID-19 pandemic and related PHE. Effective April 1, 2021, rates were adjusted to remove a percentage reduction that was put in place to meet the budget neutrality requirement previously mandated by section 1834(a)(9)(D)(ii) of the Social Security Act. See the table below for average Medicare rates in former CBAs, using a simple average of rates in each CBA.

Average Medicare reimbursement rates in former CBAs	**E1390**	**E1392**
As of January 1, 2022	$ 85.31	$ 41.81
As of April 1, 2021	$ 81.25	$ 39.82
As of January 1, 2021	$ 73.88	$ 36.20
As of January 1, 2020	$ 73.98	$ 36.25
As of January 1, 2019	$ 72.92	$ 35.72
As of January 1, 2018	$ 77.03	$ 36.06

CMS also issued a final rule in December 2021 (CMS-1738-P) to establish payment methodologies that will be effective after the COVID-19 PHE for DMEPOS products and services covered under Medicare. We believe that Medicare rates will not change for the length of the PHE, except for inflation and sequestration adjustments that typically occur annually each January but have not yet been announced.

CMS established three different fee schedule adjustment methodologies for non-CBAs after the termination of the COVID-19 PHE: (1) for non-contiguous non-CBAs; (2) for contiguous non-CBAs defined as rural areas; and (3) for non-rural non-CBAs within the contiguous United States. The final payment methodology sets the fee schedule amounts to 100% of the Medicare rates in all non-rural areas. This will reduce Medicare rates after the PHE is over in the current areas that are considered non-rural but not covered by a former CBA, as those areas are currently receiving a 75/25 blended reimbursement rate.

In January 2021, CMS announced what would have been the payment amounts for the competitive bidding round 2021. As a reminder, the bids for oxygen were based on the HCPCS code E1390, which is for stationary oxygen, and there were 130 regions bid. The simple average of the 2018 single payment amounts for these regions for this code was $73.98. The simple average of the payment amounts for these regions for this code was $122.61, or an average increase of 65.7%. If CMS were to have implemented these rate changes, the average payment amounts in these regions for POCS (codes E1390 and E1392) would have been $157.60, which is significantly higher than the $110.07 per month being paid as of January 1, 2021.

Medicare payment rates are based upon whether the beneficiary resides in a (former) CBA, or in a rural or non-rural non-CBA, or in non-contiguous states. Non-CBA payment rates are based on regional pricing, that are derived from former competitive bidding payment rates. In rural areas and non-contiguous states, payment rates are based on a higher 50-50 blended rate, to account for higher servicing costs in those areas. We estimate that approximately 18% of our patients are eligible to receive the higher reimbursement rates based on the geographic locations of our current patient population. Effective March 1, 2021, CMS announced that the rates as of January 1, 2021 were incorrectly calculated, and retroactively adjusted the rates, which are reflected in the table below. The Medicare rates announced previously were a simple average of $136.24 for HCPCS code E1390 and $44.69 for HCPCS code E1392, which were increased to $136.84 and $44.99, respectively. Effective April 1, 2021, rates were adjusted to remove a percentage reduction that was put in place to meet the budget neutrality requirement previously mandated by section 1834(a)(9)(D)(ii) of the Social Security Act. See the table below for average Medicare rates in rural areas, using a simple average of rates in each state.

Average Medicare reimbursement rates in rural areas	E1390	E1392
As of January 1, 2022	$ 151.15	$ 48.39
As of April 1, 2021	$ 143.48	$ 47.13
As of January 1, 2021	$ 136.84	$ 44.99
As of January 1, 2020	$ 136.71	$ 44.93
As of January 1, 2019	$ 134.71	$ 44.32
As of January 1, 2018	$ 76.31	$ 41.91

Rates in non-former CBAs that are not defined as rural are set based on the rates in former CBAs. See the table below for average Medicare rates in these non-former CBAs, non-rural areas, using a simple average of rates in each state. These rates are typically updated annually each January as they are subject to the Consumer Price Index (CPI) and sequestration adjustments, but are also subject to adjustments during the year due to legislative rulings. Effective April 1, 2021, rates were adjusted to remove a percentage reduction that was put in place to meet the budget neutrality requirement previously mandated by section 1834(a)(9)(D)(ii) of the Social Security Act. Note that the 2021 rates listed below include CARES Act increased rates due to the COVID-19 PHE, which may not be in place for all of 2022. Once the Administration ends the COVID-19 PHE, the rates in these non-former CBAs, non-rural areas are expected to adjust down to the former CBA rates listed in the table above.

Average Medicare reimbursement rates in non-former CBAs, non-rural areas	E1390	E1392
As of January 1, 2022	$ 115.14	$ 43.69
As of April 1, 2021	$ 109.39	$ 42.12
As of January 1, 2021 (retroactively revised March 1, 2021)	$ 104.07	$ 40.06
As of January 1, 2020	$ 74.84	$ 36.87
As of January 1, 2019	$ 72.32	$ 35.64
As of January 1, 2018	$ 69.31	$ 38.10

CMS is required to conduct future rounds of competitive bidding, which could reduce reimbursement rates, negatively impact the premium for POCs over other oxygen modalities, or limit beneficiary access to our technologies. Cumulatively in previous rounds of competitive bidding, we were offered contracts for a substantial majority of the CBAs and product categories for which we submitted bids. Effective January 1, 2017, we believe we had access to over 90% of the Medicare oxygen therapy market based on our analysis of the 103 CBAs that we won out of the 130 total CBAs. These 130 CBAs represented approximately 36% of the Medicare market with the remaining approximately 64% of the market not subject to competitive bidding. As of January 1, 2019, we can choose to accept Medicare oxygen patients throughout the United States. As of July 2018, we currently operate in all 50 states in the U.S. We did not sell or rent to patients in Hawaii due to the licensure requirements from inception to June 2018.

We cannot guarantee that we will be offered contracts in subsequent rounds of competitive bidding. In all five rounds of competitive bidding in which we have participated, we have gained access to certain CBAs and been excluded from other CBAs.

Medicare revenue, including patient co-insurance and deductible obligations, represented 10.6% of our total revenue in the year ended December 31, 2021 and 7.5% in the year ended December 31, 2020.

Medicare reimbursement for oxygen rental equipment is limited to a maximum of 36 months within a 60-month service period, and the equipment remains the property of the home oxygen supplier. The supplier that billed Medicare for the 36th month of service continues to be responsible for the patient's oxygen therapy needs for months 37 through 60, and there is generally no additional reimbursement for oxygen generating portable equipment for these later months. CMS does not separately reimburse suppliers for oxygen tubing, cannulas and supplies that may be required for the patient. The supplier is required to keep the equipment provided in working order and in some cases, CMS will reimburse for repair costs. At the end of the five-year useful life of the equipment, the patient may request replacement equipment and, if he or she can be re-qualified for the Medicare benefit, a new maximum 36-month payment cycle out of the next 60 months of service would begin. The supplier may not arbitrarily issue new equipment. We have analyzed the potential impact to revenue associated with patients in the capped rental period and have deferred $0 associated with the capped rental period as of December 31, 2021 and December 31, 2020. Our capped patients as a percentage of total patients on service was approximately8.0% as of December 31, 2021 and 11.7% as of December 31, 2020. The percentage of capped patients may fluctuate over time as new patients come on service, patients come off of service before and during the capped rental period, and existing patients enter the capped rental period.

Our obligations to service Medicare patients over the rental period include supplying working equipment that meets each patient's oxygen needs pursuant to his/her doctor's prescription and supplying all disposables required for the patient to operate the equipment, including cannulas, filters, replacement batteries, carts and carry bags, as needed. If the equipment malfunctions, we must repair or replace the equipment. We determine what equipment the patient receives, and we can deploy used assets in working order as long as the prescription requirements are met. We must also procure a renewal from the patient's doctor to confirm the patient's need for oxygen therapy one year after the patient first receives oxygen therapy and one year after each new 36-month reimbursement period begins. The patient can choose to receive oxygen supplies and services from another supplier at any time, but the supplier may only transition the patient to another supplier in certain circumstances.

Although we continue to monitor developments regarding the implementation of the competitive bidding program, we cannot predict the outcome of the competitive bidding program on our business when fully implemented, nor the Medicare reimbursement rates that will be in effect in future years for the items subject to competitive bidding, including our products. We expect that the stationary oxygen and non-delivery ambulatory oxygen reimbursement rates will continue to fluctuate, and a large negative payment adjustment would adversely affect our business, financial condition and results of operations.

Healthcare reform measures may have a material adverse effect on our business and results of operations.

In the United States, the legislative landscape, particularly as it relates to healthcare regulation and reimbursement coverage, continues to evolve. In March 2010, the Patient Protection and Affordable Care Act was passed, which has substantially changed healthcare financing by both governmental and private insurers, and significantly impacts the U.S. medical device industry.

In addition, other legislative changes have been proposed and adopted in the United States since the Patient Protection and Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011 created, among other things, measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic sequestration reduction to several government programs. This includes aggregate reductions of Medicare reimbursements to providers up to 2% per fiscal year, which went into effect on April 1, 2013, and will remain in effect through 2030 unless additional Congressional action is taken. For example, a provision in the CARES Act and subsequent federal laws have paused the 2% Medicare sequestration reduction for claims dated from May 1, 2020 through March 31, 2022. Starting April 1, 2022, and through June 30, 2022, there will be a 1% sequestration reduction, and the full 2% sequestration reduction will resume on July 1, 2022. We expect that additional state and federal healthcare policy measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressures.

In addition to the legislative changes discussed above, the Patient Protection and Affordable Care Act requires healthcare providers to voluntarily report and return an identified overpayment within 60 days after identifying the overpayment. Failure to repay the overpayment within 60 days will result in the claim being considered a "false claim" and the healthcare provider will be subject to False Claims Act liability.

State legislative bodies also have the right to enact legislation that would impact requirements of home medical equipment providers, including oxygen therapy providers. Some states have already enacted legislation that require in-state facilities. We are monitoring all state requirements to maintain compliance with state-specific legislation and access to service patients in these states. To the extent such legislation is enacted, it could result in increased administrative costs or otherwise exclude us from doing business in a particular state, which would adversely impact our business, financial condition and results of operations.

We face uncertainties that might result from modification or repeal of any of the provisions of the Patient Protection and Affordable Care Act, including as a result of current and future executive orders, legislative actions and judicial decisions. The impact of those changes on us and potential effect on the durable medical equipment industry as a whole is currently unknown. But any changes to the Patient Protection and Affordable Care Act are likely to have an impact on our results of operations and may have a material adverse effect on our results of operations. We cannot predict what other healthcare programs and regulations will ultimately be implemented at the federal or state level or the effect of any future legislation or regulation in the United States may have on our business.

We depend upon reimbursement from Medicare, private payors, Medicaid and payments from patients for a significant portion of our revenue, and if we fail to manage the complex and lengthy reimbursement process, our business and operating results could be adversely affected.

A significant portion of our rental revenue is derived from reimbursement by third-party payors. We accept assignment of insurance benefits from customers and, in a majority of cases, invoice and collect payments directly from Medicare, private payors and Medicaid, as well as direct from patients under co-insurance provisions. For the years ended December 31, 2021, 2020 and 2019, approximately 12.9%, 9.2% and 5.9%, respectively, of our total revenue was derived from Medicare, private payors, Medicaid, and individual patients who directly receive reimbursement from third-party payors and this percentage could increase as a percent of total revenue if we increase net patient additions faster than our sales revenue growth.

Our financial condition and results of operations may be affected by the healthcare industry's reimbursement process, which is complex and can involve lengthy delays between the time that a product is delivered to the consumer and the time that the reimbursement amounts are settled. Depending on the payor, we may be required to obtain certain payor-specific documentation from physicians and other healthcare providers before submitting claims for reimbursement. Certain payors have filing deadlines and they will not pay claims submitted after such time. We are also subject to extensive pre-payment and post-payment audits by governmental and private payors that could result in material delays, refunds of monies received or denials of claims submitted for payment under such third-party payor programs and contracts. We cannot ensure that we will be able to continue to effectively manage the process which would adversely affect our business, financial condition and results of operations.

If our manufacturing facilities become unavailable or inoperable, we could be unable to continue manufacturing our products and, as a result, our business, financial condition and results of operations could be adversely affected until we are able to secure a new facility.

We assemble our products at our facilities in Plano, Texas and Goleta, California and through our contract manufacturer in the Czech Republic. No other manufacturing facilities are currently available to us, particularly facilities of the size and scope of our Texas facility. Our facilities and the equipment we use to manufacture our products would be costly to replace and could require substantial lead time to procure, repair or replace. Our facilities may be harmed or rendered inoperable by natural or man-made disasters, including, but not limited to, the COVID-19 pandemic and related PHE related facility shutdowns, fire, flood, earthquakes and power outages, which may render it difficult or impossible for us to manufacture our products for some period of time. Although we and our contract manufacturer have been able to keep our manufacturing facilities open thus far during the COVID-19 pandemic and related PHE, we cannot assure that we will be able to continue to do so indefinitely.

If any of our facilities become unavailable to us, we cannot provide assurances that we will be able to secure and equip a new manufacturing facility on acceptable terms in a timely manner. The inability to manufacture our products, combined with delays in replacing parts inventory and manufacturing supplies and equipment, may result in the loss of customers and/or harm our reputation, and we may be unable to reestablish relationships with those customers in the future. Although we have insurance coverage for certain types of disasters and business interruptions which may help us recover some of the costs of damage to our property, costs of recovery and lost income from the disruption of our business, insurance coverage of certain perils may be limited or unavailable at cost effective rates and may therefore not be sufficient to cover any or all of our potential losses and may not continue to be available to us on acceptable terms, or at all. If our manufacturing capabilities are impaired, we could not be able to manufacture, store, and ship our products in sufficient quantity or a cost effective or timely manner, which would adversely affect our business, financial condition and results of operations.

We rely upon a third-party contract manufacturer for certain manufacturing operations and our business and results of operations may be adversely affected by risks associated with their business, financial condition and the geography in which they operate.

We utilize a third-party contract manufacturer located in the Czech Republic for production of a portion of our Inogen One G3 and Inogen One G5 concentrators and for repair services for these products. Since 2018, our contract manufacturer has produced the vast majority of the concentrators required to support our European demand and we expect this to continue in 2022 and 2023. There are a number of risks associated with our dependence on a contract manufacturer, including:

- reduced control over delivery schedules and planning;
- reliance on the quality assurance procedures of a third party;
- risks associated with our contract manufacturer failing to manufacture our products according to our specifications, quality regulations, including the FDA's Quality System regulations, or otherwise manufacturing products that we or regulatory authorities deem to be unsuitable for commercial use;
- risks associated with our contract manufacturer's ability to successfully undergo FDA and other regulatory authority quality inspections;
- potential uncertainty regarding manufacturing yields and costs;
- availability of manufacturing capability and capacity, particularly during periods of high demand and the COVID-19 pandemic and related PHE;
- risks and uncertainties associated with the location or country where our products are manufactured, including potential manufacturing disruptions caused by social, geopolitical or environmental factors;
- changes in U.S. law or policy governing foreign trade, manufacturing, development and investment in the countries where we manufacture our products, including the World Trade Organization Information Technology Agreement or other free trade agreements;
- delays in delivery by suppliers due to customs clearing delays, shipping delays, scarcity of raw materials and changes in demand from us or their other customers;
- limited warranties provided to us; and
- potential misappropriation of our intellectual property.

These and other risks could impair our ability to fulfill orders, harm our sales and impact our reputation with customers. If our contract manufacturer is unable or unwilling to manufacture our products or components of our products, or if our contract manufacturer discontinues operations, we may be required to identify and qualify alternative manufacturers, which could cause us to be unable to meet our supply requirements to our customers and result in the breach of our customer agreements. The process of qualifying a new contract manufacturer and commencing volume production is expensive and time-consuming, and if we are required to change or qualify a new contract manufacturer, we would likely lose sales revenue and damage our existing customer relationships.

Failure to maintain or obtain new private payor contracts and future reductions in reimbursement rates from private payors could have a material adverse effect on our financial condition and results of operations.

A portion of our rental revenue is derived from private payors. Based on our patient population, we estimate approximately 33% of potential customers have non-Medicare insurance coverage (including Medicare Advantage plans). Failing to maintain and obtain private payor contracts from private insurance companies and employers and secure in-network provider status could have a material adverse effect on our financial condition and results of operations. In addition, private payors are under pressure to increase profitability and reduce costs. In response, certain private payors are limiting coverage or reducing reimbursement rates for the products we provide. We believe that private payor reimbursement levels will generally be reset in accordance with the Medicare reimbursement amounts determined by competitive bidding. We cannot predict the extent to which reimbursement for our products will be affected by competitive bidding or by initiatives to reduce costs for private payors. Failure to maintain or obtain new private payor contracts or the unavailability of third-party coverage or inadequacy of reimbursement for our products would adversely affect our business, financial condition and results of operations.

If we are unable to manage our anticipated growth effectively, our business could be harmed.

We have previously experienced periods of rapid growth in short periods of time. These periods of rapid growth of our business have placed a significant strain on our managerial and operational resources and systems. For example, as our business has grown, we have seen the cost per generated lead trend higher than historical averages. In addition, many of the sales representatives we hired in 2018 were unable to meet sales targets and were thus transitioned out To continue to grow our business, we must attract and retain capable personnel and manage and train them effectively, particularly related to sales representatives and supporting sales personnel. We must also upgrade our internal business processes and capabilities to create the scalability that a growing business demands.

Going forward, we plan to hire additional inside sales representatives at a more controlled pace across all three facilities to expand sales capacity, but our inside sales representative headcount was down significantly at year-end 2019 compared to year-end 2018 and, due to the impact of the COVID-19 pandemic and related PHE, it was also down at year-end 2020 compared to year-end 2019. Headcount was also down slightly at year-end 2021 compared to December 31, 2020. In 2022, we expect hiring will continue to be challenging due to the continued impacts of the COVID-19 pandemic and related PHE, so we do not expect to increase our inside sales force and instead expect to offset attrition with replacement hiring. While we believe we are making the necessary changes to improve sales management infrastructure to support sales representative training and onboarding, it will take more time to evaluate whether these changes are effective in the long term, particularly given the impact of the COVID-19 pandemic and related PHE, and to the extent they are not effective it may negatively affect our financial condition and results of operations.

In addition, we plan to hire additional sales representatives in our prescriber sales organization, primarily through Ashfield, our contract sales organization, to enhance our go-to-market capabilities in the U.S. The employment market is very challenging and there is no guarantee that they, or we, will be able to hire all of the required employees to our prescriber sales organization in the future or retain existing staff. Additionally, Ashfield will provide access to its best-in-class data-driven sales management disciplines, proprietary prescriber insights, and analytics to support our growth strategy and drive performance in the clinician sales channel. While we believe that our investments in the prescriber sales organization will enhance our growth in direct-to-consumer sales and rental revenue, it will take time for these sales representatives to be fully trained and ramped up to full productivity, and it will take time for the sales tools to be implemented across our existing prescriber sales representatives. To the extent that the sales tools being implemented, or the sales representatives hired either through us or Ashfield, are not effective, or the number of sales representatives does not reach the number anticipated, it may negatively affect our future growth and results of operations.

In addition, our sales expansion and productivity improvements for 2022 may continue to be negatively impacted due to the COVID-19 pandemic and related PHE. In connection with the COVID-19 pandemic and related PHE, we expect minimal inside sales representative headcount additions in 2022, and we expect the COVID-19 pandemic and related PHE may continue to reduce the number of oxygen therapy patients who purchase our products directly through our direct-to-consumer sales channel, and the number of sales generated from physician offices or make it more difficult to get paperwork and testing from physician offices. The reduction in nonessential travel may also continue to harm our business, particularly for our prescriber sales representatives and business-to-business partners who rely on physician office and hospital visits to drive business, and patients who rely on physicians to prescribe them oxygen therapy after in-office testing.

We also have experienced increased demand for our products in various markets associated with rising rates of COVID-19, since physicians may prescribe supplemental oxygen as a treatment for COVID-19. As a result, in these periods we saw increased demand for our products for applicable patients who may be treated in the home instead of an acute hospital setting. This demand is mostly being filled through our HME provider partners, who work closely with hospitals to discharge patients into a home treatment program. If this demand increase resumes and we cannot meet this demand, we may lose market share to competitors or lose customers, which may negatively affect our financial conditions and results of operations. In addition, even if we are able to meet any such increased demand, such an increase in business-to-business sales mix may negatively impact our gross margin as HME provider purchases have a significantly lower average selling price than direct-to-consumer purchases.

During 2019, we signed leases to expand our facilities located in Plano, Texas and Goleta, California, which commenced in 2021. Domestic expansion, combined with our use of a contract manufacturer in Europe to produce a portion of our Inogen One G3 and Inogen One G5 concentrators and perform product repairs, is expected to be sufficient to meet our manufacturing needs provided that these facilities remain operational. However, our anticipated growth may place additional strain on our supply chain and manufacturing facilities, resulting in an increased need for us to carefully monitor parts inventory, capable staffing and quality assurance. Any failure by us to manage the scalability of our process or other aspects of our growth effectively could have an adverse effect on our ability to achieve our development and commercialization goals and negatively affect our financial condition and results of operations.

We may expand through acquisitions of, or investments in, other companies, each of which may divert our management's attention, result in additional dilution to our stockholders, increase expenses, disrupt our operations, and harm our results of operations.

Our business strategy may, from time-to-time, include acquiring or investing in complementary services, technologies or businesses, such as our acquisition of New Aera in 2019. We do not have an extensive history of acquiring other companies and cannot assure you that we will successfully identify suitable acquisition candidates, integrate or manage disparate technologies, lines of business, personnel and corporate cultures, realize our business strategy or the expected return on our investment, or manage a geographically dispersed company. Any such acquisition or investment could materially and adversely affect our financial condition and results of operations. We may issue equity securities which could dilute current stockholders' ownership, incur debt, assume contingent or other liabilities and expend cash in acquisitions, which could negatively impact our financial condition, stockholder equity, and stock price. The acquisition and integration process is complex, expensive and time-consuming, and may cause an interruption of, or loss of momentum in, product development and sales activities and operations of both companies, and we may incur substantial cost and expense, as well as divert the attention of management.

Acquisitions and other strategic investments involve significant risks and uncertainties, including:

- the potential failure to achieve the expected benefits of the combination or acquisition;
- the potential failure to successfully develop or commercialize the acquired products or technology;
- unanticipated costs and liabilities;
- difficulties in integrating new products, businesses, operations, and technology infrastructure in an efficient and effective manner;
- difficulties in maintaining customer relations;
- the potential loss of key employees of the acquired businesses;
- the diversion of the attention of our senior management from the operation of our daily business;
- the potential adverse effect on our cash position to the extent that we use cash for the purchase price;
- the potential incurrence of interest expense and debt service requirements if we incur debt to pay for an acquisition;
- the potential issuance of securities that would dilute our stockholders' percentage ownership;
- the potential to incur large and immediate write-offs and restructuring and other related expenses;
- the potential of amortization expenses related to intangible assets;
- the potential failure to achieve anticipated reimbursement classifications for acquired products;
- the potential to become involved in intellectual property litigation related to such acquisitions or strategic investments; and
- the inability to maintain uniform standards, controls, policies, and procedures.

Any acquisition or investment could expose us to unknown liabilities. Moreover, we cannot assure you that we will realize the anticipated benefits of any acquisition or investment. In addition, our inability to successfully operate and integrate newly acquired businesses appropriately, effectively, and in a timely manner could impair our ability to take advantage of future growth opportunities and other advances in technology, as well as on our revenues, gross margins, and expenses.

As part of our ongoing efforts to advance patient preference and maintain our technology leadership position, we acquired New Aera in 2019 and completed our integration process. We made certain assumptions relating to the New Aera acquisition, which assumptions may have been inaccurate, including the failure to realize the expected benefits of the acquisition, failure to realize expected revenue, higher than expected operating costs, and general economic and business conditions that adversely affect the combined company following the acquisition. After integration of New Aera, and partially as a result of the negative litigation outcome in our case against the Department of Health and Human Services, we believe that our assumptions regarding New Aera will not be fully realized. We believe that there are still many risks associated with the TAV product, including whether we will be able to successfully incorporate TAV into our existing products, what sort of competition there may be for the TAV product, if and when implemented, and the other risks identified in this Annual Report on Form 10-K.

We are exposed to the credit and non-payment risk of our HME providers, distributors, private label partners and resellers, especially during times of economic uncertainty and tight credit markets, which could result in material losses.

We sell our products to certain HME providers, distributors, private label partner and resellers on unsecured credit, with terms that vary depending upon the customer's credit history, solvency, cash flow, credit limits and sales history, as well as prevailing terms with similarly situated customers and whether sufficient credit insurance can be obtained. In particular, one single customer and Medicare each represented more than 10% of our net accounts receivable balance with accounts receivable balances of $5.9 million and $2.7 million, respectively, as of December 31, 2021, and two customers each with an accounts receivable balance of $8.4 million and $7.0 million, respectively, as of December 31, 2020. Challenging economic conditions, including those associated with the COVID-19 pandemic and related PHE, may impair the ability of our customers to pay for products they have purchased, and as a result, our reserve for doubtful accounts could increase and, even if increased, may turn out to be insufficient. Moreover, even in cases where we have insolvency risk insurance to protect against a customer's bankruptcy, insolvency or liquidation, this insurance typically contains a significant deductible and co-payment obligation and does not cover all instances of non-payment. Our exposure to credit risks of our business partners may increase if our business partners and their end customers are adversely affected by global or regional economic conditions, including those associated with the COVID-19 pandemic and related PHE. One or more of these business partners could delay payments or default on credit extended to them, either of which could adversely affect our business, financial condition and results of operations.

We generate a substantial portion of our revenue internationally and are subject to various risks relating to such international activities, which could adversely affect our operating results. In addition, any disruption or delay in the shipping of our products, whether domestically or internationally, may have an adverse effect on our financial condition and results of operations.

During the years ended December 31, 2021, 2020 and 2019, approximately 22.2%, 20.1% and 21.5%, respectively, of our total revenue was generated from customers located outside of the United States. We believe that a significant percentage of our future revenue will continue to come from international sources as we expand our international operations and develop opportunities in other countries. Engaging in international business inherently involves a number of difficulties and risks, including:

- required compliance with anti-bribery laws, such as the U.S. Foreign Corrupt Practices Act and U.K. Bribery Act, data privacy regulations, such as the European Union General Data Protection Regulation (GDPR), labor laws, and anti-competition regulations;
- export or import delays and restrictions;
- obtaining and maintaining regulatory clearances, approvals and certifications;
- laws and business practices favoring local companies;
- difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
- unstable economic, political, and regulatory conditions;
- supply chain complexities;
- fluctuations in currency exchange rates;
- fluctuations in demand due to country-specific tenders and tender uncertainty and capital expenditure constraints;
- potentially adverse tax consequences, tariffs, customs charges, bureaucratic requirements, and other trade barriers;
- any other government actions, by the United States, China or other countries, that impose barriers or restrictions that would impact our ability to sell or ship products to customers; and
- difficulties protecting or procuring intellectual property rights.

If one or more of these risks occurs, it could require us to dedicate significant resources to remedy, and if we are unsuccessful in finding a solution, our financial condition and results of operations will suffer.

In addition, on June 23, 2016, the United Kingdom (U.K.) held a referendum in which voters approved an exit from the European Union, commonly referred to as "Brexit." This decision created an uncertain political and economic environment in the U.K. and other European Union countries, and the formal process for leaving the European Union has taken years to complete. The U.K. formally left the European Union on January 31, 2020 and began a transition period which expired on December 31, 2020.

In December 2020, the U.K. and the European Union agreed on a trade and cooperation agreement, under which the U.K. and the European Union will now form two separate markets governed by two distinct regulatory and legal regimes. The trade and cooperation agreement covers the general objectives and framework of the relationship between the U.K. and the European Union, including as it relates to trade, transport and visas. Notably, under the trade and cooperation agreement, U.K. service suppliers no longer benefit from automatic access to the entire European Union single market, U.K. goods no longer benefit from the free movement of goods and there is no longer the free movement of people between the U.K. and the European Union. Depending on the application of the terms of the trade and cooperation agreement, we could face new regulatory costs and challenges.

Adverse consequences concerning Brexit or the future of the European Union could include deterioration in global economic conditions, instability in global financial markets, political uncertainty, volatility in currency exchange rates or adverse changes in the cross-border agreements currently in place, any of which could have an adverse impact on our financial results in the future.

A portion of our international product sales are currently denominated in U.S. dollars and fluctuations in the value of the U.S. dollar relative to foreign currencies could decrease demand for our products and adversely impact our financial performance. For example, if the value of the U.S. dollar increases relative to foreign currencies, our products could become more costly to the international consumer and therefore less competitive in international markets. Our results of operations and cash flows are, therefore, subject to fluctuations due to changes in foreign currency exchange rates. The volatility of exchange rates depends on many factors that we cannot forecast with reliable accuracy. We have experienced and will continue to experience fluctuations in our net income or loss as a result of transaction gains or losses related to revaluing certain current asset and current liability balances that are denominated in currencies other than the functional currency of the entities in which they are recorded.

For example, for the year ended December 31, 2021 we experienced a net foreign currency loss of $0.7 million, for the year ended December 31, 2020 we experienced a net foreign currency gain of $0.6 million, and for the year ended December 31, 2019 we experienced a net foreign currency loss of $0.2 million. Fluctuations in currency exchange rates could have an adverse impact on our financial results in the future. While we have a hedging program for Euros that attempts to manage currency exchange rate risks to an acceptable level based on management's judgment of the appropriate trade-off between risk, opportunity, and cost, this hedging program does not completely eliminate the effects of currency exchange rate fluctuations. In addition, currency hedging may result in a reduction or increase in revenue should the currency strengthen or decline during the contract period. A discussion of the hedging program is contained in Item 7A. Quantitative and Qualitative Disclosures about Market Risk in this Annual Report on Form 10-K for the year ended December 31, 2021. Additional information on our hedging arrangements is also contained in Note 3 – Fair value measurements and Item 3 – Quantitative and Qualitative Disclosures About Market Risk in the notes in our consolidated financial statements in this Annual Report on Form 10-K.

We rely on shipping providers to deliver products to our customers globally. Labor, tariff, or World Trade Organization-related disputes, piracy, physical damage to shipping facilities or equipment caused by severe weather or terrorist incidents, congestion at shipping facilities, inadequate equipment to load, dock, and offload our products, energy-related tie-ups, shipping delays associated with the COVID-19 pandemic and related PHE, or other factors could disrupt or delay shipping or offloading of our products domestically and internationally. Such disruptions or delays may have an adverse effect on our financial condition and results of operations.

Failure to comply with anti-bribery, anti-corruption, and anti-money laundering laws, including the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, and similar laws associated with our activities outside of the United States could subject us to penalties and other adverse consequences.

We are subject to the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, the United Kingdom Bribery Act of 2010 and possibly other anti-corruption, anti-bribery and anti-money laundering laws in the more than fifty-nine countries around the world where we conduct activities and sell our products. We face significant risks and liability if we fail to comply with the FCPA and other anti-corruption and anti-bribery laws that prohibit companies and their employees and third-party business partners, such as distributors or resellers, from authorizing, offering or providing, directly or indirectly, improper payments or benefits to foreign government officials, political parties or candidates, employees of public international organizations including healthcare professionals, or private-sector recipients for the corrupt purpose of obtaining or retaining business, directing business to any person, or securing any advantage.

We leverage various third parties to sell our products and conduct our business abroad. We, our distributors and channel partners, and our other third-party intermediaries and manufacturer may have direct or indirect interactions with officials and employees of government agencies or state-owned or affiliated entities (such as in the context of obtaining government approvals, registrations, or licenses) and may be held liable for the corrupt or other illegal activities of these third-party business partners and intermediaries, our employees, representatives, contractors, partners, and agents, even if we do not explicitly authorize such activities. In many foreign countries, particularly in countries with developing economies, it may be a local custom that businesses engage in practices that are prohibited by the FCPA or other applicable laws and regulations. We provide training to all employees, including management, to ensure compliance with the FCPA. As such, we intend to continue to implement an FCPA/anti-corruption compliance program to ensure compliance with such laws, but we face the risk that individual actions of our employees and agents, as well as those companies to which we outsource certain of our business operations, will not take actions in violation of our policies and applicable law, for which we have to defend ourselves and may be ultimately held responsible.

Any violation of the FCPA, other applicable anti-bribery, anti-corruption laws, and anti-money laundering laws could result in whistleblower complaints, adverse media coverage, investigations, loss of export privileges, severe criminal or civil sanctions and, in the case of the FCPA, suspension or debarment from U.S. government contracts, which could have a material and adverse effect on our reputation, business, operating results and prospects. In addition, responding to any enforcement action or related investigation may result in a materially significant diversion of management’s attention and resources and significant defense costs and other professional fees.

If we fail to comply with U.S. export control and economic sanctions or fail to expand and maintain an effective sales force or successfully develop our international distribution network, our business, financial condition and results of operations may be adversely affected.

We currently derive the majority of our revenue from rentals or sales generated from our own direct sales force. Failure to maintain or expand our direct sales force could adversely affect our financial condition and results of operations. Additionally, we use international distributors to augment our sales efforts, certain of which are exclusive distributors in certain foreign countries. We cannot assure you that we will be able to successfully retain or develop our relationships with third-party distributors internationally.

In addition, we are subject to United States export control and economic sanctions laws relating to the sale of our products, the violation of which could result in substantial penalties being imposed against us. In particular, we have secured annual export licenses from the U.S. Treasury Department's Office of Foreign Assets Control to sell our products to a distributor and hospital and clinic end-users in Iran. The use of this license requires us to observe strict conditions with respect to products sold, end-user limitations and payment requirements. Although we believe we have maintained compliance with license requirements, there can be no assurance that the license will not be revoked, be renewed in the future or that we will remain in compliance. More broadly, if we fail to comply with export control laws or successfully develop our relationship with international distributors, our sales could fail to grow or could decline, and our ability to grow our business could be adversely affected. Distributors that are in the business of selling other medical products may not devote a sufficient level of resources and support required to generate awareness of our products and grow or maintain product sales. If our distributors are unwilling or unable to market and sell our products, or if they do not perform to our expectations, we could experience delayed or reduced market acceptance and sales of our products resulting in adverse results of operations.

We may be subject to substantial warranty or product liability claims or other litigation in the ordinary course of business that may adversely affect our business, financial condition and results of operations.

As manufacturers of medical devices, we may be subject to substantial warranty or product liability claims or other litigation in the ordinary course of business that may require us to make significant expenditures to defend these claims or pay damage awards. For example, our Inogen One systems contain lithium ion batteries, which, under certain circumstances, can be a fire hazard. We, as well as our key suppliers, maintain product liability insurance, but this insurance is limited in amount and subject to significant deductibles. There is no guarantee that insurance will be available or adequate to protect against all claims. Our insurance policies are subject to annual renewal and we may not be able to obtain liability or product insurance in the future on acceptable terms or at all. In addition, our insurance premiums could be subject to increases in the future, which may be material. If the coverage limits are inadequate to cover our liabilities or our insurance costs continue to increase as a result of warranty or product liability claims or other litigation, then our business, financial condition and results of operations may be adversely affected.

We may also be subject to other types of claims arising from our normal business activities. These may include claims, suits, and proceedings involving labor and employment, wage and hour, commercial, alleged securities laws violations or other investor claims, patent defense and other matters. The outcome of any litigation, regardless of its merits, is inherently uncertain. Any claims and lawsuits, and the disposition of such claims and lawsuits, could be time-consuming and expensive to resolve, divert management attention and resources, and lead to attempts on the part of other parties to pursue similar claims. Any adverse determination related to litigation could require us to change our technology or our business practices, pay monetary damages or enter into royalty or licensing arrangements, which could adversely affect our business, financial condition and results of operations.

Increases in our operating costs could have a material adverse effect on our business, financial condition and results of operations.

Reimbursement rates are established by fee schedules mandated by Medicare, private payors and Medicaid, and are likely to be set, in part, to federal and state government budgetary constraints. As a result, with respect to Medicare and Medicaid related revenue, we may not be able to offset the effects of general inflation on our operating costs through increases in prices for our products, as these inflation adjustments are subject to annual approval outside of our control. In particular, labor and related costs account for a significant portion of our operating costs and we compete with other healthcare providers to attract and retain qualified or skilled personnel and with various industries for administrative and service employees. This competitive environment could result in increased labor costs, which we have seen in 2021 as the labor market has tightened and there is increased competition for certain roles. As a result, increases in our operating costs including personnel-related costs could adversely affect our financial condition and results of operations.

We depend on the services of our senior executives and other key technical personnel, the loss of whom could negatively affect our business.

Our success depends upon the skills, experience and efforts of our senior executives and other key technical personnel, including certain members of our engineering, accounting and compliance staff as well as our sales and marketing personnel. Our President and Chief Executive Officer, Nabil Shabshab, joined us in February 2021, our Executive Vice President, Chief Commercial Officer, George Parr, joined us in April 2021, our Executive Vice President, Chief Technology Officer, Stanislav Glezer, joined us in June 2021, our Executive Vice President, General Counsel, Jason Somer, joined us in July 2021, and our Executive Vice President, Finance and Chief Financial Officer, Michael Sergesketter, joined us in December 2021 in an interim capacity while a search for a permanent candidate is underway.

If experienced employees leave, we could experience inefficiencies or a lack of business continuity due to loss of historical knowledge and a lack of familiarity of the new employees with business processes, operating requirements, policies and procedures. It is important to our success that these key employees quickly adapt to and excel in their new roles. If they are unable to do so, our business and financial results could be materially adversely affected. In addition, much of our corporate expertise is concentrated in relatively few employees, the loss of which for any reason could negatively affect our business. Competition for our highly skilled employees is intense and we cannot prevent the resignation of any employee. We have experienced increased turnover at all levels since the start of the COVID-19 pandemic and general labor shortages in various areas of our business, all of which could have a material adverse impact on our business. We may need to increase employee wages and benefits in order to attract and retain the personnel necessary to achieve our goals, and our business, operations, and financial results may suffer if we are unable to do so. We do not maintain "key man" life insurance on any of our senior executives. None of our senior executive team is bound by written employment contracts to remain with us for a specified period. In addition, we have not entered into non-compete agreements with members of our executive management team. The loss of any member of our executive management team could harm our ability to implement our business strategy and respond to the market conditions in which we operate.

We and our vendors and service providers rely on information technology networks and systems, and if we are unable to protect against service interruptions, data corruption, cybersecurity risks, data security incidents and/or network security breaches, our operations could be disrupted and our business could be negatively affected.

We rely on information technology networks and systems to process, transmit and store electronic, customer, operational, compliance, and financial information; to coordinate our business; and to communicate within our company and with customers, suppliers, partners and other third parties. These information technology networks and systems may be susceptible to damage, disruptions or shutdowns, hardware or software failures, power outages, computer viruses, cybersecurity risks, data security incidents, telecommunication failures, user errors or catastrophic events. Like other companies, we have experienced data security incidents before.

For example, on April 13, 2018, we announced that messages within an employee email account were accessed by unknown persons outside of our company without authorization. Some of the messages and attached files in that email account contained personal information belonging to our rental customers. We immediately took steps to secure customer information and hired a leading forensics firm to investigate the incident and to bolster our security. The unauthorized access of the potentially impacted email account appears to have occurred between January 2, 2018 and March 14, 2018. We notified approximately 30,000 current and former rental customers of this incident as well as the applicable regulatory authorities. We also provided resources, including credit monitoring and an insurance reimbursement policy, to assist all potentially affected individuals. We have incurred remedial, legal and other costs in connection with this incident. We have insurance coverage in place for certain potential liabilities and costs relating to service interruptions, data corruption, cybersecurity risks, data security incidents and/or network security breaches, but this insurance is limited in amount, subject to a deductible, and may not be adequate to cover us for all costs arising from these incidents.

If our information technology networks and systems suffer unauthorized access, severe damage, disruption or shutdown, and our business does not effectively identify or resolve the issues in a timely manner, our operations could be disrupted, we could be subject to regulatory and consumer lawsuits and our business could be negatively affected. In addition, cybersecurity risks and data security incidents could lead to potential unauthorized access to or acquisition of confidential information (including protected health information), and data loss and corruption. There is no assurance that we will not experience service interruptions, security breaches, cybersecurity risks and data security incidents, or other information technology failures in the future.

Due to the COVID-19 pandemic and related PHE, we have an increased number of employees working remotely. As a result, we may have increased cybersecurity or data security risks, due to increased use of home wi-fi networks and virtual private networks, as well as increased disbursement of physical machines. While we implement IT controls to reduce the risk of a cybersecurity and data security breach, there is no guarantee that these measures will be adequate to safeguard all systems with an increased number of employees working remotely.

The methods used to obtain unauthorized access, disable or degrade service or sabotage systems are constantly evolving and may be difficult to anticipate or to detect for long periods of time. As a result of these types of risks and attacks, we have implemented and periodically review and update systems, processes, and procedures to protect against unauthorized access to or use of data and to prevent data loss. For example, we have increased the security of our systems by requiring all email users to change their passwords following our recent data security incident and sooner than they would have otherwise been required to. We also implemented multi-factor authentication for remote email access and have taken additional steps to further limit access to our systems. However, the ever-evolving threats mean we and our third-party service providers and vendors must continually evaluate and adapt our respective systems and processes and overall security environment. There is no guarantee that these measures will be adequate to safeguard against all data security breaches, system compromises or misuses of data.

The compromise of our technology systems resulting in the loss, disclosure, misappropriation of, or access to, customers', employees' or business partners' information or failure to comply with regulatory or contractual obligations with respect to such information could result in legal claims or proceedings, liability or regulatory penalties under laws protecting the privacy of personal information, disruption to our operations and damage to our reputation, any or all of which could adversely affect our business. The costs to remediate breaches and similar system compromises that do occur could adversely affect our results of operations.

Any new laws, regulations, other legal obligations or industry standards, or any changed interpretation of existing laws, regulations or other standards may require us to incur additional costs and restrict our business operations. For example, many jurisdictions have enacted laws requiring companies to notify individuals of data security breaches involving certain types of personal data. These mandatory disclosures regarding a security breach could result in negative publicity to us, which may cause our customers to lose confidence in the effectiveness of our data security measures which could adversely affect our business, financial condition and results of operations.

Increasing data privacy regulations could impact our business and expose us to increased liability.

We must comply with increasingly complex and rigorous regulatory standards enacted to protect business and personal data in the U.S., Europe and elsewhere. For example, the European Union adopted the General Data Protection Regulation (GDPR), which became effective on May 25, 2018. The GDPR imposes additional obligations on companies regarding the processing of personal data and provides certain individual privacy rights to natural persons whose data is stored. Compliance with existing, proposed and recently enacted laws (including implementation of the privacy and process enhancements called for under the GDPR) and regulations can be costly and any failure to comply with these regulatory standards could subject us to legal and reputational risks. In addition, we are required under the GDPR to respond to customers' Subject Access Reports (SARs) within a certain time period, which entails determining what personal data is being processed, the purpose of any such data processing, to whom such personal data has been disclosed and whether personal data is being disclosed for the purpose of making automated decisions relating to that customer. We may dedicate significant resources to responding to our customers' SARs, which could adversely affect our business, financial condition and results of operations. Misuse of or failure to secure or properly process personal information could also result in violation of data privacy laws and regulations, proceedings against us by governmental entities or others, damage to our reputation and credibility and could have a negative impact on revenues and profits. As the regulatory environment related to information security, data collection and use, and privacy becomes increasingly rigorous, with new and constantly changing requirements applicable to our business, compliance with those requirements could continue to result in significant costs.

Following the GDPR, a number of states in the U.S. have introduced bills, which, if passed, would impose operational requirements on U.S. companies similar to the requirements reflected in the GDPR. In 2018, California passed the California Consumer Privacy Act (CCPA) and in 2021, Virginia passed the Consumer Data Protection Act (CDPA), which gives consumers significant rights over the use of their personal information, including the right to object to the "sale" of their personal information. These rights may restrict our ability to use personal information in connection with our business operations. The CCPA and CDPA also provides a private right of action for security breaches. Washington and Massachusetts have introduced significant privacy bills and Congress is debating federal privacy legislation, which if passed, may restrict our business operations and require us to incur additional costs for compliance.

Any new laws, regulations, other legal obligations or industry standards, or any changed interpretation of existing laws, regulations or other standards may require us to incur additional costs and restrict our business operations.

Our financial condition and results of operations may vary significantly from quarter-to-quarter due to a number of factors, which may lead to volatility in our stock price.

Our quarterly revenue and results of operations have varied in the past and may continue to vary significantly from quarter-to-quarter. This variability may lead to volatility in our stock price as research analysts and investors respond to these quarterly fluctuations. These fluctuations are due to numerous factors, including: fluctuations in consumer demand for our products; seasonal cycles in consumer spending; HME providers' ability to adopt and finance POC purchases and restructure their businesses to remove delivery expenses; our ability to design, manufacture and deliver products to our consumers in a timely and cost-effective manner; quality control problems in our manufacturing operations; our ability to timely obtain adequate quantities of the components used in our products; new product introductions and enhancements by us and our competitors; unanticipated increases in costs or expenses; declines in sales personnel productivity; increased marketing cost per generated lead; unanticipated regulatory reimbursement changes that could result in positive or negative impacts to our earnings; changes or updates to generally accepted accounting principles; additional legal costs associated with pending legal matters; and fluctuations in foreign currency exchange rates.

In particular, due to the COVID-19 pandemic and related PHE, we have seen and expect to continue to see a disruption in our normal seasonal trends, as, due to the mandates and behaviors emanating from the COVID-19 pandemic and related PHE, including shelter-in-place orders, reduced travel, and lower consumer confidence, we did not see the typical seasonal increases in direct-to-consumer sales in 2020 that we have seen in prior years. As more HME providers adopt POCs in their businesses, we expect that this could change our historical seasonality in the domestic business-to-business channel as well, which was previously influenced mainly by consumer buying patterns. The foregoing factors are difficult to forecast, and these, as well as other factors, could materially and adversely affect our quarterly and annual results of operations. We have experienced significant revenue growth in the past, but we may not achieve similar growth rates, profit margins and/or net income (loss) in future periods.

You should not rely on our operating results for any prior quarterly or annual period as an indication of our future operating performance. If we are unable to maintain adequate revenue growth and cost control, our operating results could suffer, and our stock price could decline, primarily because a significant amount of our expenses are fixed and would take additional time to reduce. 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.

If the market opportunities for our products are smaller than we believe they are, our revenues may be adversely affected and our business may suffer.

Our projections regarding (i) the size of the oxygen therapy market, both in the United States and internationally, (ii) the size and percentage of the long-term oxygen therapy market that is subject to competitive bidding in the United States, (iii) the number of oxygen therapy patients, (iv) the number of patients requiring ambulatory and stationary oxygen, (v) the number of patients who rely on the delivery model, (vi) the percentage of the long-term oxygen therapy market serviced by Medicare, Medicare Advantage, and other third party-payors, (vii) the size of the retail long-term oxygen therapy market and how the opportunity may change as POC penetration increases, (viii) the share of POCs as a percentage of the total oxygen therapy spend, and (ix) the impact of the COVID-19 pandemic and related PHE on our business and our markets generally are based on estimates that we believe are reliable. These estimates may prove to be incorrect, new data or studies may change the estimated incidence or prevalence of patients requiring long-term oxygen therapy, or the type of long-term oxygen therapy patients. The COVID-19 pandemic and related PHE may also reduce the number of oxygen therapy patients worldwide due to the higher risk of mortality of elderly patients with existing respiratory diseases if they are exposed to the virus. The number of patients in the United States and internationally may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our products, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business.

An adverse outcome of a sales and use tax audit or change in U.S. tax laws could have a material adverse effect on our results of operations and financial condition.

We operate in multiple taxing jurisdictions and certain revenue streams may be subject to sales and use taxAny changes, ambiguity, or uncertainty in taxing jurisdictions' administrative interpretations, decisions, policies and positions, including the position of taxing authorities with respect to taxability of our revenue also materially impact our sales and use tax liabilities. The California State Board of Equalization conducted a sales and use tax audit of our operations in California in 2008. As a result of the audit, the California State Board of Equalization confirmed that our sales are not subject to California sales and use tax. We believe that our sales of concentrators and accessories may be subject to sales and use tax in certain other states, but that there are exemptions from sales and use tax in most states. There can be no assurance, however, that other states may agree with our position and we may be subject to an audit that may not be resolved in our favor. Such an audit could be expensive and time-consuming and result in substantial management distraction. If the matter were to be resolved in a manner adverse to us, it could have a material adverse effect on our results of operations and financial condition.

Changes in accounting principles, or interpretations thereof, could have a significant effect on our financial condition and results of operations.

We prepare our consolidated financial statements in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP). These principles are subject to interpretation by the Securities and Exchange Commission (SEC) and various bodies formed to interpret and create appropriate accounting principles. A change in these principles can have a significant effect on our reported results and may even retroactively affect previously reported transactions. Additionally, the adoption of new or revised accounting principles may require that we make significant changes to our systems, processes and controls.

For example, the U.S.-based Financial Accounting Standards Board (FASB) is currently working together with the International Accounting Standards Board (IASB) on several projects to further align accounting principles and facilitate more comparable financial reporting between companies who are required to follow U.S. GAAP under SEC regulations and those who are required to follow International Financial Reporting Standards outside of the United States. These efforts by the FASB and IASB may result in different accounting principles under U.S. GAAP that may result in materially different financial results for us in areas including, but not limited to, principles for recognizing revenue and lease accounting. Additionally, significant changes to U.S. GAAP resulting from the FASB's and IASB's efforts may require that we change how we process, analyze and report financial information and that we change financial reporting controls.

It is not clear if or when these potential changes in accounting principles may become effective, whether we have the proper systems and controls in place to accommodate such changes and the impact that any such changes may have on our financial condition and results of operations.

Our ability to recognize the benefits of deferred tax assets is dependent on future cash flows and taxable income.

We recognize the expected future tax benefit from deferred tax assets when the tax benefit is considered to be more likely than not of being realized; otherwise, a valuation allowance is applied against deferred tax assets. Assessing the recoverability of deferred tax assets requires management to make significant estimates related to expectations of future taxable income. Estimates of future taxable income are based on forecasted cash flows from operations and the application of existing tax laws in each jurisdiction. To the extent that future cash flows and taxable income differ significantly from estimates, our ability to realize the deferred tax assets could be impacted. In the future, our estimates could change requiring a valuation allowance or impairment of our deferred tax assets. Additionally, future changes in tax laws could limit our ability to obtain the future tax benefits represented by our deferred tax assets. See Note 6 – Income taxes in the notes of our consolidated financial statements in this Annual Report on Form 10-K for additional information and factors that could impact the Company's ability to realize the deferred tax assets.

The adoption and interpretation of new tax legislation, tax rulings, or exposure to additional tax liabilities, could materially affect our financial condition, results of operations, and cash flows.

We are subject to income and other taxes in the U.S. and other foreign jurisdictions in which we do business. As a result, our provision for income taxes is derived from a combination of applicable tax rates in the various places we operate. Significant judgment is required for calculating our income tax provision.

Current economic and political conditions make tax laws and regulations, or their interpretation and application, in any jurisdiction subject to significant change. Changes in tax law or tax rulings, or changes in interpretations of existing law, could adversely affect our financial condition and results of operations. For example, changes to the U.S. tax laws enacted in December 2017 had a significant impact on our deferred tax assets, income tax provision and effective tax rate for the year ended December 31, 2017. The new Administration and Congress could make changes to existing tax law, including an increase in the corporate tax rate or the tax rate on foreign earnings. In addition, many countries in Europe, as well as a number of other countries and organizations, have recently proposed or recommended changes to existing tax laws or have enacted new laws that could significantly increase our tax obligations in many countries where we do business or require us to change the manner in which we operate our business. Changes to existing tax law in the U.S. or other foreign jurisdictions could adversely affect our financial condition and results of operations.

The Medicare Fee-For-Service (FFS) sequestration reduction has and may continue to negatively affect our revenue and profits.

Medicare FFS claims with dates of service on or after April 1, 2013 are subject to a 2% sequestration reduction in Medicare payments, including claims for DMEPOS, including in competitive bidding areas. The claims payment adjustment is applied to all claims after determining co-insurance, any applicable deductible, and any applicable Medicare secondary payment adjustments. These reductions are included in rental revenue adjustments. This sequestration reduction was scheduled to continue until further notice. However, a provision in the CARES Act temporarily paused the 2% Medicare sequestration reduction for claims dated from May 1, 2020 through December 31, 2020 and the CARES Act also extends the end date of the Medicare sequestration reduction by one year, through 2030, in order to offset the 2020 suspension. The Consolidated Appropriations Act of 2021 was signed into law on December 27, 2020 and extended the suspension period to March 31, 2021. U.S. House of Representatives bill H.R. 1868 was signed into law on April 14, 2021 and extended the suspension period to December 31, 2021, but increased the fiscal year 2030 sequestration cuts. In December 2021 through the Protecting Medicare and American Farmers from Sequester Cuts Act, the 2% Medicare sequestration benefit that was set to expire December 31, 2021 has been extended until March 31, 2022. The sequestration then resumes with a 1% reduction to rates from April 1, 2022 until June 30, 2022, with the full 2% Medicare sequestration resuming starting July 1, 2022. Once the sequestration reduction is reinstated, this could adversely affect our financial condition and results of operations.

The implementation of prior authorization rules for DMEPOS under Medicare could negatively affect our business and financial condition.

CMS has issued a final rule to require Medicare prior authorization (PA) for certain DMEPOS that the agency characterizes as "frequently subject to unnecessary utilization" and that have an average purchase fee of $1,000 or greater, or an average rental fee schedule of $100 or greater. The final rule was published on December 30, 2015 and specified an initial master list of 135 items that could potentially be subject to PA. Initially stationary oxygen (code E1390) was included on the master list, but was later removed. On April 22, 2019, stationary oxygen (E1390) was again added to the list of potential codes that could be subject to PA. On November 8, 2019, CMS revised the criteria for inclusion on the master list and added 212 DMEPOS items, including portable oxygen concentrators (E1392), to the master list. The master list is updated annually and published in the Federal Register. The presence of an

item on the master list does not automatically mean that a PA is required. CMS selects a subset of these master list items for its "Required Prior Authorization List." There will be a notice period of at least 60 days prior to implementation. The ruling does not create any new clinical documentation requirements, instead the same information necessary to support Medicare payment will be required *prior* to the item being furnished to the beneficiary. CMS has proposed that reasonable efforts are made to provide a PA decision within 10 days of receipt of all applicable information, unless this timeline could seriously jeopardize the life or health of the beneficiary or the beneficiary's ability to regain maximum function, in which case the proposed PA decision would be 2 business days. CMS will issue additional sub-regulatory guidance on these timelines in the future. If our products are subject to prior authorization, it could reduce the number of patients qualified to come on service using their Medicare benefits, it could delay the start of those patients while we wait for the prior authorization to be received, and/or it could decrease sales productivity. As a result, this could adversely affect our business, financial conditions and results of operations.

Risks related to the regulatory environment

We are subject to extensive federal and state regulation, and if we fail to comply with applicable regulations, we could suffer severe criminal or civil sanctions and be required to make significant changes to our operations that could adversely affect our business, financial condition and results of operations.

The federal government and all states in which we currently operate regulate various aspects of our business. In particular, our operations are subject to state laws governing, among other things, distribution of medical equipment and certain types of home health activities, and we are required to obtain and maintain licenses in many states to act as a durable medical equipment supplier. Certain of our employees are subject to state laws and regulations governing the professional practice of respiratory therapy.

As a healthcare provider participating in governmental healthcare programs, we are subject to laws directed at preventing fraud and abuse, which subject our marketing, billing, documentation and other practices to strict government scrutiny. To ensure compliance with Medicare, Medicaid and other regulations, government agencies or their contractors often conduct routine audits and request customer records and other documents to support our claims submitted for payment of services rendered. Government agencies or their contractors also periodically open investigations and audits and obtain information from healthcare providers. Violations of federal and state laws or regulations can result in severe criminal, civil and administrative fines, penalties and sanctions, including debarment, suspension or exclusion from Medicare, Medicaid and other government reimbursement programs, any of which would have a material adverse effect on our business.

Changes in healthcare laws and regulations and new interpretations of existing laws and regulations may affect permissible activities, the relative costs associated with doing business, and reimbursement amounts paid by federal, state and other third-party payors. There have been and will continue to be regulatory initiatives affecting our business and we cannot predict the extent to which future legislation and regulatory changes could have a material adverse effect on our business.

We are subject to significant regulation by numerous government agencies, including the U.S. Food and Drug Administration, or FDA. We cannot market or commercially distribute our products without obtaining and maintaining necessary regulatory clearances or approvals and such approvals may be revoked or revised if an agency like the FDA believes it necessary.

Our products are medical devices subject to extensive regulation in the United States and in the foreign markets where we distribute our products. The FDA and other U.S. and foreign governmental agencies regulate, among other things, with respect to medical devices:

- design, development and manufacturing;
- testing, labeling, content and language of instructions for use and storage;
- clinical trials;
- product safety;
- marketing, sales and distribution;
- pre-market clearance and approval;
- record keeping;
- advertising and promotion;
- recalls and field safety 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;
- post-market approval studies; and
- product import and export.

Before we can market or sell a medical device in the United States, we must obtain either 510(k) clearance, clearance under the de novo process or approval of a pre-market approval application from the FDA, unless an exemption applies. In the 510(k) clearance process, the FDA must determine that a proposed device is "substantially equivalent" to a device legally on the market, known as a "predicate" device, with respect to intended use, technology and safety and effectiveness, in order to clear the proposed device for marketing.

Our commercial products have received 510(k) clearance by the FDA. If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, our product introductions or modifications could be delayed or canceled, which, depending on the specific action, could cause the majority of our sales to decline or cease altogether. In addition, the FDA may determine that future products will require the more costly, lengthy and uncertain pre-market approval process. Although we do not currently market any devices subject to pre-market approval, the FDA may demand that we obtain a pre-market approval prior to marketing certain future products. In addition, if the FDA disagrees with our determination that a product we currently market is subject to an exemption from pre-market review, the FDA may require us to submit a 510(k), de novo application or pre-market approval application in order to continue marketing the product. Further, even with respect to those future products where a pre-market approval is not required, we cannot assure you that we will be able to obtain the 510(k) clearances with respect to those products or do so in a timely fashion.

The FDA can delay, limit or deny clearance or approval of a device for many reasons, including:

- we may not be able to demonstrate to the FDA's satisfaction that our products are safe and effective for their intended uses;
- the data from our pre-clinical studies and clinical trials may be insufficient to support clearance or approval, where required; and
- the manufacturing process or facilities we use may not meet applicable Quality System Regulations.

Medical devices may only be promoted and sold for the indications for which they are approved or cleared. In addition, even if the FDA has approved or cleared a product, it can take action affecting such product approvals or clearances if serious safety or other problems develop in the marketplace. Delays in obtaining clearances or approvals could adversely affect our ability to introduce new products or modifications to our existing products in a timely manner, which would delay or prevent commercial sales of our products. Additionally, the FDA and other regulatory authorities have broad enforcement powers. Regulatory enforcement or inquiries, or other increased scrutiny on us, could affect the perceived safety and performance of our products and dissuade our customers from using our products.

If we modify our FDA cleared devices, we may need to seek additional clearances or approvals, which, if not granted, would prevent us from selling such modified products.

Any modification we make to our products that could significantly affect their safety or effectiveness, or would constitute a material change in intended use, manufacture, design, materials, labeling, or technology requires the submission and clearance of a new 510(k) pre-market notification, a de novo application or, possibly, pre-market approval. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review and disagree with any manufacturer's decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. We have modified some of our 510(k) cleared products and have determined that in certain instances new 510(k) clearances or pre-market approval are not required. We plan to make similar determinations regarding modifications to our 510(k) products, which may include the redesign of the G5 System motherboard pending validation testing. If the FDA disagrees with our determinations and requires us to submit new 510(k) notifications or pre-market approval for modifications to our previously cleared 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 penalties or fines.

The FDA issued a new Final Guidance titled Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE) in March 2020. The intent of the guidance is to help address the urgent COVID-19 PHE. It may expand the availability of devices that support patients with respiratory insufficiency due to COVID-19. The guidance allows certain modifications to applicable FDA-cleared respiratory devices without requiring

compliance with the pre-market requirements such as submitting a new 510(k). Manufacturers must ensure the device is safe and effective prior to placing the modified device on the market. This guidance and any future guidance or enforcement policy be the FDA may introduce new competitive products that could compete with our products with an easier regulatory pathway which could harm our business, financial condition and results of operations If Inogen uses this guidance to commercialize devices that do not have the FDA clearance, these products will have to go through FDA 510(k) clearance in the future, and may not be granted such clearance, which would mean we would have to withdraw these products from the market when the FDA terminates or revokes such guidance or enforcement policy, which could harm our business, financial condition and results of operations.

If we fail to comply with FDA or state regulatory requirements, we can be subject to enforcement action.

Even after we have obtained regulatory clearance or approval to market a product, we have ongoing responsibilities under FDA regulations. The FDA and state authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state agencies, which may include any of the following sanctions:

- adverse publicity, warning letters, fines, injunctions, consent decrees and civil penalties;
- recalls, termination of distribution, or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- delays in the introduction of products into the market;
- refusal to grant our requests for future 510(k) clearances or approvals of new products, new intended uses, or modifications to exiting products;
- withdrawals or suspensions of current 510(k) clearances or approvals, resulting in prohibitions on sales of our products; and
- criminal prosecution.

Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and have a material adverse effect on our reputation, business, results of operations and financial condition.

A recall of our products, either voluntarily or at the direction of the FDA or another governmental authority, or the discovery of serious safety issues with our products that leads to corrective actions, could have a significant adverse effect on us.

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design, labeling or manufacture of a product or in the event that a product poses an unacceptable risk to health. Manufacturers may also, under their own initiative, recall a product if any material deficiency in a device is found or withdraw a product to improve device performance or for other reasons. Similar regulatory agencies in other countries have similar authority to recall devices because of material deficiencies or defects in design or manufacture that could endanger health. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Any recall would divert management attention and financial resources, could cause the price of our stock to decline and expose us to product liability or other claims and harm our reputation with customers. A recall involving our Inogen concentrators could be particularly harmful to our business, financial condition and results of operations.

We are required to timely report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. Repeated product malfunctions may result in a voluntary or involuntary product recall. Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new approvals or clearances for the device before we may market or distribute the corrected device. Seeking such approvals or clearances 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 adverse publicity, FDA warning letters, product seizure, injunctions, administrative penalties, or civil or criminal fines. We may also be required to bear other costs or take other actions that may have a negative impact on our sales as well as face significant adverse publicity or regulatory consequences, which could harm our business, including our ability to market our products in the future.

Any adverse event involving our products, whether in the United States or abroad, could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection, mandatory recall or other enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and results of operations.

If we, our contract manufacturer, or our component manufacturers fail to comply with the FDA's Quality System Regulation, our manufacturing operations could be interrupted, and our product sales and operating results could suffer.

We, our contract manufacturer, and our component manufacturers are required to comply with the FDA's Quality System Regulation, or QSR, which covers the procedures and documentation of the design, calibration, testing, production, control, quality assurance, labeling, packaging, storage and shipping of our devices. The FDA audits compliance with the QSR through periodic announced and unannounced inspections of manufacturing and other facilities. We and our component manufacturers have been, and anticipate in the future being, subject to such inspections. Although we believe our manufacturing facilities and those of our component manufacturers are in compliance with the QSR, we cannot provide assurance that any future inspection will not result in adverse findings. If we fail to implement timely and appropriate corrective actions that are acceptable to the FDA or if our other manufacturing facilities or those of any of our component manufacturers, contract manufacturers, or suppliers are found to be in violation of applicable laws and regulations, or we or our manufacturers or suppliers fail to take prompt and satisfactory corrective action in response to an adverse inspection, the FDA could take enforcement action, including any of the following sanctions:

- adverse publicity, untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- customer notifications or repair, replacement, refunds, recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for 510(k) clearance or pre-market approval of new products or modified products;
- withdrawing 510(k) clearances or pre-market approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

Any of these sanctions could adversely affect our business, financial condition and results of operations.

Outside the United States, our products and operations are also often required to comply with standards set by industrial standards bodies, such as the International Organization for Standardization, or ISO. Foreign regulatory bodies may evaluate our products or the testing that our products undergo against these standards. The specific standards, types of evaluation and scope of review differ among foreign regulatory bodies. If we fail to adequately comply with any of these standards, a foreign regulatory body may take adverse actions similar to those within the power of the FDA. Any such action may harm our reputation and could have an adverse effect on our business, results of operations and financial condition.

The primary regulatory body in Europe is the European Commission, which includes most of the major countries in Europe. The European Commission has adopted numerous directives and standards regulating the design, manufacture, clinical trial, labeling and adverse event reporting for medical devices. Devices that comply with the requirements of a relevant directive will be entitled to bear the CE conformity marking, indicating that the device conforms to the essential requirements of the applicable directives and, accordingly, can be commercially distributed throughout Europe. The method of assessing conformity varies depending on the class of the product, but normally involves a combination of self-assessment by the manufacturer and a third-party assessment by a "Notified Body." An assessment by a Notified Body of one country within the European Union is required in order for a manufacturer to commercially distribute the product throughout the European Union.

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

Approximately 22.2%, 20.1% and 21.5% of our total revenue was from sales outside of the United States for the years ended December 31, 2021, 2020, and 2019, respectively. We have sold our products in a total of 59 international countries or overseas regions outside of the United States through our wholly owned subsidiary, distributors or directly to large "house" accounts. In order to market our products in the European Union or other foreign jurisdictions, we must obtain and maintain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies from country to country and can involve additional product testing. The time required to obtain approval abroad may be longer than the time required to obtain FDA clearance.

For example, the European Union requires that manufacturers of medical devices obtain the right to bear the "CE" conformity marking which designates compliance with existing directives and standards regulating the design, manufacture and distribution of medical devices in member countries of the European Union. In 2017, the European Union adopted the European Medical Device Regulation (Council Regulations 2017/745) which imposes stricter requirements for the marketing and sale of medical devices, including new clinical evaluation, quality system, and post-market surveillance requirements. The regulation had a three-year implementation period, with full application of the regulation occurring in May 2021 and replacing the pre-existing directives on medical devices in the European Union. Since May 2021, medical devices marketed in the European Union will require certification according to these new requirements, except that devices with valid CE certificates, issued pursuant to the Medical Device Directive before May 2021, including our oxygen therapy products with CE Marks issued under the Medical Device Directive, may be placed on the market until May 2024. Only medical devices that comply with certain conformity requirements of the Medical Device Directive are currently allowed to be marketed within the European Union and our products will be required to comply with the European Medical Device Regulation (MDR). New products that failed to be certified with the MDR by May 2021 may not be marketed or sold in the European Union. Similarly, existing products with CE Marks issued under the Medical Device Directive (MDD) may not be placed on the market in the European Union after May 2024. The extension of the existing certificates under the MDD or obtaining a new certificate under the MDR is required for continued marketing in the European Union after May 18, 2022. We are preparing the filing of the MDR submissions in the earlier part of 2022.

The foreign regulatory approval process, including with respect to MDR, includes many of the risks associated with obtaining FDA clearance and we may not obtain foreign regulatory approvals on a timely basis, if at all. FDA clearance does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries. However, the failure to obtain clearance or approval in one jurisdiction may have a negative impact on our ability to obtain clearance or approval elsewhere. If we do not obtain or maintain necessary approvals to commercialize our products in markets outside the United States, we may be required to discontinue sales in those countries which would negatively affect our overall market penetration, revenues, results of operations and financial condition.

If the FDA disagrees with us that certain of our data collection and analysis methods do not constitute clinical trials, our business may be harmed.

We gather and analyze certain de-identified retrospective patient data as part of our product development and improvement. We believe that these data collection methods do not constitute clinical trials and, therefore, typically do not pursue or obtain regulatory permission from the FDA or institutional review boards (IRBs) before collecting or analyzing such data. If the FDA disagrees with our interpretation, we may be subject to regulatory enforcement including warning letters, fines, injunctions, consent decrees and civil penalties. In addition, we may be required to collect these types of data under the clinical trial regulatory framework.

Clinical development is a long, expensive, and uncertain process and is subject to delays and the risk that products may ultimately prove unsafe or ineffective in treating the indications for which they are designed. Completion of clinical trials may take several years or more. We may experience numerous unforeseen events in relation to a clinical trial process that could delay or prevent us from receiving regulatory clearance or approval for new products or modifications of existing products, including new indications for existing products, including:

- delays or failure in obtaining approval of our clinical trial protocols from the FDA, other regulatory authorities, or IRBs;
- we, the applicable IRBs, the Data Safety Monitoring Board for such trial, or the FDA or other applicable regulatory authorities may require that we or our investigators suspend or terminate our data collection for various reasons, including, among others (i) failure to conduct the clinical trial in accordance with regulatory requirements, including the FDA's current Good Clinical Practice (GCP), regulations, or our clinical protocols, (ii) by the FDA or other applicable regulatory authority resulting in the imposition of a clinical hold, or (iii) lack of adequate patient informed consent; and
- delays if the FDA concludes that our financial relationships with our data collection partners result in a perceived or actual conflict of interest that may have affected the interpretation or integrity of the data collected. If these relationships and any related compensation to or ownership interest by our data collection partners carrying out the study result in perceived or actual conflicts of interest, or if the FDA concludes that the financial relationship may have affected interpretation of the data, the integrity of the data collected or analyzed may be questioned and the utility of the data itself may be jeopardized, which could result in the delay or rejection by the FDA. Any such delay or rejection could prevent us from commercializing any of our products currently in development.

Any delays in completing our data collection and analysis will increase our costs, slow down our product development and regulatory authorization process and jeopardize our ability to commence sales and generate associated revenue with respect to the applicable product. Any of these occurrences may significantly harm our business, financial condition, results of operations and prospects.

We are subject to complex billing and record-keeping requirements in order to substantiate our claims for payment under federal, state and commercial healthcare reimbursement programs, and our failure to comply with existing requirements, or changes in those requirements or interpretations thereof, could adversely affect our business, financial condition and results of operations.

We are subject to complex billing and record-keeping requirements in order to substantiate our claims for payment under federal, state and commercial healthcare reimbursement programs. Our records also are subject to routine and other reviews by third-party payors, which can result in delays in payments or refunds of paid claims. We could experience a significant increase in pre-payment reviews of our claims by the Durable Medical Equipment Medicare Administrative Contractors, which could cause substantial delays in the collection of our Medicare accounts receivable as well as related amounts due under supplemental insurance plans.

Current law provides for a significant expansion of the government's auditing and oversight of suppliers who care for patients covered by various government healthcare programs. Examples of this expansion include audit programs being implemented by the Durable Medical Equipment Medicare Administrative Contractors, the Unified Program Integrity Contractors, the Recovery Audit Contractors, and the Comprehensive Error Rate Testing contractors, operating under the direction of CMS, and the various state Medicaid Fraud Control Units.

We have been informed by these auditors that healthcare providers and suppliers of certain durable medical equipment product categories are expected to experience further increased scrutiny from these audit programs. When a government auditor ascribes a high billing error rate to one or more of our locations, it generally results in protracted pre-payment claims review, payment delays, refunds and other payments to the government and/or our need to request more documentation from providers than has historically been required. It may also result in additional audit activity in other company locations or Durable Medical Equipment Medicare Administrative Contractors jurisdiction. We cannot currently predict the adverse impact that these audits, methodologies and interpretations might have on our business, financial condition or results of operations, but such impact could be material.

We may be subject to fines, penalties or injunctions if we are determined to be promoting the use of our products for unapproved or "off-label" uses, resulting in damage to our reputation and business.

Our promotional materials and training methods must comply with the FDA and other applicable laws and regulations, including the prohibition of the promotion of a medical device for a use that has not been cleared or approved by the FDA. Physicians may use our products off-label, as the FDA does not restrict or regulate a physician's choice of treatment within the practice of medicine. If the FDA determines that our promotional materials or training constitutes promotion of an off-label use that is either false or misleading, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, which could have an adverse effect on our reputation and results of operations.

Failure to comply with the Federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, the Health Information Technology for Economic and Clinical Health Act, or HITECH Act, and implementing regulations could result in significant penalties.

Numerous federal and state laws and regulations, including HIPAA and the HITECH Act, govern the collection, dissemination, security, use and confidentiality of patient-identifiable health information. HIPAA and the HITECH Act require us to comply with standards for the use and disclosure of protected health information within our company and with third parties. The Privacy Standards and Security Standards under HIPAA establish a set of basic national privacy and security standards for the protection of individually identifiable health information by health plans, healthcare clearinghouses and certain healthcare providers, referred to as covered entities, and the business associates with whom such covered entities contract for services. Notably, whereas HIPAA previously directly regulated only these covered entities, the HITECH Act, which was signed into law as part of the stimulus package in February 2009, makes certain of HIPAA's privacy and security standards also directly applicable to covered entities' business associates. As a result, both covered entities and business associates are now subject to significant civil and criminal penalties for failure to comply with Privacy Standards and Security Standards.

HIPAA requires healthcare providers like us to develop and maintain policies and procedures with respect to protected health information that is used or disclosed, including the adoption of administrative, physical and technical safeguards to protect such information from unauthorized disclosure. The HITECH Act expands the notification requirement for breaches of patient-identifiable health information, restricts certain disclosures and sales of patient-identifiable health information and provides a tiered system for civil monetary penalties for HIPAA violations. The HITECH Act also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney fees and costs associated with pursuing federal civil actions. Additionally, certain states have adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA.

If we are determined to be out of compliance with existing or new laws and regulations related to patient health information, we could be subject to criminal or civil sanctions. New health information standards, whether implemented pursuant to HIPAA, the HITECH Act, congressional action or otherwise, could have a significant effect on the manner in which we handle healthcare related data and communicate with payors, and the cost of complying with these standards could be significant.

The 2013 final HITECH omnibus rule modified the breach reporting standard in a manner that made more data security incidents qualify as reportable breaches. Any liability from a failure to comply with the requirements of HIPAA or the HITECH Act could adversely affect our results of operations and financial condition. The costs of complying with privacy and security related legal and regulatory requirements are burdensome and could have a material adverse effect on our results of operations.

Regulations requiring the use of "standard transactions" for healthcare services issued under HIPAA may negatively affect our profitability and cash flows.

Pursuant to HIPAA, final regulations have been implemented to improve the efficiency and effectiveness of the healthcare system by facilitating the electronic exchange of information in certain financial and administrative transactions while protecting the privacy and security of the information exchanged.

The HIPAA transaction standards are complex, and subject to differences in interpretation by third-party payors. For instance, some third-party payors may interpret the standards to require us to provide certain types of information, including demographic information not usually provided to us by physicians. As a result of inconsistent application of transaction standards by third-party payors or our inability to obtain certain billing information not usually provided to us by physicians, we could face increased costs and complexity, a temporary disruption in accounts receivable and ongoing reductions in reimbursements and net revenue. Changes and updates to HIPAA transaction standards could prove technically difficult, time-consuming or expensive to implement, all of which could harm our business.

If we fail to comply with state and federal fraud and abuse laws, including anti-kickback, Physician Self-Referral Law, false claims and anti-inducement laws, we could face substantial penalties and our business, results of operations and financial condition could be adversely affected.

The Federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce the referral of an individual to a person for the furnishing of, or in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid, or other federal healthcare programs. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common financial arrangements from prosecution, the exceptions and safe harbors are drawn narrowly, and any remuneration to or from a prescriber or purchaser of healthcare products or services may be subject to scrutiny if it does not qualify for an exception or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability. Failure to meet all requirements of a safe harbor is not determinative of a kickback issue but could subject the practice to increased scrutiny by the government.

The Physician Self-Referral Law, commonly known as the "Stark Law," prohibits a physician from referring a patient to an entity with which the physician (or an immediate family member of the physician) has a financial relationship, for the furnishing of certain designated health services (DHS) for which payment may be made by Medicare or Medicaid, unless an exception applies. Violation of the Stark Law could result in denial of payment, disgorgement of reimbursements received under a non-compliant arrangement, civil penalties, and exclusion from Medicare, Medicaid or other federal healthcare programs. Although we believe that we have structured our provider arrangements to comply with current Stark Law requirements, regulatory authorities may determine otherwise.

The Federal False Claims Act prohibits any person from knowingly presenting or causing to be presented a false claim for payment to the federal government, or knowingly making or causing to be made a false statement to get a false claim paid. The Federal False Claims Act allows any person to bring suit in the name of the government alleging false and fraudulent claims presented to or paid by the government (or other violations of the statute) and to share in any amounts paid by the entity to the government in fines or settlement. Such suits, known as *qui tam* actions, have increased significantly in the healthcare industry in recent years. Sanctions under this federal law may include civil monetary penalties, exclusion from federal and state healthcare programs, criminal fines and imprisonment. In addition, the Patient Protection and Affordable Care Act, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. In addition, the Patient Protection and Affordable Care Act provides that the government may assert that a claim that 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 statutes. Because of the breadth of these laws and the narrowness of the safe harbors and exceptions, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Such a challenge, regardless of the outcome, could have a material adverse effect on our business, business relationships, reputation, financial condition and results of operations. The majority of states also have statutes or regulations similar to the federal anti-kickback, physician self-referral, and false claims laws, which apply to items or services, reimbursed under Medicaid and other state programs, or in several states, apply regardless of payor. Penalties under these state laws can be comparable to those under their federal equivalents.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, also created the federal Physician Payments Sunshine Act, which requires applicable manufacturers of drugs, devices, biologicals, and medical supplies covered under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to CMS, information related to payments or other transfers of value made to physicians, as defined, and teaching hospitals, as well as ownership and investment interests in such manufacturer held by physicians and their immediate family members. Additionally, the Substance Use-Disorder Prevention that Promoted Opioid Recovery and Treatment for Patients and Communities Act enacted in 2018, extends the reporting and transparency requirements for physicians under the Physician Payments Sunshine Act to physician assistants, nurse practitioners and other mid-level practitioners, with reporting requirements going into effect in 2022 for payments made in 2021. Failure to submit the required information under the federal Physician Payment Sunshine Act may result in civil monetary penalties of up to an aggregate of $0.18 million per year (and up to an aggregate of $1.177 million per year for "knowing failures"), subject to an annual adjustment for inflation.

In addition, there has been a recent trend of increased federal and state regulation of payments and other transfers of value made to applicable recipients, including physicians. Certain states mandate implementation of compliance programs and/or the tracking and annual reporting of gifts, compensation and other remuneration to physicians and other applicable recipients. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance and/or reporting requirements in multiple jurisdictions increase the possibility that a healthcare company may violate one or more of the requirements.

The Federal Civil Monetary Penalties Law grants authority to the HHS Office of Inspector General (OIG) to seek civil monetary penalties (CMPs) against an individual or entity based on a wide variety of conduct including violations of the Anti-Kickback Statute, Stark Law, and False Claims Act. An entity that offers to or transfers remuneration to any individual eligible for benefits under Medicare or Medicaid that such entity knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any Medicare or Medicaid payable item or service may be liable for CMPs. This is commonly known as a beneficiary inducement. We sometimes offer customers various discounts and other financial incentives in connection with the sales of our products. While it is our intent to comply with all applicable laws, including the safe harbor regulation for discounts, the federal government may find that our marketing activities violate the law. If we are found to be in non-compliance, we could be subject to CMPs of up to $0.022 million (subject to annual adjustment for inflation) for each wrongful act, assessment of three times the amount claimed for each item or service and exclusion from the federal or state healthcare programs.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restriction of our operations or exclusion from participation in the federal healthcare programs. Any penalties, damages, fines, curtailment or restructuring or our operations could harm our ability to operate our business and our results of operations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state fraud laws may prove costly. HHS makes annual inflation-related increases to the civil monetary penalties in its regulations pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015. The HHS Annual Civil Monetary Penalties Inflation Adjustment Final Rule issued on November 15, 2021 sets forth adjusted civil monetary penalty amounts that apply to penalties assessed on or after November 15, 2021, if the violation occurred on or after November 2, 2015.

We are also exposed to the risks of fraud, misconduct, or other illegal activity by our employees and third parties who act for us or on our behalf, such as our independent contractors, consultants, commercial partners, and vendors. It is not always possible to identify and deter misconduct by employees and third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with federal and state healthcare fraud and abuse laws. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Foreign governments tend to impose strict price controls, which may adversely affect our future profitability.

We have sold our products in a total of 59 international countries or overseas regions outside the United States through our wholly owned subsidiary, distributors or directly to large "house" accounts. In some foreign countries, particularly in the European Union, the pricing of medical devices is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to supply data that compares the cost-effectiveness of our products versus other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, it may not be profitable to sell our products in certain foreign countries, which would negatively affect the long-term growth of our business.

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

Our research and development programs as well as our manufacturing operations involve the controlled use of hazardous materials. Accordingly, we are subject to international, federal, state and local laws governing the use, handling and disposal of these materials. Although we believe that our safety procedures for handling and disposing of these materials comply in all material respects with the standards prescribed by state and federal regulations of each country in which we conduct business, we cannot completely eliminate the risk of accidental contamination or injury from these materials. In the event of an accident or failure to comply with environmental laws, we could be held liable for resulting damages, and any such liability could exceed our insurance coverage and adversely affect our financial condition and results of operations.

Regulatory requirements under Proposition 65 could adversely affect our business.

We are subject to California's Proposition 65, or Prop 65, which requires a specific warning on any product that contains a substance listed by the State of California as having been found to cause cancer or birth defects, unless the level of such substance in the product is below a safe harbor level. Prop 65 required that all businesses must be in compliance by August 30, 2018 with new regulations that require modifications to product warnings and for businesses to coordinate with upstream vendors or downstream customers for the 800+ regulated chemicals in consumer products and assess whether new occupational exposure warnings need to be posited in California facilities. We have taken steps to add warning labels to our products packaged in California and manufactured after August 30, 2018. Although we cannot predict the ultimate impact of these requirements, they could reduce overall consumption of our products or leave consumers with the perception (whether or not valid) that our products do not meet their health and wellness needs, all of which could adversely affect our business, financial condition andresults of operations.

Risks related to our intellectual property

If we are unable to secure and maintain patent or other intellectual property protection for the intellectual property used in our products, we will lose a significant competitive advantage, which may adversely affect our future profitability.

Our commercial success depends, in part, on obtaining, defending, and maintaining 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. Furthermore, we might in the future opt to license intellectual property from other parties. If we, or the other parties from whom we would license intellectual property, fail to obtain, defend, and maintain adequate patent or other intellectual property protection for intellectual property used in our products, or if any protection is reduced or eliminated, others could use the intellectual property used in our products, resulting in harm to our competitive business position. In addition, patent and other intellectual property protection may not:

- prevent our competitors from duplicating our products;
- prevent our competitors from gaining access to our proprietary information and technology;
- prevent our competitors from producing counterfeit products;
- prevent our competitors or other parties from suing us for alleged infringement; or
- permit us to gain or maintain a competitive advantage.

Any of our patents may be challenged, invalidated, circumvented or rendered unenforceable. We cannot provide assurance that we will be successful should one or more of our patents be challenged for any reason. If our patent claims are rendered invalid or unenforceable, or narrowed in scope, the patent coverage afforded our products could be impaired, which could make our products less competitive.

As of December 31, 2021, we have twenty-seven pending U.S. and international patent applications, forty-seven issued U.S. patents, and nineteen issued foreign patents relating to the design and construction of our oxygen concentrators, our intelligent delivery technology and our TAV product, including its proprietary nasal interface. We cannot specify which of these patents individually or as a group will permit us to gain or maintain a competitive advantage. Patents may be subject to reexamination, *inter partes* review, post-grant review, and derivation proceedings in the U.S. Patent and Trademark Office or comparable proceedings in other patent offices worldwide, or challenges to inventorship in court. Foreign patents may be subject to opposition or comparable proceedings in the corresponding foreign patent offices and courts. Any of these proceedings could result in loss of the patent or denial of the patent application, or loss or reduction in the scope of one or more of the claims of the patent or patent application. Changes in either patent laws or in interpretations of patent laws may also diminish the value of our intellectual property or narrow the scope of our protection. Interference, reexamination, *inter partes* review, post grant review, defense, opposition, inventorship, and derivation proceedings may be costly and time consuming, and we, or the other parties from whom we might potentially license intellectual property, may be unsuccessful in defending against such proceedings. Thus, any patents that we own or might license may provide limited or no protection against competitors. In addition, our pending patent applications and those we may file in the future may have claims narrowed during prosecution or may not result in patents being issued. Even if any of our pending or future applications are issued, they may not provide us with any competitive advantage or adequate protection from allegations of infringement, whether valid or frivolous, which may result in the incurrence of material defense costs. Our patents and patent applications are directed to particular aspects of our products. Other parties may develop and obtain patent protection for more effective technologies, designs or methods for oxygen therapy. If these developments were to occur, it would likely have an adverse effect on our sales. Our ability to develop additional patentable technology is also uncertain.

Non-payment or delay in payment of patent fees or annuities, whether intentional or unintentional, may also result in the loss of patents or patent rights important to our business. Many countries, including certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to other parties. In addition, many countries limit the enforceability of patents against other parties, including government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the patent. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as do the laws of the United States, particularly in the field of medical products and procedures.

Our products could infringe or appear to infringe the intellectual property rights of others, which may lead to patent and other intellectual property litigation that could itself be costly, could result in the payment of substantial damages or royalties, prevent us from using technology that is essential to our products, and/or force us to discontinue selling our products.

The medical device industry in general has been characterized by extensive litigation and administrative proceedings regarding patents and other intellectual property rights. Our competitors hold a significant number of patents relating to respiratory therapy devices and products. Third parties have in the past asserted and may in the future assert that we are employing their proprietary technology without authorization. For example, Breathe Technologies, Inc. (Breathe), a subsidiary of Hill-Rom Holdings, filed a lawsuit against us, New Aera, Inc., Silverbow Development LLC, and one of our employees on November 21, 2019 in the United States District Court for the Northern District of California. The lawsuit alleged, among other things, willful infringement of a patent assigned to Breathe, that inventorship was incorrectly assigned and that Breathe has rights to certain patents filed by New Aera, Inc. and Silverbow Development LLC, breach of contract, inducing breach of contract, interference with contract, and violation of California Business and Professional Code section 17200. While we settled our lawsuit with Breathe in January 2021, if we fail in defending against lawsuits or claims brought against us in the future, we could be subject to substantial monetary damages, injunctive relief, and loss of valuable intellectual property rights, and we cannot predict the outcome of any lawsuit. An adverse determination or protracted defense costs of such lawsuits could have a material effect on our business and operating results.

From time to time, we have also commenced litigation to enforce our intellectual property rights. For example, we previously pursued litigation against Inova Labs, Inc. (a subsidiary of ResMed Corp.) for infringement of two of our patents seeking damages, injunctive relief, costs, and attorneys' fees. While we settled our lawsuit with Inova Labs in June 2016, an adverse decision in any other legal action could limit our ability to assert our intellectual property rights, limit the value of our technology or otherwise negatively affect our business, financial condition and results of operations.

Monitoring unauthorized use of our intellectual property is difficult and costly. Unauthorized use of our intellectual property may have occurred or may occur in the future. Although we have taken steps to minimize the risk of this occurring, any such failure to identify unauthorized use and otherwise adequately protect our intellectual property would adversely affect our business. Moreover, if we are required to commence litigation, whether as a plaintiff or defendant, not only will this be time-consuming, but we will also be forced to incur significant costs and divert our attention and efforts of our employees, which could, in turn, result in lower revenue and higher expenses.

We cannot provide assurance that our products or methods do not infringe or appear to not infringe the patents or other intellectual property rights of third parties and if our business is successful, the possibility may increase that others will assert infringement claims against us whether valid or frivolous.

Determining whether a product infringes a patent involves complex legal and factual issues, defense costs and the outcome of a patent litigation action are often uncertain. We have not conducted an extensive search of patents issued or assigned to other parties, including our competitors, and no assurance can be given that patents containing claims covering or appearing to cover our products, parts of our products, technology or methods do not exist, have not been filed or could not be filed or issued. Because of the number of patents issued and patent applications filed in our technical areas, our competitors or other parties may assert that our products and the methods we employ in the use of our products are covered by U.S. or foreign patents held by them. In addition, because patent applications can take many years to issue and because publication schedules for pending applications may vary by jurisdiction and some patent applications may not be published in the U.S., there may be applications now pending of which we are unaware and which may result in issued patents that our current or future products infringe or appear to infringe. Also, because the claims of published patent applications can change between publication and patent grant, there may be published patent applications that may ultimately issue with claims that we infringe. There could also be existing patents that one or more of our products or parts may infringe and of which we are unaware. As the number of competitors in the market for respiratory products and the number of patents issued in this area grows, the possibility of patent infringement claims against us increases. In certain situations, we may determine that it is in our best interests to voluntarily challenge a party's patents in litigation or other proceedings, including declaratory judgment actions, patent reexaminations, post grant reviews, or *inter partes* reviews. As a result, we may become involved in unwanted protracted litigation that could be costly, result in diversion of management's attention, require us to pay damages and/or licensing royalties and force us to discontinue selling our products.

Infringement and other intellectual property claims and proceedings brought against us, whether successful or not, could result in substantial costs and harm to our reputation. Such claims and proceedings can also distract and divert management and key personnel from other tasks important to the success of the business. We cannot be certain that we will successfully defend against allegations of infringement of patents or other intellectual property rights. In the event that we become subject to a patent infringement or other intellectual property related lawsuit and if the asserted patents or other intellectual property were upheld as valid and enforceable and we were found to infringe the asserted patents or other intellectual property, or violate the terms of a license to which we are a party, we could be required to do one or more of the following:

- cease selling or using any of our products that incorporate the asserted intellectual property, which would adversely affect our revenue;
- pay damages for past use of the asserted intellectual property, which may be substantial;
- obtain a license from the holder of the asserted intellectual property, which license may not be available on reasonable royalty terms, if at all, and which could reduce profitability; and
- redesign or rename, in the case of trademark claims, our products to avoid infringing the intellectual property rights of third parties, which may not be possible and could be costly and time-consuming if it is possible to do so.

If we are unable to prevent unauthorized use or disclosure of trade secrets, unpatented know-how and other proprietary information, our ability to compete will be harmed.

We rely on a combination of trade secrets, copyrights, trademarks, confidentiality agreements and other contractual provisions and technical security measures to protect certain aspects of our technology, especially where we do not believe that patent protection is appropriate or obtainable. We require our employees and consultants to execute confidentiality agreements in connection with their employment or consulting relationships with us. We also require our employees and consultants to disclose and assign to us all inventions conceived during the term of their employment or engagement while using our property or that relate to our business. We also require our corporate partners, outside scientific collaborators and sponsored researchers, advisors and others with access to our confidential information to sign confidentiality agreements. We also have taken precautions to initiate reasonable safeguards to protect our information technology systems. However, these measures may not be adequate to safeguard our proprietary intellectual property and conflicts may, nonetheless, arise regarding ownership of inventions and other intellectual property. Such conflicts may lead to the loss or impairment of our intellectual property or to expensive litigation to defend our rights against competitors who may be better funded and have superior resources. Our employees, consultants, contractors, outside clinical collaborators and other advisors may unintentionally or willfully disclose our confidential information to competitors. In addition, confidentiality agreements may be unenforceable or may not provide an adequate remedy in the event of unauthorized disclosure. Enforcing a claim that a third party illegally obtained and is using our trade secrets is expensive and time-consuming, and the outcome is unpredictable. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary, and in such cases we could not assert any trade secret rights against such party. As a result, other parties may be able to use our proprietary technology or information, and our ability to compete in the market would be harmed.

“Inogen,” “Inogen One,” “Inogen One G2,” “Inogen One G3,” “G4,” “G5,” “Live Life in Moments, not Minutes,” “Never Run Out of Oxygen,” “Oxygen Therapy on Your Terms,” “Oxygen.Anytime.Anywhere,” “Reclaim Your Independence,” “Intelligent Delivery Technology,” “Inogen At Home,” the Inogen design, “TIDAL ASSIST,” “TAV,” and “SIDEKICK” are registered trademarks with the United States Patent and Trademark Office of Inogen, Inc. We own a pending application for “Inogen” with the United States Patent and Trademark Office. We own trademark registrations for the mark “Inogen” in Argentina, Australia, Canada, Chile, China, Columbia, Ecuador, South Korea, Mexico, Europe (European Union registration), the United Kingdom, Iceland, India, Israel, Japan, Kuwait, New Zealand, Norway, Paraguay, Peru, Turkey, Singapore, Switzerland, and Uruguay. We own pending applications for the mark “Inogen” in Brazil, India, Malaysia, and South Africa. We own a trademark registration for the mark “イノジェン” in Japan. We own trademark registrations for the marks “印诺真” and “艾诺根” in China. We own trademark registrations for the mark “Inogen One” in Australia, Canada, China, South Korea, Mexico, Europe (European Union registration), and the United Kingdom. We own a trademark registration for the mark “Satellite Conserver” in Canada. We own a trademark registration for the mark “Inogen At Home” in Europe (European Union Registration) and the United Kingdom. We own trademark registrations for the mark “G4” in Europe (European Union registration) and the United Kingdom. We own trademark registrations for the mark “G5” in Europe (European Union Registration) and the United Kingdom. We own a trademark application for the Inogen design in Bolivia. We own a trademark registration for the Inogen design in China. We own a trademark registration for the mark “إنوجن” in Saudi Arabia. Other service marks, trademarks, and trade names referred to in this Annual Report on Form 10-K are the property of their respective owners.

We may be subject to damages resulting from claims that our employees, agents or we have wrongfully used or disclosed alleged trade secrets of other companies.

Some of our employees and consultants, including employees who joined us following our acquisition of New Aera, were previously employed by or contracted with other medical device companies focused on the development of oxygen therapy products, including our competitors. We may be subject to claims that these employees or agents have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. For example, Breathe Technologies, Inc. (Breathe), a subsidiary of Hill-Rom Holdings, filed a lawsuit against us, New Aera, Inc., Silverbow Development, LLC, and one of our employees on November 21, 2019 in the United States District Court for the Northern District of California. The lawsuit alleged, among other things, willful infringement on certain patents, declared that inventorship was incorrectly assigned and their rights to certain patents filed by New Aera, Inc. and Silverbow Development, LLC, breach of contract, inducing breach of contract, interference with contract, and violation of California Business and Professional Code section 17200. While we settled our lawsuit with Breathe, if we fail in defending against such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights and may be enjoined from using valuable technology in our products. Even if we are successful in defending against these claims, litigation could result in substantial costs, damage to our reputation and be a distraction to management.

Risks related to being a public company

We will incur increased costs as a result of operating as a public company and our management will be required to devote substantial time to compliance initiatives and corporate governance practices.

As a public company, especially now that we are no longer an "emerging growth company," we will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002 and rules enforced by the Public Companies Oversight Board (PCAOB) subsequently implemented by the SEC and the NASDAQ Global Select Market impose numerous requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Also, the Securities Exchange Act of 1934, as amended, or the Exchange Act, requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. Our management and other personnel will need to devote a substantial amount of time to compliance with these laws and regulations. These requirements have increased and will continue to increase our legal, accounting, external audit and financial compliance costs and have made and will continue to make some activities more time consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to incur substantial costs to maintain the same or similar coverage. These rules and regulations could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or our board committees or as executive officers.

Overall, we estimate that our incremental costs resulting from operating as a public company, including compliance with these rules and regulations, may be between $3.0 million and $5.0 million per year. However, these rules and regulations 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 and public accounting firms are subject to PCAOB compliance audits. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

The Sarbanes-Oxley Act requires, among other things, that we assess and document the effectiveness of our internal control over financial reporting annually and the effectiveness of our disclosure controls and procedures quarterly. In particular, Section 404(a) of the Sarbanes-Oxley Act, or Section 404(a), requires us to perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting. Section 404(b) of Sarbanes-Oxley Act, or Section 404(b), also requires our independent registered public accounting firm to attest to the effectiveness of our internal control over financial reporting. Now that we are no longer an "emerging growth company," our independent registered public accounting firm is required to undertake an assessment of our internal control over financial reporting, and the cost of our compliance with Section 404(b) is higher. Our compliance with applicable provisions of Section 404 will require that we incur substantial accounting expense and expend significant management time on compliance-related issues as we implement additional corporate governance practices and comply with reporting requirements.

Furthermore, investor perceptions of our company may suffer if deficiencies are found, and this could cause a decline in the market price of our stock. Irrespective of compliance with Section 404, any failure of our internal control over financial reporting could have a material adverse effect on our stated operating results and harm our reputation. If we are unable to implement these requirements effectively or efficiently, it could harm our operations, financial reporting, or financial results and could result in an adverse opinion on our internal controls from our independent registered public accounting firm.

Failure to maintain effective internal controls could cause our investors to lose confidence in us and adversely affect the market price of our common stock. If our internal controls are not effective, we may not be able to accurately report our financial results or prevent fraud.

Section 404 of the Sarbanes-Oxley Act, or Section 404, requires that we maintain internal control over financial reporting that meets applicable standards. We may err in the design, operation or documentation of our controls, and all internal control systems, no matter how well designed and operated, can provide only reasonable assurance that the objectives of the control system are met. Because there are inherent limitations in all control systems, there can be no absolute assurance that all control issues have been or will be detected. If we are unable, or are perceived as unable, to produce reliable financial reports due to internal control deficiencies, investors could lose confidence in our reported financial information and operating results, which could result in a negative market reaction.

We are required to disclose significant changes made in our internal controls and procedures on a quarterly basis. Now that we are no longer an "emerging growth company," our independent registered public accounting firm is also required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404. Our independent registered public accounting firm may issue a report that is adverse in the event it is not satisfied with the level at which our controls are documented, designed or operating. Our remediation efforts may not enable us to avoid a material weakness in the future. Additionally, to comply with the requirements of being a public company, we may need to undertake various actions, such as implementing new internal controls and procedures and hiring accounting or internal audit staff or consultants, which may adversely affect our results of operations and financial condition.

Although prior material weaknesses have been remediated, we cannot assure you that our internal controls will continue to operate properly or that our financial statements will be free from error. There may be undetected material weaknesses in our internal control over financial reporting, as a result of which we may not detect financial statement errors on a timely basis. Moreover, in the future we may implement new offerings and engage in business transactions, such as acquisitions, reorganizations or implementation of new information systems that could require us to develop and implement new controls and could negatively affect our internal control over financial reporting and result in material weaknesses.

If we identify new material weaknesses in our internal control over financial reporting, if we are unable to comply with the requirements of Section 404 in a timely manner, if we are unable to assert that our internal controls over financial reporting are effective, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting, we may be late with the filing of our periodic reports, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be negatively affected. As a result of such failures, we could also become subject to investigations by the stock exchange on which our securities are listed, the SEC, or other regulatory authorities, and become subject to litigation from investors and stockholders, which could harm our reputation, financial condition or divert financial and management resources from our core business.

Risks related to our common stock

We expect that our stock price will fluctuate significantly, you may have difficulty selling your shares, and you could lose all or part of your investment.

Our stock is currently traded on NASDAQ, but we can provide no assurance that we will be able to maintain an active trading market on NASDAQ or any other exchange in the future. If an active trading market does not develop, you may have difficulty selling any of our shares of common stock that you buy. In addition, 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. These factors include:

- actual or anticipated quarterly variation in our results of operations or the results of our competitors;
- announcements of secondary offerings;
- announcements by us or our competitors of new commercial products, significant contracts, commercial relationships or capital commitments;
- issuance of new or changed securities analysts' reports or recommendations for our stock;
- developments or disputes concerning our intellectual property or other proprietary rights;
- commencement of, or our involvement in, litigation;
- market conditions in the oxygen therapy market;
- reimbursement or legislative changes in the oxygen therapy market;

- failure to complete significant sales;
- manufacturing disruptions that could occur if we were unable to successfully expand our production in our current or an alternative facility or due to any other reason;
- any future sales of our common stock or other securities;
- any major change to the composition of our board of directors or management;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- the other factors described in this "Risk Factors" section; and
- general economic conditions and slow or negative growth of our markets.

The stock market in general and market prices for the securities of technology-based companies like ours in particular, have from time-to-time experienced volatility that often has been unrelated to the operating performance of the underlying companies. These broad market and industry fluctuations may adversely affect the market price of our common stock, regardless of our operating performance. In several recent situations where the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock.

Stockholder litigation has been filed against us in the past, and a class action securities lawsuit and related derivatives complaints against us are currently pending, as discussed in the "Legal Proceedings" section of this Annual Report on Form 10-K. While we are continuing to defend such actions vigorously, the defense of such actions can be costly, divert the time and attention of our management and harm our operating results, and any judgment against us or any future stockholder litigation could result in substantial costs.

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

The trading market for our common stock will rely in part on the research and reports that equity research analysts publish about us and our business. We will not have any control of the analysts or the content and opinions included in their reports. The price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

Future sales of shares could cause our stock price to decline.

Our stock price could decline as a result of sales of a large number of shares of our common stock or the perception that these sales could occur. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

We have also registered the offer and sale of all shares of common stock that we may issue under our equity compensation plans. In addition, in the future, we may issue additional shares of common stock or other equity or debt securities convertible into common stock in connection with a financing, acquisition, litigation settlement, and employee arrangements or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause our stock price to decline.

Our directors, executive officers and principal stockholders will continue to have substantial control over us and could limit your ability to influence the outcome of key transactions, including changes of control.

As of December 31, 2021, our executive officers, directors and stockholders who owned more than 5% of our outstanding common stock and their respective affiliates beneficially owned or controlled approximately 53.6% of the outstanding shares of our common stock. Accordingly, these executive officers, directors and stockholders who owned more than 5% of our outstanding common stock and their respective affiliates, acting as a group, have substantial influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of our assets or any other significant corporate transactions. These stockholders may also delay or prevent a change of control of us, even if such a change of control would benefit our other stockholders. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management and limit the market price of our common stock.

Provisions in our certificate of incorporation and bylaws may have the effect of delaying or preventing a change of control or changes in our management. Our amended and restated certificate of incorporation and amended and restated bylaws include provisions that:

- authorize our board of directors to issue, without further action by the stockholders, up to 10,000,000 shares of undesignated preferred stock;
- require that any action to be taken by our stockholders be affected at a duly called annual or special meeting and not by written consent;
- specify that special meetings of our stockholders can be called only by our board of directors, the Chairman of the board of directors, or the Chief Executive Officer;
- 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;
- establish that our board of directors is divided into three classes, Class I, Class II and Class III, with each class serving staggered three-year terms;
- provide that our directors may be removed only for cause;
- 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;
- specify that no stockholder is permitted to cumulate votes at any election of directors; and
- require a super-majority of votes to amend certain of the above-mentioned provisions.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or combine with us.

We have never paid dividends on our capital stock, and we do not anticipate paying any cash dividends in the foreseeable future.

We have paid no cash dividends on any of our classes of capital stock to date and currently intend to retain our future earnings to fund the development and growth of our business. In addition, we may become subject to covenants under future debt arrangements that place restrictions on our ability to pay dividends. As a result, capital appreciation, if any, of our common stock is expected to be your sole source of gain for the foreseeable future.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

As of December 31, 2021, we lease approximately 51,000 square feet of manufacturing and office space at our corporate headquarters in Goleta, California under a lease that expires in March 2030; approximately 154,000 square feet of manufacturing and office space in Plano, Texas under a lease that expires in April 2031; and approximately 94,000 square feet of office space in Cleveland, Ohio under a lease that expires in September 2024. In addition, we lease approximately 4,000 square feet of office space in Smyrna, Tennessee; Huntsville, Alabama; Aurora, Colorado; and Breukelen in the Netherlands with lease terms of 3 years. We also own land and office space in Manitowoc, Wisconsin. We believe that our existing facilities are adequate to meet our current business requirements and that if additional space is required, it will be available on commercially reasonable terms. In addition, we believe that our properties are in good condition and are adequate and suitable for their intended purposes.

ITEM 3. LEGAL PROCEEDINGS

Securities class action and derivative lawsuits

On March 6, 2019, plaintiff William Fabbri filed a lawsuit against Inogen, Scott Wilkinson, and Alison Bauerlein, in the United States District Court for the Central District of California on behalf of a purported class of purchasers of the Company's securities. On March 21, 2019, plaintiff Steven Friedland filed a substantially similar lawsuit against the same defendants in the same court. On May 20, 2019, the court issued an order consolidating the two lawsuits under the name *In re Inogen, Inc. Sec. Litig.,* No. 2:19-cv-01643-FMO-AGR, appointing Dr. John Vasil and Paragon Fund Management as lead plaintiffs, and appointing Robbins Geller Rudman & Dowd LLP and Glancy Prongay & Murray LLP as lead plaintiffs' counsel. On July 10, 2019, the lead plaintiffs filed a consolidated amended complaint on behalf of a purported class of purchasers of the Company's common stock between November 8, 2017 and May 7, 2019. The complaint generally alleges that the defendants failed to disclose that: (i) Inogen had overstated the true size of the total addressable market for its portable oxygen concentrators and had misstated the basis for its calculation of the total addressable market; (ii) Inogen had falsely attributed its sales growth to the strong sales acumen of its sales force, rather than to deceptive sales practices; (iii) the growth in Inogen's domestic business-to-business sales to home medical equipment providers was inflated, unsustainable and was eroding direct-to-consumer sales; and (iv) Inogen's decision to focus on sales over rentals of portable oxygen concentrators harmed its ability to serve the Medicare market, in violation of sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended. The complaint seeks compensatory damages in an unspecified amount, costs and expenses, including attorneys' fees and expert fees, prejudgment and post-judgment interest and such other relief as the court deems proper. On January 2, 2020, the court dismissed the consolidated amended complaint with leave to amend. On January 9, 2020, the plaintiffs filed a second amended complaint generally alleging substantially similar claims as those in the previous complaint. On January 23, 2020, the defendants filed a motion to dismiss the second amended complaint. On September 2, 2020, the court denied the defendants' motion to dismiss without prejudice and instructed defendants to file another motion to dismiss if the parties are unable to resolve the issues relating to the second amended complaint. The Company filed its motion to dismiss on October 28, 2020. On August 13, 2021, the court granted Defendants' motion to dismiss, and on September 27, 2021, the court entered judgment dismissing the action in its entirety.

On June 26, 2019, plaintiff Twana Brown filed a shareholder derivative lawsuit against Inogen, Scott Wilkinson, Alison Bauerlein, Benjamin Anderson-Ray, Scott Beardsley, R. Scott Greer, Raymond Huggenberger, Heath Lukatch, Loren McFarland, and Heather Rider in the United States District Court for the Central District of California. The complaint purports to bring claims on behalf of Inogen against the individual defendants for breaches of their fiduciary duties as directors and/or officers of Inogen, unjust enrichment, waste of corporate assets and violations of section 14(a) of the Securities Exchange Act of 1934, as amended. The complaint generally alleges similar claims to the securities class action. The complaint seeks compensatory damages and restitution in an unspecified amount, changes to the Company's corporate governance and internal procedures, costs and expenses, including attorneys' fees and expert fees, and such other relief as the court deems proper. On August 5, 2019, the court issued an order staying the derivative action pending the resolution of the motion to dismiss stage in *In re Inogen, Inc. Sec. Litig.* Between October 7, 2019 and October 31, 2019, three additional shareholder derivative complaints were filed in the United States District Court for the Central District of California based on similar factual allegations. These lawsuits purport to bring claims on behalf of Inogen for breach of fiduciary duty, unjust enrichment, waste of corporate assets, insider trading and misappropriation of information, and violations of section 14(a) of the Securities Exchange Act of 1934, as amended. On January 13, 2020, the court consolidated the four derivative lawsuits before it under the name *In re Inogen, Inc. S'holder Deriv. Litig*., Lead Case No. 2:19-cv-5568-FMO-AGR and ordered that the consolidated action be stayed pending the resolution of the motion to dismiss stage in *In re Inogen, Inc., Sec. Litig.* On November 10, 2021, the plaintiffs filed a Notice of Voluntary Dismissal Without Prejudice. On February 8, 2022, the court dismissed the California derivative action without prejudice.

On September 13, 2019, plaintiff Dustin Weller filed a shareholder derivative lawsuit against Inogen, Scott Wilkinson, Alison Bauerlein, Benjamin Anderson-Ray, Scott Beardsley, R. Scott Greer, Raymond Huggenberger, Heath Lukatch, Loren McFarland, and Heather Rider in the United States District Court for the District of Delaware captioned *Weller v. Wilkinson, et al*., No. 1:19-cv-01723-MN. On October 17, 2019, plaintiff Sharokh Soltanipour filed a shareholder derivative lawsuit against the same defendants in the same court, captioned *Soltanipour v. Wilkinson, et al*., No. 1:19-cv-1968-MN. The complaints generally allege similar claims to those in *In re Inogen, Inc., S'holder Deriv. Litig.* The complaints purport to bring claims on behalf of Inogen for breach of fiduciary duty, unjust enrichment, waste of corporate assets, abuse of control, gross mismanagement, insider selling and misappropriation of information, violations of section 14(a) of the Securities Exchange Act of 1934, as amended, and for contribution from certain of the individual defendants. The complaints seek compensatory damages in unspecified amounts, changes to the Company's corporate governance and internal procedures, return of compensation, disgorgement of profits from sale of stock, costs and expenses, including attorneys' fees and expert fees, and such other relief as the court deems proper. On May 15, 2020, the court consolidated the two derivative lawsuits before it under the name *In re Inogen, Inc. S'holder Deriv. Litig*., Lead Case No. 1:19-cv-01723-MN-JLH. On July 8, 2020, the court ordered that the consolidated action be stayed pending the resolution of the motion to dismiss in the securities class action, *In re Inogen, Inc., Sec. Litig*. On November 3, 2021, the court approved the parties' stipulation to voluntarily dismiss the Delaware derivative action without prejudice.

Other litigation

In addition to the lawsuits discussed above, the Company is party to various legal proceedings arising in the normal course of business. The Company carries insurance, subject to specified deductibles under the policies, to protect against losses from certain types of legal claims. At this time, the Company does not anticipate that any of these other proceedings arising in the normal course of business will have a material adverse effect on the Company's business. Regardless of the outcome, litigation can have an adverse impact on the Company because of defense and settlement costs, diversion of management resources, and other factors.

ITEM 4. MINE SAFETY DISCLOSURES

None.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market information and holders

Our common stock has been publicly traded on the NASDAQ Global Select Market under the symbol "INGN" since February 14, 2014. Prior to that time, there was no public market for our common stock.

Stock performance graph

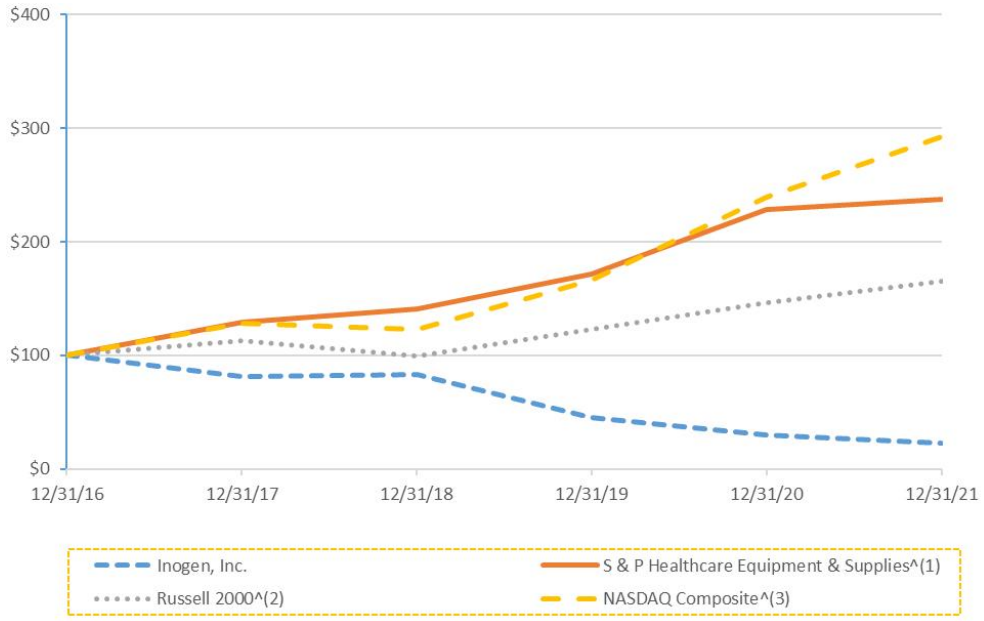
This performance graph shall not be deemed "soliciting material" or to be "filed" with the SEC for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any filing of ours under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing.

The following graph compares the performance of our common stock for the periods indicated with the performance of the S & P Healthcare and Supplies Index, the Russell 2000 Index, and the NASDAQ Composite Index from December 31, 2016 to December 31, 2021. This graph assumes an investment of $100 on December 31, 2016 in each of our common stock, the NASDAQ Composite Index, the S & P Healthcare Equipment and Supplies Index, the Russell 2000 Index and assumes reinvestment of dividends, if any. The stock price performance shown on the graph below is not necessarily indicative of future stock price performance.

STOCKHOLDER RETURN PERFORMANCE GRAPH

COMPARISON OF THE 5 YEAR CUMULATIVE TOTAL RETURN

Among Inogen, Inc., the S & P Healthcare Equipment and Supplies Index, the Russell 2000 Index and the NASDAQ Composite Index



	12/31/16	12/31/17	12/31/18	12/31/19	12/31/20	12/31/21
Inogen, Inc.	$ 100.00	$ 81.49	$ 83.40	$ 45.57	$ 29.53	$ 22.43
S & P Healthcare Equipment & Supplies^(1)	100.00	129.50	140.90	171.41	228.15	237.88
Russell 2000^(2)	100.00	113.14	99.37	122.62	145.90	165.70
NASDAQ Composite^(3)	100.00	128.24	123.26	166.19	239.08	292.42

(1) The S&P Healthcare Equipment and Supplies Index is a capitalization weighted-average index compiled of healthcare companies in the S&P 500 Index.

(2) The Russell 2000 Index is a small-cap stock market index of the bottom 2,000 stocks in the Russell 3000 Index.
(3) The NASDAQ Composite is a market-value weighted index of all common stocks listed on the NASDAQ.

Stockholders

As of February 18, 2022, there were 21 registered stockholders of record for our common stock. The actual number of stockholders 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 and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend policy

We have never declared or paid any cash dividends on our common stock or any other securities. We anticipate that we will retain all available funds and any future earnings, if any, for use in the operation of our business and do not anticipate paying cash dividends in the foreseeable future. In addition, future debt instruments we issue may materially restrict our ability to pay dividends on our common stock. Payment of future cash dividends, if any, will be at the discretion of our board of directors after taking into account various factors, including our financial condition, operating results, current and anticipated cash needs, the requirements of then-existing debt instruments and other factors our board of directors deems relevant.

Securities authorized for issuance under equity compensation plans

The information required by this Item regarding equity compensation plans is incorporated by reference to the information set forth in PART III Item 12 of this Annual Report on Form 10-K.

Unregistered sales of equity securities

None.

Issuer purchases of equity securities

None.

ITEM 6. [RESERVED]

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of the financial condition and results of our operations should be read in conjunction with the consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those discussed in the section titled "Risk Factors" included elsewhere in this Annual Report on Form 10-K.

The purpose of Management's Discussion and Analysis (MD&A) is to provide an understanding of Inogen's financial condition, results of operations and cash flows by focusing on changes in certain key measures from year to year. The MD&A is provided as a supplement to, and should be read in conjunction with, our Consolidated Financial Statements and accompanying Notes. The MD&A is organized in the following sections:

- COVID-19 pandemic and related PHE
- Overview
- Basis of presentation
- Results of operations
- Liquidity and capital resources
- Sources of funds
- Uses of funds
- Non-GAAP financial measures
- Critical accounting policies and estimates

COVID-19 pandemic and related PHE

The novel coronavirus outbreak of COVID-19 has had and likely will continue to have significant adverse effects on businesses and healthcare institutions around the world. While it is not possible at this time to estimate the overall impact that the COVID-19 pandemic and related public health emergency (PHE) could have on our business, the continued spread of COVID-19, both across the United States and throughout the world, and the measures taken by the governments of countries and local authorities affected has adversely impacted and could likely continue to adversely impact patient mobility, care accessibility, diagnosis rates, demand for our products, our business operations, including manufacturing, due to supply chain constraints, hiring and continued employment of our employees and contractors, shipment, cost of our products, and our financial condition and operating results.

Our priorities during the COVID-19 pandemic and related PHE include protecting the health and safety of our employees and supporting our patients and customers. Given the COVID-19 impact to the respiratory system, we anticipate that it is possible that the demand for long-term oxygen therapy will increase due to new cases of chronic respiratory failure or exacerbation or progression of preexisting respiratory conditions will sustain or increase, although this is not based on clinical data. We also believe stationary oxygen concentrators, and, secondarily, portable oxygen concentrators (POCs) could help meet the needs of global healthcare systems by allowing appropriate patients to use oxygen therapy at home to treat respiratory symptoms.

However, the COVID-19 pandemic and related PHE adversely impacted our consolidated operating results starting in the second quarter of 2020. We experienced lower direct-to-consumer sales starting toward the end of the first quarter of 2020, which we believe was primarily associated with shelter-in-place orders, self-quarantine, reduced mobility and travel, and reduced access to clinicians for diagnosis and follow-up for chronic obstructive pulmonary disease (COPD) patients related to the mandates and behaviors emanating from the COVID-19 pandemic and PHE. In periods with lower COVID-19 spread, we saw improved consumer demand for our products, which we believe was due to increasing vaccination rates and other effective containment measures, higher consumer confidence, mobility and interest in travel, versus lower demand in periods with higher COVID-19 spread. Those impacts were in addition to our traditional seasonality in consumer buying patterns. We continue to believe that potential future shelter-in-place orders, reduced travel, lower consumer confidence, or the impacts of new variants could reduce consumer demand in future periods.

Despite the COVID-19 pandemic and related PHE adverse impacts to direct-to-consumer sales, we experienced increased rental setups in the second quarter of 2020 through 2021, which we believe was due to Medicare and commercial payors reducing some of the administrative burden for oxygen therapy and our focus on the rental channel of the business. We believe this change will continue to contribute to increased rental setups during the remainder of the COVID-19 pandemic and related PHE. We have also seen increased reimbursement rates in some areas for Medicare beneficiaries, which have increased rental revenue during the COVID-19 pandemic and related PHE and are expected to continue to do so for the remainder of the COVID-19 pandemic and related PHE.

In the business-to-business channel, there have been certain surges in demand for oxygen concentrators by our home medical equipment (HME) providers worldwide during the COVID-19 pandemic and related PHE in specific markets with significant COVID-19 case rates due to the tendency of hospitals to discharge COVID-19 impacted patients for treatment at home during rehabilitation due to space and labor shortages in hospitals. However, overall business-to-business demand has been lower because of the COVID-19 pandemic and related PHE due to lower patient travel, physician offices limiting patient interactions for COPD patient referrals, HME providers minimizing patient interactions in response to the COVID-19 pandemic and related PHE, which includes replacing existing oxygen patient setups with POCs, and HME providers turning their purchasing focus to stationary oxygen concentrators to treat COVID-19 patients. Also, sales in Europe declined due to the temporary closure and reduced operating capacity of certain respiratory assessment centers and continued tender delays in certain markets due to the COVID-19 pandemic. Similar to our direct-to-consumer sales channel, business-to-business sales improved in periods with lower COVID-19 spread, higher consumer confidence, interest in travel, and availability of effective vaccines. In addition, this channel is impacted by COPD patient referral volumes in our core markets of the United States and Europe, which tends to improve in periods with lower COVID-19 spread due to a patient's willingness to see their physician. However, supply constraints, primarily due to limited semiconductor chip availability, negatively impacted sales in 2021 mainly in the domestic business-to-business channel, as discussed in more detail below.

During 2020 and 2021, we were able to broadly maintain our operations, but in the first quarter of 2022 we were forced to temporarily suspend production due to the semiconductor chip shortages discussed below. As seen in this temporary production halt, the COVID-19 pandemic and related PHE have caused and could continue to cause disruption to our supply chain that could impact our operations, limit our growth, and increase our cost of goods sold.

For example, we have seen higher semiconductor chip demand and reduced semiconductor chip availability in 2021 and the first quarter of 2022, which has impacted our ability to produce and sell systems and batteries. We expect availability issues to continue through 2022, which has impacted and will continue to impact our ability to produce and sell systems and batteries until supply stabilizes. The semiconductor chip shortage is being experienced across many industries, placing additional pressure on existing supplies. We have attempted to mitigate the impact of this increased supply shortage, but it has and will likely continue to negatively impact our ability to manufacture product, including with respect to the temporary production halt discussed below, as these chips are used across all of our portable oxygen concentrators, in both our batteries and printed circuit boards on our systems and, if we are not able to obtain sufficient components going forward, we could be forced to slowdown or temporarily halt production again. We are continuing to focus our mitigation efforts on product redesign, seeking increased commitments on supply and shipment dates from our regular suppliers, sourcing from the open semiconductor channel, and using appropriate pricing actions such as the price increase we implemented on September 1, 2021 to help offset some of the increased cost, but we expect increasing challenges in terms of supply constraint and inflationary pressure moving forward.

We saw inflated costs related to the acquisition of semiconductor chips begin to negatively impact our cost of goods sold in the second half of 2021, and we expect this to have an increased impact on our cost of goods sold throughout 2022. Even though we paid significant costs in the second half of 2021 associated with acquiring chips on the open market, most of these costs increased our prepaid expense and inventory given that these components were not yet in finished products that were sold during the period. We believe based on our assessment and industry feedback that these supply shortages and increased costs are likely to continue through 2022. In addition to the semiconductor chip limitations, we are continuing to see supply chain constraints and cost inflation for other components used in our products albeit to a lower degree. Due to semiconductor chip shortages as of late December 2021, we temporarily suspended manufacturing operations beginning January 3, 2022, at our Texas and California locations as well as at Foxconn, our contract manufacturer in the Czech Republic. We have since secured the required semiconductor supplies to resume production and restarted our manufacturing operations at all three locations in early February. While we have been able to restart manufacturing operations at all locations, we are still seeing challenges in terms of available supply and we believe the supply shortages continue to represent an increased risk to the business for 2022.

Additionally, we have experienced, along with most other companies across many industries, the macro-economic impact of a challenging employment environment related to hiring and retaining employees and wage inflation. We expect that these hiring, retention, and wage inflation challenges, as well as challenges related to maintaining our current workforce, will continue into 2022. These hiring, retention, and cost challenges may negatively affect our ability to grow our business and keep our best employees or increase our cost of operations. In response to these challenges, we have implemented more flexible workplace requirements depending on the role, such as increasing ability for remote work, but we still expect to be challenged by the macro-economic employment environment.

The COVID-19 pandemic and related PHE has also and could continue to lead to volatility in consumer access to our products due to government actions impacting our ability to produce and ship products or impacting consumers' movements and access to our products. The COVID-19 pandemic and related PHE has caused demand to fluctuate for our products across all channels due to the global economic environment and changes to physician visits, interactions, testing requirements and diagnosis. Additionally, while we planned for sales and marketing expansion in 2021, we saw lower hiring and increased attrition in our direct-to-consumer sales force primarily due to increased competition for sales professionals in 2021. The labor shortage trend for qualified sales professionals may continue in 2022, limiting our ability to grow in future periods.

The health and safety of our people and their families continues to be our primary focus.Our ability to continue to operate without any significant negative operational impacts will in part depend on our ability to protect our employees. As the COVID-19 pandemic and related PHE has developed, we have taken numerous steps to help ensure the health and safety of our employees and their families. We follow recommended actions of government and health authorities to protect our employees, with particular measures in place for those working in our manufacturing facilities, and those with patient, prescriber, or customer face-to-face interactions. Employees whose tasks can be done offsite have been allowed to work from home and most of our personnel continue to work from home. We have also worked closely with local and national officials to keep our manufacturing facilities open due to the essential nature of our products.

For additional information on risk factors that could impact our results, please refer to "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K.

Overview

We are a medical technology company that primarily develops, manufactures and markets innovative POCs used to deliver supplemental long-term oxygen therapy to patients suffering from chronic respiratory conditions. Long-term oxygen therapy is defined as the provision of oxygen therapy for use at home in patients who have chronic low blood oxygen levels (hypoxemia). Traditionally, these patients have relied on stationary oxygen concentrator for use in the home and oxygen tanks or cylinders for mobile use, which we call the delivery model. The tanks and cylinders must be delivered regularly and have a finite amount of oxygen, which requires patients to plan activities outside of their homes around delivery schedules and a finite oxygen supply. Additionally, patients must attach long, cumbersome tubing to their stationary concentrators simply to enable mobility within their homes. Our proprietary Inogen One® systems concentrate the air around the patient to offer a single source of supplemental oxygen anytime, anywhere with a portable device weighing as little as approximately 2.8 pounds with a single battery. Our Inogen One systems range from 2.6 to 6.5 hours of battery life with a single battery and can be plugged into an outlet as needed. We believe our Inogen One systems reduce the patient's reliance on stationary concentrators and scheduled deliveries of tanks with a finite supply of oxygen, thereby improving patient quality of life and fostering mobility.

We employ a direct-to-consumer market and rental strategy that we believe contributes to our leadership position in the POC market. Our direct-to-consumer market and rental strategy means that we (i) advertise directly to consumers, process their physician paperwork, and provide clinical support as needed and (ii) bill Medicare or insurance on the patient's behalf in the United States. We believe that we are the only POC manufacturer offering patients both a purchase and a rental option to acquire an oxygen therapy device.

We derive the majority of our revenue from the sale and rental of our Inogen One systems and related accessories to patients, insurance carriers, home healthcare providers, resellers, charitable organizations, and distributors, including our private label partner. We sell multiple configurations of our Inogen One and Inogen At Home systems with various batteries, accessories, warranties, power cords and language settings. Our goal is to design, build and market oxygen solutions that redefine how long-term oxygen therapy is delivered.

To accomplish this goal and to grow our revenue, we intend to:

- *Expand our domestic direct-to-consumer sales and prescriber sales teams and increase productivity.* We expect minimal net new inside direct-to-consumer sales hires in the near term due to the size and quality of the candidate pool and expected attrition, but as part of our growth plans, we are increasing our focus on improving performance and productivity of our existing sales force. Going forward, except as otherwise limited by the impact of the COVID-19 pandemic and related PHE, our plan is to continue to expand sales capacity while focusing on increased productivity driven by improved sales management discipline, insights-informed tools, and optimized patient lead generation.

  During the year ended December 31, 2021, the number of inside direct-to-consumer sales representatives decreased to 292 from 300 as of December 31, 2020. In 2021, hiring was challenging due to the continued impacts of the COVID-19 pandemic and related PHE. We hope to offset attrition with replacement hiring in 2022 while we opportunistically increase the total inside direct-to-consumer sales representatives if and when required while maintaining our hiring standards and being mindful of the supply constraints.

  We also plan to expand our prescriber sales team to drive increased physician referrals for patient rentals. This specialized sales team consisted of 35 sales representatives and 6 support personnel as of December 31, 2021. In addition, we are using a third-party contract sales organization, Ashfield, that will only represent Inogen in the field, to enhance our go-to-market capabilities in the U.S. As of January 2022, we had approximately 47 dedicated sales representatives, 10 sales representations with accepted offers that will be in the field early March 2022, and 12 concierge service representatives to our prescriber sales team. Additionally, Ashfield will provide access to its best-in-class data-driven sales management disciplines, proprietary prescriber insights, and analytics to support our growth strategy and drive performance in the clinician sales channel. The combined sales organization, Inogen and Ashfield, will benefit from access to Ashfield's comprehensive offering of analytics tools, sales operations support, and personalized concierge services that will help drive productivity and efficiency.

- *Expand our domestic direct-to-consumer marketing efficiently and, optimize pricing.* We slightly increased marketing efforts in 2021 to continue to drive patient awareness of our products and patient inquiries about their ability to switch from their current oxygen products to our technology as patient interest increased, so media and advertising costs increased to $35.2 million in 2021 compared to $34.2 million in 2020. We plan to increase and optimize marketing spend to drive consumer and physician awareness of our products in 2022 and beyond. We raised prices as of September 1, 2021 to partially offset rising product costs. We plan to continue to monitor the progression of the COVID-19 pandemic and related PHE in the United States and may adjust our marketing plan accordingly.

- *Expand our rental revenues.* We are evolving our operating model to focus the enhanced prescriber sales team on rental opportunities with our direct-to-consumer sales team focusing mainly on cash sales. We believe the new specialized operating model will drive higher rental setups as we expand prescriber and payor awareness of our products and services.

  Due to the COVID-19 pandemic and related PHE, Medicare and commercial payors have reduced some of the administrative burden for oxygen therapy, which also contributed to increased rental setups in the second quarter of 2020 through 2021. We believe this change will continue to contribute to increased rental setups during the remainder of the COVID-19 pandemic and related PHE. We have also seen increased reimbursement rates in some areas for Medicare beneficiaries, which have increased rental revenue during the COVID-19 pandemic and related PHE and are expected to continue to do so for the remainder of the COVID-19 pandemic and related PHE. CMS has finalized additional changes to the administrative requirements to dispense and bill for oxygen therapy, which is discussed in more detail in the Third-party reimbursement section of Item 1 above. These changes may reduce the administrative burden and increase patient access to our products; however, we still need additional clarity on how it will be implemented.

- *Expand our domestic HME provider and reseller sales.* We are also focused on building our domestic business-to-business partnerships, including relationships with distributors, key accounts, resellers, our private label partner, traditional HME providers, and charitable organizations. We offer patient-preferred, low service cost products and services to help providers convert their businesses to a non-delivery POC business model.

  Supplemental oxygen is a treatment prescribed by healthcare professionals for patients with hypoxemia, which in some cases may be caused or exacerbated by COVID-19. While there have been surges in demand for oxygen concentrators by our HME providers during the COVID-19 pandemic and related PHE in specific markets with significant COVID-19 case rates, domestic business-to-business demand in 2020 was lower because of the COVID-19 pandemic and related PHE due to lower retail sales, lower patient travel, physician offices limiting patient interactions for COPD patient referrals, HME providers minimizing patient interactions in response to the COVID-19 pandemic and related PHE which includes replacing existing oxygen patient setups with POCs, and HME providers turning their purchasing focus to stationary oxygen concentrators to treat COVID-19 patients. Domestic HME provider demand increased in the fourth quarter of 2020 and in the year ended December 31, 2021, primarily due to increased demand for POCs as hospital systems and stationary oxygen concentrator supply were strained to keep up with the increase in COVID-19 cases and increased patient ambulation and consumer confidence.

  However, in spite of the increased demand, in the third and fourth quarters of 2021 we saw supply constraints associated with the semiconductor chip shortage that limited growth in this channel, and we expect this to continue in the near-term in 2022, specifically in the first quarter as we were forced to temporarily halt production from early January 2022 to early February 2022 due to these supply constraints.

- *Increase international business-to-business adoption.* Although our main growth opportunity remains POC adoption in the United States given what we still believe is a relatively low penetration rate, we believe there is a sizable international market opportunity, particularly in Europe where there is existing oxygen reimbursement for respiratory conditions. In order to take advantage of these international markets, we have partnered with distributors who serve those markets and key customers in them. We additionally have an Inogen base of operations for sales and customer service in the Netherlands and use Foxconn to support the majority of our European sales volumes. We have sold our products in a total of 59 international countries and overseas regions.

  Current Inogen products are commercialized in the European Union under Medical Device Directive (MDD) certificates, expiring on May 18, 2022. The extension of the existing certificates under the MDD or obtaining a new certificate under the European Medical Devices Regulation (MDR) is required for continued marketing in the European Union after May 18, 2022. We are preparing the filing of the MDR submissions in the earlier part of 2022 and have verified our ability to meet most of the demand in terms of existing orders up to the MDD certificate expiration. Additionally, we are in the process of applying for select European country level exemptions if supply is constrained and prevents us placing adequate supply into the EU supply chain before May 18, 2022. We are also securing the necessary certification from the United Kingdom and Switzerland which we believe would be completed in Q1 2022.

As in the United States, there have been surges in demand for oxygen concentrators by our international HME customers during the COVID-19 pandemic in specific markets with significant COVID-19 case rates. However, international demand declined in the second quarter of 2020 continuing through the first quarter of 2021, primarily due to the temporary closures and reduced operating capacity of certain European respiratory assessment centers due to the COVID-19 pandemic, continued tender delays in certain European markets, and decreased sales in other markets, primarily Canada. In addition, as in the United States, providers turned their focus to supplying stationary oxygen concentrators with higher flow characteristics in response to the COVID-19 pandemic. We experienced increased demand during 2021, which we believe was due to improving COVID-19 vaccination rates and increased ambulation of patients in Europe, increased operational capacity of certain European respiratory assessment centers, and increased sales in certain markets associated with spikes in COVID-19 cases in such instances. To grow our international sales markets, we are also in the process of developing regulatory and sales pathways to capture opportunities in new and emerging markets.

Over time, as the U.S. and European markets mature, our growth will depend on our ability to drive POC adoption in developing or emerging markets, where limited oxygen therapy treatment and reimbursement exists today. However, growth may also be limited by regulatory and reimbursement clearances, currency fluctuations, capital expenditure constraints, ongoing restructuring challenges, and tender uncertainty.

- *Invest in our oxygen product offerings to develop innovative products and expand clinical evidence* We incurred $16.6 million, $14.1 million and $9.4 million in 2021, 2020 and 2019, respectively, in research and development costs, and we intend to continue to make such investments in the foreseeable future.

  We launched our fifth-generation POC, the Inogen One G5 in 2019. The Inogen One G5 weighs 4.7 pounds and produces 1,260 ml per minute of oxygen output, with very quiet operation at 38 dBA and our longest battery life at 6.5 hours for a single battery and up to 13 hours for a double battery. We estimate that the Inogen One G5 is suitable for over 90% of ambulatory long-term oxygen therapy patients based on our analysis of the patients who have contacted us and their clinical needs. We expect the Inogen One G5 to obsolete the Inogen One G3® over the short-term. The Inogen One G5 represented more than 80% of total domestic POC units sold in 2021, showing the strong demand for this product from both patients and providers.

  Inogen Connect, our connectivity platform on our Inogen One G4® and Inogen One G5 products in the United States and Canada is compatible with Apple and Android platforms and includes patient features such as purity status, battery life, product support functions, notification alerts, and remote software updates. We believe home oxygen providers will also find features such as remote troubleshooting, equipment health checks, and location tracking to help drive operational efficiencies when transitioning away from the oxygen tank delivery model.

  We plan to also invest in clinical studies to evaluate expected improvements in clinical, economic and patient reported outcomes associated with the use of our products as part of our efforts to drive payor and prescriber advocacy for our products.

- *Expand our product offerings.* We are primarily focused on creating innovative, evidence-based chronic respiratory care solutions to strengthen and build preference and advocacy for our respiratory therapies and brand across patients, prescribers, and payors. We plan to do this with an expanded, high quality, connected, and innovative product portfolio that strengthens our differentiation. We are also committed to pursuing complementary acquisition opportunities to strengthen our technology, product offerings, and channel access.

  In August 2019, we acquired New Aera. New Aera's patented and Food and Drug Administration (FDA)-cleared Tidal Assist® Ventilator (TAV®) system is designed to deliver increased air flow and pressure from an approximately 4-ounce pocket-size unit, features a state-of-the-art nasal pillow interface, and is compatible with certain oxygen concentrators, oxygen cylinders, wall gas, and certain medical air sources. TAV therapy with oxygen has been clinically demonstrated during periods of exercise to reduce breathlessness, increase exercise endurance, and improve oxygen saturation for patients suffering from certain chronic lung disease compared to oxygen therapy alone. We plan to only sell this product across our domestic direct-to-consumer channel and in our domestic business-to-business channel in 2022, and we expect limited contributions to revenue in its existing configuration.

We have been developing and refining the manufacturing of our Inogen One systems since 2004. While nearly all of our manufacturing and assembly processes were originally outsourced, assembly of the compressors, sieve beds, concentrators and certain manifolds were brought in-house in order to improve quality control and reduce cost. In support of our European sales, we use a contract manufacturer located in the Czech Republic to manufacture high volume products and perform product repairs to improve delivery to our European accounts. We expect to maintain our assembly operations for our products at our facilities in Texas and California. In 2022, we are focused on securing supply for components to make our products in spite of the higher costs of semiconductor chips, reducing the cost of our Inogen One G5 product (excluding semiconductor chips), and increasing the robustness of our supply chain to reduce potential component constraints as we grow our business.

We also use lean manufacturing practices to maximize manufacturing efficiency. We rely on third-party manufacturers to supply several components of our products. We typically enter into master service agreements for these components that specify quantity and quality requirements and delivery terms. In certain cases, these agreements can be terminated by either party upon relatively short notice. We have elected to source certain key components from single sources of supply, including our batteries, motors, valves, TAV-compatible stationary concentrators, columns, and some molded plastic components. In some cases, maintaining a single source of supply can allow us to control production costs and inventory levels and to manage component quality, but also may lead to supply availability risks, and means our ability to maintain production is dependent on these single source suppliers, which may put us at an increased risk of supply disruption, as we have seen from the production halt we implemented in early January 2022 through early February 2022. In order to help mitigate against the risks related to a single source of supply, for certain components we qualify alternative suppliers and develop contingency plans for responding to disruptions. However, a continued reduction or halt in supply from one of these single-source suppliers, any dual-sourced suppliers or any other limited source suppliers with similar sub-component suppliers could limit or prevent our ability to manufacture our products or devices untilone or more sufficient replacement suppliers is found and qualified. For additional discussion of potential risks related to our manufacturing and raw materials, please see the risk factor entitled "*We obtain some of the components, subassemblies and completed products included in our products from a single source or a limited group of manufacturers or suppliers, and in some cases those components are available in only limited supplies from limited manufacturers or suppliers, andthe partial or complete loss of one or more of these manufacturers or suppliers could cause significant production delays or stoppages, an inability to meet customer demand, substantial loss in revenue, and an adverse effect on our financial condition and results of operations.*"

Historically, we have generated a majority of our revenue from sales and rentals to customers in the United States. In the years ended December 31, 2021, 2020 and 2019, approximately 22.2%, 20.1% and 21.5%, respectively, of our total revenue was from sales to customers outside the United States, primarily in Europe. Approximately 74.1%, 73.6% and 70.2% of the non-U.S. revenue for the years ended December 31, 2021, 2020 and 2019, respectively, was invoiced in Euros with the remainder invoiced in United States dollars. We have sold our products in a total of 59 international countries and overseas regions outside the United States through our wholly-owned subsidiary, distributors or directly to large "house" accounts, which include gas companies, HME oxygen providers, and resellers. In those instances, we sell to and bill the distributor or "house" accounts directly, leaving responsibility for the patient billing, support and clinical setup to the local provider.

Our total revenue was $358.0 million, $308.5 million and $361.9 million for the years ended December 31, 2021, 2020 and 2019, respectively. The increase in total revenue in the year ended December 31, 2021 compared to the prior year was primarily due to an increase in direct-to-consumer sales and international business-to-business sales, primarily associated with reduced impact of the COVID-19 pandemic and related PHE, and an increase in rental revenue. We generated net income (loss) of $(6.3) million, $(5.8) million and $21.0 million in the years ended December 31, 2021, 2020 and 2019, respectively. We generated Adjusted EBITDA of $29.5 million, $21.6 million and $43.3 million in the years ended December 31, 2021, 2020 and 2019, respectively (see "Non-GAAP financial measures" for reconciliations between U.S. GAAP and non-GAAP results). As of December 31, 2021, our retained earnings were $69.3 million.

Sales revenue

Our future financial performance will be driven in part by the growth in sales of our Inogen One POCs, and, to a lesser extent, sales of batteries, other accessories, our Inogen At Home stationary oxygen concentrators and our TAV products. We plan to grow our system sales in the coming years through multiple strategies including: hiring additional sales representatives directly or through our contract sales organization, improving productivity, investing in consumer and physician awareness and advocacy through increased sales and marketing efforts, expanding our clinical evidence, expanding our sales infrastructure and efforts outside of the United States, expanding our business-to-business sales through key strategic partnerships, and enhancing our product offerings through additional product launches, although, as mentioned above, these plans have been and may continue to be impacted by the COVID-19 pandemic and related PHE. While we believe most HME providers are still in the process of converting their business model to a non-delivery model and purchase POCs, growth has been challenged and we expect it could continue to be challenged due to the COVID-19 pandemic and related PHE, their ongoing restructuring efforts, lack of access to available credit, provider capital expenditure constraints, and potential changes in reimbursement rates.

Our direct-to-consumer and prescriber sales processes involve numerous interactions with the individual patient, their physician and the physician's staff, and includes an in-depth analysis and review of our product, the patient's diagnosis and prescribed oxygen therapy, including procuring an oxygen prescription, although, as discussed above, this process has been disrupted due to the COVID-19 pandemic and related PHE and we expect that such disruption will continue for the duration of the COVID-19 pandemic and related PHE. The patient may consider whether to finance the product through an Inogen-approved third party or purchase the equipment. Product is not deployed until both the prescription and payment are received. Once a full system is deployed, the patient has 30 calendar days to return the product, subject to the payment of a minimal processing and handling fee. Approximately 6-10% of consumers who purchase a system return the system during this 30-day return period.

Our business-to-business efforts are focused on selling to distributors, HME oxygen providers, our private label partner, resellers, and charitable organizations who are based inside and outside of the United States. This process involves interactions with various key customer stakeholders including sales, purchasing, product testing, and clinical personnel. Businesses that have patient demand that can be met with our products place purchase orders to secure product deployment. This may be influenced based on outside factors, including the result of tender offerings, changes in insurance plan coverage or reimbursement rates, business restructuring activities toward a non-delivery model, capital constraints, and overall changes in the net oxygen therapy patient populations, and is presently being impacted by the COVID-19 pandemic and related PHE. Products are shipped freight on board (FOB) Inogen dock domestically, and based on financial history and profile, businesses may either prepay or receive extended payment terms. Products are shipped both FOB Inogen dock and Delivery Duty Paid (DDP) for certain international shipments depending on the shipper used. DDP shipments are Inogen's property until title has transferred which is upon duty being paid and delivered to the customer. As a result of these factors, product purchases can be subject to changes in demand by customers.

We sold approximately 175,800 systems in 2021, 178,900 systems in 2020 and 201,100 systems in 2019. Management focuses on system sales as an indicator of current business success.

Rental revenue

Our rental process involves numerous interactions with the individual patient, their physician and the physician's staff. The process includes an in-depth analysis and review of our product, the patient's diagnosis and prescribed oxygen therapy, and their medical history to confirm the appropriateness of our product for the patient's oxygen therapy and compliance with Medicare and private payor billing requirements, which often necessitates additional physician evaluation and/or testing for oxygen. Once the product is deployed, the patient receives instruction on product use and may receive a clinical titration from our licensed staff to confirm the product meets the patient's medical oxygen needs prior to billing. As a result, the period of time from initial contact with a patient to billing can vary significantly and be up to one month or longer. However, during the COVID-19 PHE, CMS has reduced the paperwork requirements for Medicare oxygen therapy patients, as discussed in more detail in the Reimbursement section below. CMS has also adopted additional changes to the administrative requirements to dispense and bill for oxygen therapy, which is discussed in more detail in the Reimbursement section below, which may reduce the administrative burden and increase patient access to our products.

Rental revenue increased in 2021 compared to 2020, primarily due to a greater number of patients on service, higher Medicare reimbursement rates, and higher billable patients as a percent of total patients on service. Medicare reimbursement rates for oxygen therapy have increased, as detailed in the Reimbursement section below. In addition, as part of the various stimulus bills in 2020 (also discussed in more detail in the Reimbursement section below), the 2% Medicare sequestration reduction was temporarily paused, and Medicare reimbursement rates for non-rural, non-competitive bid areas through the duration of the COVID-19 PHE were increased to a 75/25 blended rate retroactive to March 6, 2020, which increased the rates in 2021 while the COVID-19 PHE continued. The 50/50 blended rate for HME providers in rural and non-contiguous, non-competitive bid areas was extended permanently as part of the final rule published in December 2021. We plan to add new rental patients on service in future periods through multiple strategies, including expanding our prescriber sales team, expanding our direct-to-consumer marketing efforts, investing in patient and physician awareness and advocacy, expanding clinical evidence, and securing additional insurance contracts.

A portion of rentals include a capped rental period during which no additional reimbursement is allowed unless additional criteria are met. In this scenario, the ratio of billable patients to total patients on service is critical to maintaining rental revenue growth as patients on service increases. Medicare has noted a certain percentage of beneficiaries, approximately 25%, based on their review of Medicare claims, reach the 36th month of eligible reimbursement and enter the capped rental period. The percentage of capped patients may fluctuate over time as new patients come on service, patients come off of service before and during the capped rental period, and existing patients enter the capped rental period.

We had approximately 42,900, 32,200 and 25,300 oxygen rental patients as of December 31, 2021, 2020 and 2019, respectively. Management focuses on patients on service as a leading indicator of likely future rental revenue; however, actual rental revenue recognized is subject to a variety of other factors, including reimbursement levels by payor, patient location, the number of capped patients, write-offs for uncollectable balances, and rental revenue adjustments.

Reimbursement

We rely significantly on reimbursement from Medicare and private payors, including Medicare Advantage plans, Medicaid and patients for our rental revenue. A discussion of third-party reimbursement is contained in Item 1, *Third-party reimbursement* in this Annual Report on Form 10-K. For the years ended December 31, 2021, 2020 and 2019, approximately 81.9%, 81.5% and 81.1%, respectively, of our rental revenue was derived from Medicare's traditional fee-for-service reimbursement programs.

Basis of presentation

The following describes the line items set forth in our consolidated statements of comprehensive income (loss).

Revenue

We classify our revenue in two main categories: sales revenue and rental revenue. There will be fluctuations in mix between business-to-business sales, direct-to-consumer sales and rental revenue from period-to-period. Product selling prices and gross margins may fluctuate as we introduce new products, our product costs change, we have changes in purchase volumes, and as currency variations occur. For example, the higher costs for semiconductor chips has had a negative impact on our gross margin, and we expect that will continue in 2022. Thus, to the extent that these higher costs continue, our overall gross margin should decline. In addition, the gross margin of the sales to direct-to-consumer sales and rental customers are generally higher than business-to-business accounts, so to the extend our sales of direct-to-consumers sales and rental customers are higher than sales to our business-to-business customers, our overall gross margins should improve, and, conversely, to the extent our sales are higher to our business-to-business customers than our sales to direct-to-consumer sales and rental customers, our overall gross margins should decline. Quarter-over-quarter results may vary due to seasonality in both the international and domestic markets, as discussed in Item 1. *Seasonality* and elsewhere in this Annual Report on Form 10-K.

Sales revenue

Our sales revenue is primarily derived from the sale of our Inogen One systems, Inogen At Home systems, TAV systems, and related accessories to individual consumers, our private label partner, HME providers, distributors, resellers, and charitable organizations worldwide. Sales revenue is classified into two areas: business-to-business sales and direct-to-consumer sales. Generally, our direct-to-consumer sales have higher gross margins than our business-to-business sales.

Rental revenue

Our rental revenue is primarily derived from the rental of our Inogen One and Inogen At Home systems to patients through reimbursement from Medicare, private payors and Medicaid, which typically also includes a patient responsibility component for patient co-insurance and deductibles. Rental revenue increased in 2021, primarily due to higher patients on service, higher billable patients as a percent of total patients on service, and higher Medicare reimbursement rates. We expect our rental revenue to increase in future periods as we scale the rental intake and sales teams and increase new rental setups. In addition, for the duration of the COVID-19 PHE, we expect to benefit from higher Medicare reimbursement rates and reduced administrative requirements for oxygen therapy enacted due to the COVID-19 PHE. We also expect that our rental revenue will be impacted by the number of our sales and rental intake representatives, reimbursement rate changes, including the impact of COVID-19 PHE changes, the level of and response from potential customers to direct-to-consumer marketing spend, product launches, the number of billable patients and denial rates, and other uncontrollable factors such as changes in the market and competition.

Cost of revenue

Cost of sales revenue

Cost of sales revenue consists primarily of costs incurred in the production process, including component materials, assembly labor and overhead, warranty expense, provisions for slow-moving and obsolete inventory, rework and delivery costs for items sold. Labor and overhead expenses consist primarily of personnel-related expenses, including wages, bonuses, benefits, and stock-based compensation for manufacturing, logistics, repair, manufacturing engineering, and quality assurance employees and temporary labor. Cost of sales revenue also includes manufacturing freight in, depreciation expense, facilities costs and materials. Provisions for warranty obligations are included in cost of sales revenue and are provided for at the time of revenue recognition.

We continue to make progress towards reducing the average unit costs of our products (excluding the impact of the semiconductor chip cost increases) as a result of our ongoing efforts to develop lower-cost systems, negotiate with our suppliers, improve our manufacturing processes, and increase production volume and yields. However, we have experienced and expect to continue experiencing supply chain disruptions through 2022, primarily associated with semiconductor chips used in our batteries and printed circuit boards which are components of our portable oxygen concentrators, which drove up the cost of our products in 2021 and which we expect will continue to drive up the cost of our products in 2022.

As a result, we saw these inflated costs negatively impact our cost of goods sold in the third and fourth quarters of 2021, and we expect this to have an increased impact on our material costs in 2022 until supply and demand get closer to equilibrium. Even though we paid significant costs in the third and fourth quarters of 2021 associated with these chips, most of these costs increased our prepaid expense and inventory given that these components were not yet sold in finished products during the period. We believe based on our assessment and industry feedback that these supply shortages and are likely to continue through first half of 2022. In addition to the semiconductor chip limitations, we are continuing to see supply chain constraints for other components used in our products. As a result of the semiconductor chip shortages, we temporarily suspended manufacturing operations at our Texas and California locations from January 3, 2022 to February 7, 2022 and Foxconn, our Czech Republic-based OEM, suspended manufacturing due to the same supply constraints from January 3, 2022 to February 9, 2022. While we were able to resume manufacturing operations, we are still seeing challenges in terms of available supply, and we believe this is an increased risk to the business in 2022. As a result, in the interim we expect to be supply constrained and unable to meet all customer demand for our products.

Recent United States policies related to global trade and tariffs may also increase our average unit cost. The current economic environment has introduced greater uncertainty with respect to potential trade regulations, including changes to United States policies related to global trade and tariffs. We continue to monitor the Section 301 tariffs being imposed by the United States on certain imported Chinese materials and products in addition to potential retaliatory responses from other nations. In 2021 and 2020, the impact of the China tariffs on our financial results was minimal as we have received some exemptions, negotiated cost sharing and price reductions with suppliers, and re-allocated purchases. Assuming the Chinese tariffs stay at the current levels, we currently expect the overall financial impact to our business to be minimal to the average unit cost for 2022.

For these reasons, we expect sales gross margin percentage to fluctuate over time based on the sales channel mix, product mix, and changes in average selling prices and cost per unit.

Cost of rental revenue

Cost of rental revenue consists primarily of depreciation expense; service costs for rental patients, including rework costs, material, labor, freight, and consumable disposables; and logistics costs.

We expect rental gross margin percentage to increase over time, primarily associated with higher rental revenue per patient on service and lower costs per patient on service. We expect the average cost of rental revenue per patient on service to decline in future periods as a result of our ongoing efforts to reduce average unit cost of our systems as well as reductions in depreciation, service costs, and logistics costs.

Operating expense

Research and development

Our research and development expense consists primarily of personnel-related expenses, including wages, bonuses, benefits and stock-based compensation for research and development and engineering employees, facility costs, laboratory supplies, product development materials, consulting fees and related costs, clinical study costs, and testing costs for new product launches as well as enhancements to existing products. We have made substantial investments in research and development since our inception. Our research and development efforts have focused primarily on the tasks required to enhance our technologies and to support development and commercialization of new and existing products.

We plan to continue to invest in research and development activities to stay at the forefront of patient preference in oxygen therapy. We expect research and development expense to increase in absolute dollars in future periods as we continue to invest in our engineering and technology teams to support our new and enhanced product research and development efforts and manufacturing improvements. We expect increased research and development costs associated with broadening our product portfolio including incorporating the TAV technology into our oxygen concentrator.

Sales and marketing

Our sales and marketing expense primarily supports our direct-to-consumer sales and rental strategy and consists mainly of personnel-related expenses, including wages, bonuses, commissions, benefits, and stock-based compensation for sales, marketing, customer service, rental intake, and clinical service employees. It also includes expenses for media and advertising, printing, informational kits, dues and fees, credit card fees, recruiting, training, sales promotional activities, travel and entertainment expenses as well as allocated facilities costs.

Sales and marketing expense increased in 2021 compared to 2020, primarily associated with higher personnel-related expense, consulting costs, credit card/financing fees, and advertising expense. Our average direct-to-consumer sales representative headcount was down approximately 12% in the twelve months ended December 31, 2021 from the comparative period in the prior year as attrition outpaced hiring, primarily due to increased competition for sales professionals in 2021. We continue to look to add new sales representatives, while maintaining our hiring standards and being mindful of the supply constraints. Headcount was down slightly as of December 31, 2021 compared to December 31, 2020. We expect minimal net new hires in the near term due to the size and quality of the candidate pool and expected attrition, but as part of our growth plans, we are increasing our focus on improving productivity of our existing sales force. Going forward, except as otherwise limited by the impact of the COVID-19 pandemic and related PHE, our plan is to continue to expand sales capacity while focusing on increased productivity, improved sales personnel and lead distribution systems, and improved training. We expect an increase in sales and marketing expense in future periods as we continue to invest in our business, including expanding our sales and sales support team which includes our prescriber sales team, increasing our rental infrastructure, increasing media spend to drive consumer awareness, and rising patient support costs as our patient and customer base increases.

General and administrative

Our general and administrative expense consists primarily of personnel-related expenses, including wages, bonuses, benefits, and stock-based compensation for employees in our compliance, finance, medical billing, order intake, regulatory and clinical affairs, legal, human resources, and information technology (IT) departments as well as facilities costs, sales bad debt expense, and board of directors' expenses, including stock-based compensation. In addition, general and administrative expense includes professional services, such as legal, patent registration and defense costs, insurance, consulting and accounting services, including audit and tax services, and travel and entertainment expenses. In addition, general and administrative expense includes changes in the fair value of the New Aera earnout liability, as discussed below.

We expect general and administrative expense to increase in future periods as the number of administrative personnel grows and we continue to introduce new products, broaden our customer base and grow our business. We expect general and administrative expense to increase in absolute dollars as we continue to invest in corporate infrastructure to support our growth including personnel-related expenses, professional services fees and compliance costs associated with operating as a public company. Those costs include increases in our regulatory and clinical affairs, legal, accounting, medical billing, human resources, and IT personnel, as well as increases in additional consulting, legal and accounting fees, facilities costs, insurance costs, and board of directors' compensation.

Other income (expense), net

Our other income (expense), net consists primarily of interest income earned on cash equivalents and marketable securities as well as foreign currency gains and (losses).

Income taxes

We account for income taxes in accordance with Accounting Standards Codification (ASC) 740—*Income Taxes*. Under ASC 740, income taxes are recognized for the amount of taxes payable or refundable for the current period and deferred tax liabilities and assets are recognized for the future tax consequences of transactions that have been recognized in our consolidated financial statements or tax returns. A valuation allowance is provided when it is more likely than not that some portion, or all, of the deferred tax asset will not be realized.

We account for uncertainties in income tax in accordance with ASC 740-10—*Accounting for Uncertainty in Income Taxes*. ASC 740-10 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. This accounting standard also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition.

The accounting for stock-based compensation will increase or decrease our effective tax rate based upon the difference between our stock-based compensation expense and the deductions taken on our U.S. tax return, which depends upon the stock price at the time of employee option exercise or award vesting. We recognize excess tax benefits or deficiencies on a discrete basis, and we anticipate our effective tax rate will vary from year-to-year depending on our stock price in each period.

Results of operations

Comparison of years ended December 31, 2021 and 2020

Revenue

(amounts in thousands)	Years ended December 31,		Change 2021 vs. 2020		% of Revenue	
	2021	2020	$	%	2021	2020
Sales revenue	$ 311,730	$ 280,189	$ 31,541	11.3%	87.1%	90.8%
Rental revenue	46,273	28,298	17,975	63.5%	12.9%	9.2%
Total revenue	$ 358,003	$ 308,487	$ 49,516	16.1%	100.0%	100.0%

Sales revenue increased $31.5 million for the year ended December 31, 2021 from the year ended December 31, 2020, or an increase of 11.3% from the comparable year. The increase was primarily attributable to increased direct-to-consumer sales and international business-to-business sales, primarily due to increased average selling prices and increased consumer demand, and the reduced impact of the COVID-19 pandemic and related PHE, partially offset by supply chain constraints limiting product availability. We sold approximately 175,800 oxygen systems during the year ended December 31, 2021 compared to approximately 178,900 oxygen systems sold during the year ended December 31, 2020, or a decrease of 1.7%. The decrease in the number of systems sold resulted mainly from a decrease in sales in the domestic business-to-business channels, primarily due to supply chain constraints.

Rental revenue increased $18.0 million for the year ended December 31, 2021 from the year ended December 31, 2020, or an increase of 63.5% from the comparable year. The increase in rental revenue was primarily related to higher rental patients on service, higher Medicare reimbursement rates, and higher billable patients as a percent of total patients on service.

(amounts in thousands)	Years ended December 31,		Change 2021 vs. 2020		% of Revenue	
Revenue by region and category	2021	2020	$	%	2021	2020
Business-to-business domestic sales	$ 91,371	$ 96,423	$ (5,052)	-5.2%	25.5%	31.3%
Business-to-business international sales	79,460	62,147	17,313	27.9%	22.2%	20.1%
Direct-to-consumer domestic sales	140,899	121,619	19,280	15.9%	39.4%	39.4%
Direct-to-consumer domestic rentals	46,273	28,298	17,975	63.5%	12.9%	9.2%
Total revenue	$ 358,003	$ 308,487	$ 49,516	16.1%	100.0%	100.0%

Domestic business-to-business sales decreased 5.2% for the year ended December 31, 2021 compared to the year ended December 31, 2020. The decrease was primarily due to supply chain constraints that limited sales primarily in the second half of 2021.

International business-to-business sales increased 27.9% for the year ended December 31, 2021 compared to the year ended December 31, 2020, mostly driven by the reduced impact of the COVID-19 pandemic with increased vaccination rates and increased operating capacity of certain European respiratory assessment centers, and in response to the COVID-19 pandemic and related PHE due to greater demand for POCs for COVID-19 patients at hospital discharge in certain markets with high case rates of COVID-19. In the year ended December 31, 2021, sales in Europe as a percentage of total international sales revenue increased slightly to 86.8% versus 85.8% in the comparative period in 2020.

Domestic direct-to-consumer sales increased 15.9% for the year ended December 31, 2021 compared to the year ended December 31, 2020, primarily due to increased average selling prices and increased demand for POCs which we believe was primarily due to higher vaccination rates within our patient population and increased ambulation, additional stimulus payments, and improved consumer confidence. This led to improved sales representative productivity and increased average revenue per order in the comparative periods. This was partially offset by lower average inside sales representative headcount, which was down approximately 12% from the comparative period in 2020.

Domestic direct-to-consumer rentals increased 63.5% for the year ended December 31, 2021 compared to the year ended December 31, 2020, primarily due to an increase in patients on service, increased Medicare reimbursement rates, and higher billable patients as a percent of total patients on service.

Cost of revenue and gross profit

(amounts in thousands)	Years ended December 31, 2021	Years ended December 31, 2020	Change 2021 vs. 2020 $	Change 2021 vs. 2020 %	% of Revenue 2021	% of Revenue 2020
Cost of sales revenue	$ 161,824	$ 156,764	$ 5,060	3.2%	45.2%	50.8%
Cost of rental revenue	19,696	13,543	6,153	45.4%	5.5%	4.5%
Total cost of revenue	$ 181,520	$ 170,307	$ 11,213	6.6%	50.7%	55.2%
Gross profit - sales revenue	$ 149,906	$ 123,425	$ 26,481	21.5%	41.9%	40.0%
Gross profit - rental revenue	26,577	14,755	11,822	80.1%	7.4%	4.8%
Total gross profit	$ 176,483	$ 138,180	$ 38,303	27.7%	49.3%	44.8%
Gross margin percentage - sales revenue	48.1%	44.1%				
Gross margin percentage - rental revenue	57.4%	52.1%				
Total gross margin percentage	49.3%	44.8%				

Cost of sales revenue increased $5.1 million for the year ended December 31, 2021 from the year ended December 31, 2020, or an increase of 3.2% from the comparable year. The increase in cost of sales revenue was primarily attributable to higher bill of material costs as well as higher material cost per unit and labor and overhead per unit. The year ended December 31, 2021 included $3.2 million of higher material costs associated with open-market purchases of semiconductor chips used in its batteries and POCs.

Cost of rental revenue increased $6.2 million for the year ended December 31, 2021 from the year ended December 31, 2020, or an increase of 45.4% from the comparable year. The increase in cost of rental revenue was primarily due to an increase in total patients on service, which led to increased rental asset depreciation expense and servicing costs. Cost of rental revenue included $8.9 million of rental asset depreciation for the year ended December 31, 2021 compared to $5.7 million for the year ended December 31, 2020.

Sales revenue gross margin percentage increased to 48.1% for the year ended December 31, 2021 from 44.1% for the year ended December 31, 2020. The increase was primarily related to higher average selling prices and decreased mix of domestic business-to-business sales, which have a lower gross margin than direct-to-consumer and international sales, partially offset by higher labor and overhead per unit and material cost per unit due to higher component cost versus the comparative year. Total worldwide business-to-business sales revenue accounted for 54.8% of total sales revenue in the year ended December 31, 2021 versus 56.6% in the year ended December 31, 2020.

Rental revenue gross margin percentage increased to 57.4% for the year ended December 31, 2021 from 52.1% for the year ended December 31, 2020, primarily due to higher billable patients as a percent of total patients on service and higher Medicare reimbursement rates, partially offset by higher servicing costs and depreciation expense per patient on service.

Research and development expense

(amounts in thousands)	Years ended December 31, 2021	Years ended December 31, 2020	Change 2021 vs. 2020 $	Change 2021 vs. 2020 %	% of Revenue 2021	% of Revenue 2020
Research and development expense	$ 16,576	$ 14,080	$ 2,496	17.7%	4.6%	4.6%

Research and development expense increased $2.5 million for the year ended December 31, 2021 from the year ended December 31, 2020, or an increase of 17.7% over the comparable period, primarily due to a $1.7 million increase in personnel-related expenses and $0.6 million in product development expenses.

Sales and marketing expense

(amounts in thousands)	Years ended December 31, 2021	Years ended December 31, 2020	Change 2021 vs. 2020 $	Change 2021 vs. 2020 %	% of Revenue 2021	% of Revenue 2020
Sales and marketing expense	$ 112,815	$ 97,520	$ 15,295	15.7%	31.5%	31.6%

Sales and marketing expense increased $15.3 million for the year ended December 31, 2021 from the year ended December 31, 2020, or an increase of 15.7% from the comparable period, primarily attributable to an increase of $9.0 million of personnel-related expenses, $2.4 million of consulting fees, $2.1 million in credit card and financing fees, $1.0 million in media and advertising costs, and $0.4 million in travel and entertainment expenses. In the year ended December 31, 2021, we spent $35.2 million in media and advertising costs versus $34.2 million in the comparative period in 2020.

General and administrative expense

	Years ended December 31,		Change 2021 vs. 2020		% of Revenue	
(amounts in thousands)	2021	2020	$	%	2021	2020
General and administrative expense	$ 37,852	$ 38,605	$ (753)	-2.0%	10.6%	12.5%

General and administrative expense decreased $0.8 million for the year ended December 31, 2021 from the year ended December 31, 2020, or a decrease of 2.0% from the comparable period. The decrease was primarily attributable to a $12.6 million decrease in the change in fair value of the New Aera earnout liability and $1.1 million in lower consulting fees, partially offset by increases of $6.5 million in personnel-related expenses, $2.1 million in CEO transition costs, $1.2 million in legal and accounting fees, $1.1 million in officer transition costs, $0.9 million reimbursement from the CARES Act Provider Relief Fund due to the COVID-19 PHE received in the comparable period, $0.5 million in insurance expense, and $0.3 million in facilities costs.

Other income (expense)

	Years ended December 31,		Change 2021 vs. 2020		% of Revenue	
(amounts in thousands)	2021	2020	$	%	2021	2020
Interest income	$ 129	$ 909	$ (780)	-85.8%	0.0%	0.3%
Other income (expense)	(710)	5,836	(6,546)	-112.2%	-0.2%	1.9%
Total other income (expense), net	$ (581)	$ 6,745	$ (7,326)	-108.6%	-0.2%	2.2%

Total other income (expense), net decreased $7.3 million for the year ended December 31, 2021 from the year ended December 31, 2020, or a decrease of 108.6% from the comparable period. The decrease was primarily attributable to $5.3 million in other income from the CARES Act Provider Relief Fund due to lost revenues from the COVID-19 PHE received in the comparable period and not received the current year, a $1.3 million increase in net foreign currency losses, and a decrease of $0.8 million in interest income on marketable securities due to the lower interest rate environment and lower invested balances in marketable securities in the 2021 compared to 2020.

Income tax expense

	Years ended December 31,		Change 2021 vs. 2020		% of Revenue	
(amounts in thousands)	2021	2020	$	%	2021	2020
Income tax expense	$ 14,992	$ 549	$ 14,443	2630.8%	4.2%	0.2%
Effective income tax rate	*173.1%*	*-10.4%*				

Income tax expense increased $14.4 million for the year ended December 31, 2021 from the year ended December 31, 2020, primarily resulting from the recording of a valuation allowance on the use of deferred tax assets, the reduction in the fair value of the New Aera earnout liability, partially offset by an increase in excess tax benefits recognized from stock-based compensation.

Our effective tax rate in the year ended December 31, 2021 increased compared to the year ended December 31, 2020, primarily due to the recording of a valuation allowance on the use of deferred tax assets, the reduction in the fair value of the New Aera earnout liability, partially offset by an increase in excess tax benefits recognized from stock-based compensation.

Net loss

	Years ended December 31,		Change 2021 vs. 2020		% of Revenue	
(amounts in thousands)	2021	2020	$	%	2021	2020
Net loss	$ (6,333)	$ (5,829)	$ (504)	-8.6%	-1.8%	-1.9%

Net loss increased $0.5 million for the year ended December 31, 2021 from the year ended December 31, 2020, or an increase of 8.6% from the comparable period. The increase in net loss was primarily related to the recording of a valuation allowance on the use of deferred tax assets and higher operating expense, partially offset by an increase in gross profit and the reduction in the fair value of the New Aera earnout liability.

Seasonality

We believe our sales may be impacted by seasonal factors. For example, we typically experience higher total sales in the second and third quarters, as a result of consumers traveling and vacationing during warmer weather in the spring and summer months, but this may vary year-over-year. In particular, due to the COVID-19 pandemic and related PHE, we have seen and expect to continue to see a disruption in our normal seasonal trends due to the mandates and behaviors emanating from the COVID-19 pandemic and related PHE, including shelter-in-place orders, reduced travel, and lower consumer confidence, and we did not see the typical seasonal increases in direct-to-consumer sales in 2020 that we have seen in prior years, but have seen seasonality in our direct-to-consumer sales in 2021 to be similar to historical periods excluding 2020, although this may not continue in future periods. We also expect the semiconductor chip shortage to negatively impact our total revenue for 2022.Additionally, as more home medical equipment (HME) providers adopt portable oxygen concentrators in their businesses, we expect our historical seasonality in the domestic business-to-business channel could change as well, which was previously influenced mainly by consumer buying patterns.

Comparison of years ended December 31, 2020 and 2019

A discussion of changes in our results of operations during the year ended December 31, 2020 compared to the year ended December 31, 2019 has been omitted from this Annual Report on Form 10-K but may be found in “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Annual Report on Form 10-K for the year ended December 31, 2020, filed with the SEC on February 24, 2021, which discussion is incorporated herein by reference and which is available free of charge on the SECs website at www.sec.gov.

Liquidity and capital resources

As of December 31, 2021, we had cash and cash equivalents of $235.5 million, which consisted of highly liquid investments with a maturity of three months or less. In addition, we held marketable securities of $10.0 million in available-for-sale corporate bonds which had maturities greater than three months. For the years ended December 31, 2021, 2020 and 2019, we received $15.6 million, $2.4 million and $5.9 million, respectively, in proceeds related to stock option exercises and our employee stock purchase plan.

Our principal uses of cash for liquidity and capital resources in the year ended December 31, 2021 consisted of capital expenditures of $24.1 million including additional rental equipment, other property, plant and equipment, and intangible assets.

The COVID-19 pandemic and related PHE has not materially impacted our liquidity position to date, and we believe our current cash and cash equivalents provide us with a certain degree of stability and liquidity during this time of uncertainty. We believe that our current cash, cash equivalents and the cash to be generated from expected product sales and rentals will be sufficient to meet our projected operating and investing requirements for at least the next twelve months. However, our liquidity assumptions may prove to be incorrect, and we could utilize our available financial resources sooner than we currently expect. Our future funding requirements will depend on many factors, including market acceptance of our products; the cost of our research and development activities; payments from customers; the cost, timing, and outcome of litigation or disputes involving intellectual property rights, our products, employee relations, cyber security incidents, or otherwise; the cost and timing of acquisitions; the cost and timing of regulatory clearances or approvals; the cost and timing of establishing additional sales, marketing, and distribution capabilities; and the effect of competing technological and market developments. In the future, we may acquire businesses or technologies from third parties, and we may decide to raise additional capital through debt or equity financing to the extent we believe this is necessary to successfully complete these acquisitions. Our future capital requirements will also depend on many additional factors, including those set forth in the section of this Annual Report on Form 10-K entitled “Risk Factors.”

If we require additional funds in the future, we may not be able to obtain such funds on acceptable terms, or at all. In the future, we may also attempt to raise additional capital through the sale of equity securities or through equity-linked or debt financing arrangements. If we raise additional funds by issuing equity or equity-linked securities, the ownership of our existing stockholders will be diluted. If we raise additional financing by the incurrence of indebtedness, we will be subject to increased fixed payment obligations and could also be subject to restrictive covenants, such as limitations on our ability to incur additional debt, and other operating restrictions that could adversely impact our ability to conduct our business. Any future indebtedness we incur may result in terms that could be unfavorable to equity investors. There can be no assurances that we will be able to raise additional capital, which

would adversely affect our ability to achieve our business objectives. In addition, if our operating performance during the next twelve months is below our expectations, our liquidity and ability to operate our business could be adversely affected.

The following tables show a summary of our cash flows and working capital for the periods and as of the dates indicated:

(amounts in thousands)	Years ended December 31,		
Summary of consolidated cash flows	**2021**	**2020**	**2019**
Cash provided by operating activities	$ 23,633	$ 37,013	$ 40,593
Cash used in investing activities	(14,645)	(25,640)	(44,057)
Cash provided by financing activities	15,000	2,066	4,929
Effect of exchange rates on cash	(426)	486	(62)
Net increase in cash and cash equivalents	$ 23,562	$ 13,925	$ 1,403

(amounts in thousands)	December 31,	
Summary of working capital	**2021**	**2020**
Total current assets	$ 329,186	$ 305,697
Total current liabilities	61,512	56,710
Net working capital	$ 267,674	$ 248,987

Operating activities

We derive operating cash flows from cash collected from the sales and rental of our products and services. These cash flows received are partially offset by our use of cash for operating expenses to support the growth of our business.

Net cash provided by operating activities for the year ended December 31, 2021 consisted primarily of our non-cash expense items such as depreciation of equipment and leasehold improvements and amortization of our intangibles of $21.6 million, a decrease in deferred tax assets of $14.4 million, provision for sales returns and doubtful accounts of $11.1 million, stock-based compensation expense of $10.9 million, provision for inventory obsolescence and other inventory losses of $2.1 million, and net loss on disposal of rental equipment and other fixed assets of $1.5 million; partially offset by the change in fair value of earnout liability of $11.6 million and our net loss of $6.3 million. The net changes in operating assets and liabilities resulted in a net use of cash of $20.1 million.

Net cash provided by operating activities for the year ended December 31, 2020 consisted primarily of our non-cash expense items such as depreciation of equipment and leasehold improvements and amortization of our intangibles of $18.6 million, provision for sales returns and doubtful accounts of $10.5 million, stock-based compensation expense of $8.2 million, provision for rental revenue adjustments of $2.6 million, provision for inventory obsolescence and other inventory losses of $1.3 million, change in fair value of earnout liability of $1.1 million, net loss on disposal of rental equipment and other fixed assets of $0.9 million and our net loss of $5.8 million. The net changes in operating assets and liabilities resulted in no effect on cash flows from operating activities.

Net cash provided by operating activities for the year ended December 31, 2019 consisted primarily of our net income of $21.0 million as well as non-cash expense items such as provision for sales returns and doubtful accounts of $17.2 million, depreciation of equipment and leasehold improvements and amortization of our intangibles of $13.8 million, stock-based compensation expense of $9.1 million, deferred tax assets of $2.9 million, provision for rental revenue adjustments of $2.2 million, provision for inventory obsolescence and other inventory losses of $1.0 million, change in fair value of earnout liability of $0.8 million and net loss on disposal of rental equipment and other fixed assets of $0.6 million. The net changes in operating assets and liabilities resulted in a net use of cash of $27.9 million.

Investing activities

Net cash used in investing activities for each of the periods presented included cash used for acquisitions and in the production and purchase of rental assets, manufacturing equipment and tooling, computer equipment and software, leasehold improvements and other property, plant and equipment to support our expanding business, partially offset by net maturities of marketable securities.

For the year ended December 31, 2021, we invested $23.9 million in the production and purchase of rental assets and other property, equipment, and intangible assets as well as $10.0 million in corporate bonds with maturities greater than three months that were classified as marketable securities, partially offset by $19.3 million in maturities of marketable securities.

For the year ended December 31, 2020, we invested $22.8 million in corporate bonds, U.S. Treasury securities and agency mortgage-backed securities with maturities greater than three months that were classified as marketable securities, partially offset by $14.5 million in maturities of available-for-sale investments. In addition, we invested $17.6 million in the production and purchase of rental assets and other property, equipment, and intangible assets.

For the year ended December 31, 2019, we acquired New Aera for a net cash payment of $70.4 million and invested $58.7 million in corporate bonds and U.S. Treasury securities with maturities greater than three months that were classified as marketable securities, partially offset by $91.4 million in maturities of marketable securities. In addition, we invested $6.5 million in the production and purchase of rental assets and other property, equipment, leasehold improvements and intangible assets.

We expect to continue investing in property, equipment and leasehold improvements as we expand our operations. Our business is inherently capital intensive. For example, we expend significant manufacturing and production expense in connection with the development and production of our oxygen concentrator products and, in connection with our rental business, we incur expense in the deployment of rental equipment to our patients. Investments will continue to be required in order to grow our sales and rental revenue and continue to supply and replace rental equipment to our rental patients on service.

Financing activities

Historically, we have funded our operations through our sales and rental revenue, the issuance of preferred and common stock, and the incurrence of indebtedness.

For the year ended December 31, 2021, net cash provided by financing activities consisted of $15.6 million from the proceeds received from stock options that were exercised and purchases under our employee stock purchase program, partially offset by the payment of employment taxes related to the vesting of restricted stock awards and restricted stock units of $0.6 million.

For the year ended December 31, 2020, net cash provided by financing activities consisted of $2.4 million from purchases under our employee stock purchase program and the proceeds received from stock options that were exercised, partially offset by the payment of employment taxes related to the vesting of restricted stock awards and restricted stock units of $0.4 million.

For the year ended December 31, 2019, net cash provided by financing activities consisted of $5.9 million from the proceeds received from stock options that were exercised and purchases under our employee stock purchase program, partially offset by the payment of employment taxes related to the vesting of restricted stock awards and restricted stock units of $0.9 million.

Sources of funds

Our cash provided by operating activities in the year ended December 31, 2021 was $23.6 million compared to $37.0 million in the year ended December 31, 2020. As of December 31, 2021, we had cash and cash equivalents of $235.5 million.

Use of funds

Our principal uses of cash are funding our new rental asset deployments and other capital purchases, operations, and other working capital requirements and, from time-to-time, the acquisition of businesses. Over the past several years our cash flows from customer collections have remained consistent and our annual cash provided by operating activities has generally been a significant source of capital to the business, which we expect to continue in the future.

We may need to raise additional funds to support our investing operations, and such funding may not be available to us on acceptable terms, or at all. If we are unable to raise additional funds when needed, our operations and ability to execute our business strategy could be adversely affected. We may seek to raise additional funds through equity, equity-linked or debt financings. If we raise additional funds through the incurrence of indebtedness, such indebtedness would have rights that are senior to holders of our equity securities and could contain covenants that restrict our operations. Any additional equity financing may be dilutive to our stockholders.

Non-GAAP financial measures

EBITDA and Adjusted EBITDA are financial measures that are not calculated in accordance with U.S. GAAP. We define EBITDA as net income (loss) excluding interest income, interest expense, taxes and depreciation and amortization. Adjusted EBITDA also excludes stock-based compensation and change in fair value of earnout liability. Below, we have provided a reconciliation of EBITDA and Adjusted EBITDA to our net income (loss), the most directly comparable financial measure calculated and presented in accordance with U.S. GAAP. EBITDA and Adjusted EBITDA should not be considered alternatives to net income (loss) or any other measure of financial performance calculated and presented in accordance with U.S. GAAP. Our EBITDA and Adjusted EBITDA may not be comparable to similarly titled measures of other organizations because other organizations may not calculate EBITDA and Adjusted EBITDA in the same manner as we calculate these measures.

We include EBITDA and Adjusted EBITDA in this Annual Report on Form 10-K because they are important measures upon which our management assesses our operating performance. We use EBITDA and Adjusted EBITDA as key performance measures because we believe they facilitate operating performance comparisons from period-to-period by excluding potential differences primarily caused by variations in capital structures, tax positions, the impact of depreciation and amortization expense on our fixed assets and intangible assets, the impact of stock-based compensation expense and the impact of the change in fair value of the earnout liability. Because EBITDA and Adjusted EBITDA facilitate internal comparisons of our historical operating performance on a more consistent basis, we also use EBITDA and Adjusted EBITDA for business planning purposes, to incentivize and compensate our management personnel, and in evaluating acquisition opportunities. In addition, we believe EBITDA and Adjusted EBITDA and similar measures are widely used by investors, securities analysts, ratings agencies, and other parties in evaluating companies in our industry as a measure of financial performance and debt-service capabilities.

Our uses of EBITDA and Adjusted EBITDA have limitations as analytical tools and should not be considered in isolation or as a substitute for analysis of our results as reported under U.S. GAAP. Some of these limitations are:

- EBITDA and Adjusted EBITDA do not reflect our cash expenditures for capital equipment or other contractual commitments;
- although depreciation and amortization are non-cash charges, the assets being depreciated and amortized may have to be replaced in the future, and EBITDA and Adjusted EBITDA do not reflect capital expenditure requirements for such replacements;
- EBITDA and Adjusted EBITDA do not reflect changes in, or cash requirements for, our working capital needs;
- Adjusted EBITDA does not include changes in fair value of earnout liability related to our acquisitions; and
- other companies, including companies in our industry, may calculate EBITDA and Adjusted EBITDA measures differently, which reduces their usefulness as a comparative measure.

In evaluating EBITDA and Adjusted EBITDA, we anticipate that in the future we will incur expenses within these categories similar to this presentation. Our presentation of EBITDA and Adjusted EBITDA should not be construed as an inference that our future results will be unaffected by certain expenses. When evaluating our performance, EBITDA and Adjusted EBITDA should be considered alongside other financial performance measures, including U.S. GAAP results.

The following tables present a reconciliation of EBITDA and Adjusted EBITDA to our net income (loss), the most comparable U.S. GAAP measure, for each of the periods indicated:

(amounts in thousands)	**Years ended December 31,**		
Non-GAAP EBITDA and Adjusted EBITDA	**2021**	**2020**	**2019**
Net income (loss)	$ (6,333)	$ (5,829)	$ 20,950
Non-GAAP adjustments:			
Interest income	(129)	(909)	(4,712)
Provision for income taxes	14,992	549	3,322
Depreciation and amortization	21,628	18,581	13,834
EBITDA (non-GAAP)	30,158	12,392	33,394
Stock-based compensation	10,943	8,203	9,129
Change in fair value of earnout liability	(11,596)	1,053	810
Adjusted EBITDA (non-GAAP)	$ 29,505	$ 21,648	$ 43,333

Contractual obligations

The following table reflects a summary of our contractual obligations as of December 31, 2021.

(amounts in thousands)	Payments due by period				
Contractual Obligations	**Total**	**Less than 1 year**	**1-3 years**	**3-5 years**	**More than 5 years**
Operating leases - properties and other (1)	$ 29,114	$ 3,960	$ 10,346	$ 8,239	$ 6,569
Purchase obligations (2)	111,100	111,100	—	—	—
Total	$ 140,214	$ 115,060	$ 10,346	$ 8,239	$ 6,569

(1) We lease manufacturing and office space in Richardson, TX, Plano, TX, Goleta, CA, Smyrna, TN, Huntsville, AL, Aurora, CO, Cleveland, OH and Breukelen, Netherlands with terms that expire between 2022 and 2031 and miscellaneous office and processing equipment in Texas, California and Ohio with terms expiring between 2022 and 2031.

(2) We obtain individual components for our products from a wide variety of individual suppliers. Consistent with industry practice, we acquire components through a combination of purchase orders, supplier contracts, and open orders based on projected demand information. Where appropriate, the purchases are applied to inventory component prepayments that are outstanding with the respective supplier.

For additional description of contractual obligations and commitments, see the section titled “Commitments and Contingencies” in the Notes to Consolidated Financial Statements included in this Annual Report on Form 10-K.

Contingent consideration

In connection with our acquisition of New Aera, we have contingent obligations to pay up to $31.4 million in earnout payments in cash if certain future financial results are met. See the section titled “Fair Value of Earnout Liability” in the Notes to Consolidated Financial Statements included in this Annual Report on Form 10-K for further discussion.

Critical accounting policies and estimates

Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements which have been prepared in accordance with generally accepted accounting principles in the United States of America, or U.S. GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities and related disclosure of contingent assets and liabilities, revenue and expenses at the date of the financial statements. Generally, we base our estimates on historical experience and on various other assumptions in accordance with U.S. GAAP that we believe to be reasonable under the circumstances. Actual results may differ from these estimates and such differences could be material to the financial position and results of operations.

Critical accounting policies and estimates are those that we consider the most important to the portrayal of our financial condition and results of operations because they require our most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. Our critical accounting policies and estimates include those related to:

- revenue recognition; and
- acquisitions and related acquired intangible assets and goodwill.

Revenue recognition

We generate revenue primarily from sales and rentals of our products. Our products consist of our proprietary line of oxygen concentrators and related accessories. Other revenue primarily comes from service contracts, replacement parts and freight revenue for product shipments.

Revenue is recognized upon transfer of control of promised products or services to customers in an amount that reflects the consideration we expect to receive in exchange for those products or services. Revenue from product sales is generally recognized upon shipment of the product but is deferred for certain transactions when control has not yet transferred to the customer.

Our product is generally sold with a right of return and we may provide other incentives, which are accounted for as variable consideration when estimating the amount of revenue to recognize. Returns and incentives are estimated at the time sales revenue is recognized. The provisions for estimated returns are made based on known claims and estimates of additional returns based on historical data and future expectations. Sales revenue incentives within our contracts are estimated based on the most likely amounts expected on the related sales transaction and recorded as a reduction to revenue at the time of sale in accordance with the terms of the contract. Accordingly, revenue is recognized net of allowances for estimated returns and incentives.

For a fixed price, we also offer a lifetime warranty for direct-to-consumer sales for our oxygen concentrators. The revenue is allocated to the distinct lifetime warranty performance obligation based on a relative stand-alone selling price (SSP) method. We have vendor-specific objective evidence of the selling price for our equipment. To determine the selling price of the lifetime warranty, we use the best estimate of the SSP for the distinct performance obligation as the lifetime warranty is neither separately priced nor is the selling price available through third-party evidence. To estimate the selling price associated with the lifetime warranties, management considers the profit margins of service revenue, the average estimated cost of lifetime warranties and the price of extended warranties. Revenue from the distinct lifetime warranty is deferred after the delivery of the equipment and recognized based on an estimated mortality rate over five years, which is the estimated performance period of the contract based on the average patient life expectancy.

Revenue from the sale of our repair services is recognized when the performance obligations are satisfied, and collection of the receivables is probable. Other revenue from the sale of replacement parts is generally recognized when product is shipped to customers.

Freight revenue consists of fees associated with the deployment of products internationally and domestically when expedited freight options are requested or when minimum order quantities are not met. Freight revenue is generally recognized upon shipment of the product but is deferred if control has not yet transferred to the customer. Shipping and handling costs for sold products and rental assets shipped to our customers are included on the consolidated statement of comprehensive income as part of cost of sales revenue and cost of rental revenue, respectively.

The payment terms and conditions of customer contracts vary by customer type and the products and services offered. For certain products or services and customer types, we require payment before the products or services are delivered to the customer. The timing of sales revenue recognition, billing and cash collection results in billed accounts receivable and deferred revenue in the consolidated balance sheet.

Contract liabilities primarily consist of deferred revenue related to lifetime warranties on direct-to-consumer sales revenue when cash payments are received in advance of services performed under the contract. The contract with the customer states the final terms of the sale, including the description, quantity, and price of each product or service purchase.

We elected to apply the practical expedient in accordance with ASC 606—*Revenue Recognition* and did not evaluate contracts of one year or less for the existence of a significant financing component. We do not expect any revenue to be recognized over a multi-year period with the exception of revenue related to lifetime warranties.

We recognize equipment rental revenue over the non-cancelable lease term, which is one month, less estimated adjustments, per ASC 842—*Leases*. We have separate contracts with each patient that are not subject to a master lease agreement with any payor. We evaluate the individual lease contracts at lease inception and the start of each monthly renewal period to determine if there is reasonable assurance that the bargain renewal option associated with the potential capped free rental period would be exercised. Historically, the exercise of such bargain renewal option is not reasonably assured at lease inception and most subsequent monthly lease renewal periods. If we determine that the reasonable assurance threshold for an individual patient is met at lease inception or at a monthly lease renewal period, such determination would impact the bargain renewal period for an individual lease. We would first consider the lease classification (sales-type lease or operating lease) and then appropriately recognize or defer rental revenue over the lease term, which may include a portion of the capped rental period. To date, we have not deferred any amounts associated with the capped rental period. Amounts related to the capped rental period have not been material in the periods presented.

The lease term begins on the date products are shipped to patients and are recorded at amounts estimated to be received under reimbursement arrangements with third-party payors, including Medicare, private payors, and Medicaid. Due to the nature of the industry and the reimbursement environment in which we operate, certain estimates are required to record net revenue and accounts receivable at their net realizable values. Inherent in these estimates is the risk that they will have to be revised or updated as additional information becomes available. Specifically, the complexity of many third-party billing arrangements and the uncertainty of reimbursement amounts for certain services from certain payors may result in adjustments to amounts originally recorded. Such adjustments are typically identified and recorded at the point of cash application, claim denial or account review. Accounts receivable are reduced by an allowance for doubtful accounts which provides for those accounts from which payment is not expected to be received, although product was delivered and revenue was earned. Upon determination that an account is uncollectable, it is written-off and charged to the allowance. Amounts billed but not earned due to the timing of the billing cycle are deferred and recognized in revenue on a straight-line basis over the monthly billing period. For example, if the first day of the billing period does not fall on the first of the month, then a portion of the monthly billing period will fall in the subsequent month and the related revenue and cost would be deferred based on the service days in the following month.

Rental revenue is recognized as earned, less estimated adjustments. Revenue not billed at the end of the period is reviewed for the likelihood of collections and accrued. The rental revenue stream is not guaranteed, and payment will cease if the patient no longer needs oxygen or returns the equipment. Revenue recognized is at full estimated allowable reimbursement rates. Rental revenue is earned for that month if the patient is on service on the first day of the 30-day period commencing on the recurring date of service for a particular claim regardless of whether there is a change in condition or death after that date. In the event that a third-party payor does not accept the claim for payment, the consumer is ultimately responsible for payment for the products and services. We have determined that the balances are collectable at the time of revenue recognition because the patient signs a notice of financial responsibility outlining their obligations.

Included in rental revenue are unbilled amounts that were earned but not able to be billed for various reasons. The criteria for recognizing revenue had been met as of period-end, but there were specific reasons why we were unable to bill Medicare and private insurance for these amounts. As a result, we create an unbilled rental revenue accrual based on these earned revenues not billed based on a percentage of unbilled amounts and historical trends and estimates of future collectability.

Acquisitions and related acquired intangible assets and goodwill

The purchase price of an acquisition is allocated to the underlying assets acquired and liabilities assumed based upon their estimated fair values at the date of acquisition. To the extent the purchase price exceeds the fair value of the net identifiable tangible and intangible assets acquired and liabilities assumed, such excess is allocated to goodwill. We may adjust the preliminary purchase price allocation, as necessary, for up to one year after the acquisition closing date if we obtain more information regarding asset valuations and liabilities assumed.

We acquired New Aera on August 9, 2019 for $101.9 million. The excess purchase price over the fair value of net tangible assets and identifiable intangible assets acquired has been allocated to goodwill. Goodwill represents the expected synergies with the existing business, the acquired assembled workforce, and future cash flows after the acquisition. The fair value assigned to the identifiable intangible asset was determined primarily by using the excess earnings method. The key assumptions included in the excess earnings method included revenue recognized, cost of revenue and the discount rate.

Goodwill is tested for impairment on an annual basis as of October 1. Interim testing of goodwill for impairment is also required whenever an event occurs or circumstances change that would more likely than not reduce the fair value of a reporting unit or asset below its carrying amount. No impairments were recorded as of December 31, 2021 and December 31, 2020.

Finite-lived intangible assets are amortized over their useful lives and are tested for recoverability whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. Technology and customer relationship intangibles are amortized using the straight-line method.

Recent accounting pronouncements

Refer to Note 1 – Summary of significant accounting policies of the audited consolidated notesincluded in Part II, Item 8, "Financial Statements and Supplementary Data" in this Annual Report on Form 10-K for further discussion.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to various market risks, including fluctuation in foreign currency exchange rates and interest rates. Market risk is the potential loss arising from adverse changes in market rates and prices. We do not hold or issue financial instruments for trading purposes.

Foreign currency exchange risk

The principal market risk we face is foreign currency exchange risk. The majority of our revenue is denominated in U.S. dollars while the majority of our European sales are denominated in Euros. In addition, we acquired MedSupport in the second quarter of 2017 with net assets denominated in Euros. Our results of operations, certain balance sheet balances and cash flows are, therefore, subject to fluctuations due to changes in foreign currency exchange rates. The volatility of exchange rates depends on many factors that we cannot forecast with reliable accuracy. We have experienced and will continue to experience fluctuations in our net income or loss as a result of transaction gains or losses related to revaluing certain current asset and current liability balances that are denominated in currencies other than the functional currency in which they are recorded. The effect of a 10% adverse change in exchange rates on foreign denominated cash, receivables and payables as of December 31, 2021 would not have had a material effect on our financial position, results of operations or cash flows. As our operations in countries outside of the United States grow, our results of operations and cash flows will be subject to fluctuations due to changes in foreign currency exchange rates, which could harm our business in the future.

We began entering into foreign exchange forward contracts in December 2015 to protect our forecasted U.S. dollar-equivalent earnings from adverse changes in foreign currency exchange rates. These hedging contracts reduce, but will not entirely eliminate, the impact of adverse currency exchange rate movements on revenue. We performed a sensitivity analysis assuming a hypothetical 10% adverse movement in foreign exchange rates to the hedging contracts and the underlying exposures described above. As of December 31, 2021, the analysis indicated that these hypothetical market movements would not have a material effect on our financial position, results of operations or cash flows. We estimate prior to any hedging activity that a 10% adverse change in exchange rates on our

foreign denominated sales would have resulted in a $5.9 million decline in revenue for the year ended December 31,2021. We designate these forward contracts as cash flow hedges for accounting purposes. The fair value of the forward contract is separated into intrinsic and time values. The fair value of forward currency-exchange contracts is sensitive to changes in currency exchange rates. Changes in the time value are coded in other income (expense), net. Changes in the intrinsic value are recorded as a component of accumulated other comprehensive income (loss) and subsequently reclassified into revenue to offset the hedged exposures as they occur.

Interest rate fluctuation risk

We had cash and cash equivalents of $235.5 million as of December 31, 2021, which consisted of highly liquid investments with a maturity of three months or less, and $10.0 million of marketable securities with maturity dates of greater than three months. The primary goals of our investment policy are liquidity and capital preservation. We do not enter into investments for trading or speculative purposes. We believe that we do not have any material exposure to changes in the fair value of these assets as a result of changes in interest rates due to the short-term nature of our cash and cash equivalents. Declines in interest rates, however, would reduce future investment income. We considered the historical volatility of short-term interest rates and determined that it was reasonably possible that an adverse change of 100 basis points could be experienced in the near term. A hypothetical 1.00% (100 basis points) increase in interest rates would not have materially impacted the fair value of our marketable securities as of December 31, 2021 and December 31, 2020. If overall interest rates had increased or decreased by 1.00% (100 basis points), neither our interest expense nor our interest income would have been materially affected during the years ended December 31, 2021 or December 31, 2020.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements and supplementary data required by this item are included in Part IV, Item 15 of this Report.

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

The Company maintains a system of disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), which are designed to provide reasonable assurance that information required to be disclosed in the reports that the Company files or submits under the Exchange Act, is recorded, processed, summarized and reported accurately and completely within the time periods specified in the SEC’s rules and forms. These disclosure controls and procedures include, among other processes, controls and procedures designed to ensure that information required to be disclosed in the reports that the Company files or submits under the Exchange Act is accumulated and communicated to management, including the Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Due to inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Further, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions over time, or that the degree of compliance with the policies and procedures may deteriorate. Accordingly, even effective disclosure controls and procedures can only provide reasonable assurance of achieving their control objectives. Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2021. Based upon the evaluation described above, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2021, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in internal controls over financial reporting

There has been no change in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Rule 13a-15 or 15d-15 that occurred during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Limitations on effectiveness of controls

In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Because of the inherent limitations in any control system, misstatements due to error or fraud may occur and not be detected.

Management's report on internal control over financial reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act). Our management, including our Chief Executive Officer and Chief Financial Officer, conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (COSO). Based on our evaluation under the COSO framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2021 to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U.S. GAAP.

The effectiveness of our internal control over financial reporting as of December 31, 2021 has been audited by our independent registered public accounting firm, Deloitte & Touche LLP, as stated in their report, which appears herein.

Report of independent registered public accounting firm

To the stockholders and the Board of Directors of Inogen, Inc.

Opinion on Internal Control over Financial Reporting

We have audited the internal control over financial reporting of Inogen, Inc. and subsidiary (the "Company") as of December 31, 2021, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2021, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated financial statements as of and for the year ended December 31, 2021 of the Company and our report dated February 24, 2022, expressed an unqualified opinion on those financial statements.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

/s/ DELOITTE & TOUCHE LLP

Los Angeles, California
February 24, 2022

ITEM 9B. OTHER INFORMATION

Annual Meeting

Our annual meeting of stockholders will be held at 10:00 a.m. Pacific Time on Wednesday, June 8, 2022, as a virtual meeting. Holders of record at the close of business on Monday, April 11, 2022, will be entitled to vote at the meeting.

2014 Equity Incentive Plan and 2014 Employee Stock Purchase Plan "Evergreen" Determination

For 2022, our board of directors exercised its authority to not increase the shares available for issuance pursuant to the "evergreen" provisions under our 2014 Equity Incentive Plan and our 2014 Employee Stock Purchase Plan in 2020. Refer to Note 7 – Stockholders' Equity of the Notes included in Part II, Item 8, "Financial Statements and Supplementary Data" in this Annual Report on Form 10-K for further discussion of the annual share increase provisions of our 2014 Equity Incentive Plan and our 2014 Employee Stock Purchase Plan.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information called for by this item will be set forth in our Proxy Statement for the Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2021 (the "Proxy Statement") and is incorporated herein by reference.

Our board of directors has adopted a Code of Ethics and Conduct that applies to all of our employees, officers and directors, including our Chief Executive Officer, Chief Financial Officer and other executive and senior financial officers. The full text of our Code of Ethics and Conduct is posted on the investor relations page on our website which is located at *http://investor.inogen.com*. We will post any amendments to our code of business conduct and ethics, or waivers of its requirements, on our website.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item will be disclosed in the Proxy Statement and is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDERS MATTERS

The information required by this item will be disclosed in the Proxy Statement and is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item will be disclosed in the Proxy Statement and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item will be disclosed in the Proxy Statement and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this Annual Report on Form 10-K:

1. Financial Statements

   The consolidated financial statements listed in the accompanying index (page F-1) to the consolidated financial statements are filed as part of this Annual Report on Form 10-K.

2. Financial Statement Schedules

   See Schedule II – Valuation and Qualifying Accounts and Reserves included herein.

   All other schedules have been omitted because the information either has been shown in the financial statements or notes thereto or is not applicable or required under this section.

(b) Exhibits

Exhibits are filed as part of this Annual Report on Form 10-K and are hereby incorporated by reference. Refer to Exhibit Index included herein.

ITEM 16. FORM 10-K SUMMARY

Not applicable.

Inogen, Inc.
Index to Financial Statements
and Financial Statement Schedule

Report of independent registered public accounting firm

To the stockholders and the Board of Directors of Inogen, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Inogen, Inc. and subsidiary (the "Company") as of December 31, 2021 and 2020, the related consolidated statements of comprehensive income (loss), stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2021, and the related notes and the schedule listed in the Index at Item 15 (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, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2021, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 24, 2022, expressed an unqualified opinion on the Company's internal control over financial reporting.

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 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. 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 regarding 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.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current-period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Sales Revenue (Amounts Deferred for Lifetime Warranty) – Refer to Note 2 to the financial statements

Critical Audit Matter Description

The Company offers a lifetime warranty for direct-to-consumer sales of its oxygen concentrators. For a fixed price, the Company agrees to provide a fully functional oxygen concentrator for the remaining life of the patient. Lifetime warranties are only offered to patients upon the initial sale of oxygen concentrators directly from the Company and are non-transferable. Lifetime warranties are considered to be a distinct performance obligation that are accounted for separately from its sale of oxygen concentrators with a standard warranty of three years.

The revenue is allocated to the distinct lifetime warranty performance obligation based on a relative stand-alone selling price (SSP) method. The Company has vendor-specific objective evidence of the selling price for its equipment. To determine the selling price of the lifetime warranty, the Company uses its best estimate of the SSP for the distinct performance obligation as the lifetime warranty is neither separately priced nor is the selling price available through third-party evidence. To estimate the selling price associated with the lifetime warranties, management considers the profit margins of service revenue, the average estimated cost of lifetime warranties and the price of extended warranties. Revenue from the distinct lifetime warranty is deferred after the delivery of the equipment and recognized based on an estimated mortality rate over five years, which is the estimated performance period of the contract based on the average patient life expectancy. Total deferred revenue related to the lifetime warranty performance obligation totaled $18.0 million at December 31, 2021.

Determining the estimated SSP requires significant judgment by management, which is informed by considering Company specific and external data. The service period used to amortize the deferred revenue also requires significant management judgment as the Company has limited historical experience and the determination of patient life expectancy is subjective in nature. Given the lack of stand-alone transactions together with the limited amount of historical data available for such offering, performing audit procedures to evaluate the estimated SSP and the service period for lifetime warranty required high degree of auditor judgment and an increased extent of effort.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to management's judgments regarding the stand-alone selling price and deferred revenue service period included the following, among others:

- We tested the effectiveness of controls over deferred revenue for the lifetime warranty, including controls over the underlying data utilized and the selection of the stand-alone selling price and the deferred revenue service period.
- We evaluated the methodology used by management to develop the stand-alone selling price and independently estimated the stand-alone selling price selected by management. In performing these procedures, we compared the stand-alone selling price selected by management to the independent estimate, which utilized external evidence of similar term extended warranties for oxygen concentrators and the Company's profit margins.
- We evaluated the reasonableness of the deferred revenue service period by comparing to patient average life expectancy in medical and other industry publications. We further evaluated the realization of deferred revenue by evaluating the appropriateness of the underlying mortality data.

/s/ DELOITTE & TOUCHE LLP
Los Angeles, California
February 24, 2022

We have served as the Company's auditor since 2015.

Inogen, Inc.
Consolidated Balance Sheets
(amounts in thousands)

	December 31,	
	2021	**2020**
Assets		
Current assets		
Cash and cash equivalents	$ 235,524	$ 211,962
Marketable securities	9,989	19,257
Accounts receivable, net	24,452	29,717
Inventories, net	31,873	24,815
Income tax receivable	1,343	2,048
Prepaid expenses and other current assets	26,005	17,898
Total current assets	329,186	305,697
Property and equipment		
Rental equipment, net	59,073	46,953
Manufacturing equipment and tooling	12,050	10,361
Computer equipment and software	8,585	7,356
Furniture and equipment	3,167	2,293
Leasehold improvements	5,956	4,592
Land and building	125	125
Construction in process	1,639	2,344
Total property and equipment	90,595	74,024
Less accumulated depreciation	(51,669)	(45,794)
Property and equipment, net	38,926	28,230
Goodwill	32,979	33,165
Intangible assets, net	60,147	68,797
Operating lease right-of-use asset	24,912	8,827
Deferred tax asset - noncurrent	—	14,467
Other assets	3,363	2,669
Total assets	$ 489,513	$ 461,852

See accompanying notes to the consolidated financial statements.

Inogen, Inc.
Consolidated Balance Sheets (continued)
(amounts in thousands, except share and per share amounts)

	December 31,	
	2021	**2020**
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable and accrued expenses	$ 25,689	$ 33,712
Accrued payroll	17,307	7,091
Warranty reserve - current	6,480	5,740
Operating lease liability - current	3,393	1,931
Deferred revenue - current	8,568	6,994
Income tax payable	75	1,242
Total current liabilities	61,512	56,710
Long-term liabilities		
Warranty reserve - noncurrent	7,246	8,654
Operating lease liability - noncurrent	23,281	8,078
Earnout liability - noncurrent	15,386	26,940
Deferred revenue - noncurrent	11,861	11,822
Deferred tax liability - noncurrent	—	25
Total liabilities	119,286	112,229
Commitments and contingencies (Note 8)		
Stockholders' equity		
Common stock, $0.001 par value per share; 200,000,000 shares authorized; 22,731,586 and 22,131,447 shares issued and outstanding as of December 31, 2021 and 2020, respectively	23	22
Additional paid-in capital	299,463	273,521
Retained earnings	69,272	75,605
Accumulated other comprehensive income	1,469	475
Total stockholders' equity	370,227	349,623
Total liabilities and stockholders' equity	$ 489,513	$ 461,852

See accompanying notes to the consolidated financial statements.

Inogen, Inc.
Consolidated Statements of Comprehensive Income (Loss)
(amounts in thousands, except share and per share amounts)

	Years Ended December 31,		
	2021	**2020**	**2019**
Revenue			
Sales revenue	$ 311,730	$ 280,189	$ 340,546
Rental revenue	46,273	28,298	21,397
Total revenue	358,003	308,487	361,943
Cost of revenue			
Cost of sales revenue	161,824	156,764	175,974
Cost of rental revenue, including depreciation of $8,860, $5,695 and $6,253, respectively	19,696	13,543	14,108
Total cost of revenue	181,520	170,307	190,082
Gross profit			
Gross profit-sales revenue	149,906	123,425	164,572
Gross profit-rental revenue	26,577	14,755	7,289
Total gross profit	176,483	138,180	171,861
Operating expense			
Research and development	16,576	14,080	9,401
Sales and marketing	112,815	97,520	105,550
General and administrative	37,852	38,605	37,121
Total operating expense	167,243	150,205	152,072
Income (loss) from operations	9,240	(12,025)	19,789
Other income (expense)			
Interest income	129	909	4,712
Other income (expense)	(710)	5,836	(229)
Total other income (expense), net	(581)	6,745	4,483
Income (loss) before provision for income taxes	8,659	(5,280)	24,272
Provision for income taxes	14,992	549	3,322
Net income (loss)	(6,333)	(5,829)	20,950
Other comprehensive income (loss), net of tax			
Change in foreign currency translation adjustment	(800)	857	(123)
Change in net unrealized gains (losses) on foreign currency hedging	1,746	(82)	(1,566)
Less: reclassification adjustment for net (gains) losses included in net income	47	(207)	872
Total net change in unrealized gains (losses) on foreign currency hedging	1,793	(289)	(694)
Change in net unrealized gains (losses) on marketable securities	1	(6)	6
Total other comprehensive income (loss), net of tax	994	562	(811)
Comprehensive income (loss)	$ (5,339)	$ (5,267)	$ 20,139
Basic net income (loss) per share attributable to common stockholders (Note 2)	$ (0.28)	$ (0.27)	$ 0.96
Diluted net income (loss) per share attributable to common stockholders (Note 2)	$ (0.28)	$ (0.27)	$ 0.94
Weighted-average number of shares used in calculating net income (loss) per share attributable to common stockholders:			
Basic common shares	22,490,027	21,980,326	21,821,104
Diluted common shares	22,490,027	21,980,326	22,241,064

See accompanying notes to the consolidated financial statements.

Inogen, Inc.
Consolidated Statements of Stockholders' Equity
(amounts in thousands, except share amounts)

	Common stock		Additional paid-in capital	Retained earnings	Accumulated other comprehensive income (loss)	Total stockholders' equity
	Shares	Amount				
Balance, December 31, 2018	21,778,632	$ 22	$ 249,194	$ 60,484	$ 724	$ 310,424
Stock-based compensation	—	—	9,129	—	—	9,129
Employee stock purchases	47,816	—	2,748	—	—	2,748
Restricted stock awards issued, net of forfeitures	82,677	—	—	—	—	—
Vesting of restricted stock units	28,115	—	(82)	—	—	(82)
Shares withheld related to net restricted stock settlement	(15,121)	—	(846)	—	—	(846)
Stock options exercised	109,291	—	3,109	—	—	3,109
Net income	—	—	—	20,950	—	20,950
Other comprehensive loss	—	—	—	—	(811)	(811)
Balance, December 31, 2019	22,031,410	$ 22	$ 263,252	$ 81,434	$ (87)	$ 344,621
Stock-based compensation	—	—	8,203	—	—	8,203
Employee stock purchases	68,467	—	2,084	—	—	2,084
Restricted stock awards issued, net of forfeitures	(27,729)	—	—	—	—	—
Vesting of restricted stock units	49,117	—	(19)	—	—	(19)
Shares withheld related to net restricted stock settlement	(8,444)	—	(331)	—	—	(331)
Stock options exercised	18,626	—	332	—	—	332
Net loss	—	—	—	(5,829)	—	(5,829)
Other comprehensive income	—	—	—	—	562	562
Balance, December 31, 2020	22,131,447	$ 22	$ 273,521	$ 75,605	$ 475	$ 349,623
Stock-based compensation	—	—	10,943	—	—	10,943
Employee stock purchases	60,299	—	1,948	—	—	1,948
Restricted stock awards issued, net of forfeitures	(43,658)	—	—	—	—	—
Vesting of restricted stock units	101,811	—	(412)	—	—	(412)
Shares withheld related to net restricted stock settlement	(4,351)	—	(235)	—	—	(235)
Stock options exercised	486,038	1	13,698	—	—	13,699
Net loss	—	—	—	(6,333)	—	(6,333)
Other comprehensive income	—	—	—	—	994	994
Balance, December 31, 2021	22,731,586	$ 23	$ 299,463	$ 69,272	$ 1,469	$ 370,227

See accompanying notes to the consolidated financial statements.

Inogen, Inc.
Consolidated Statements of Cash Flows
(amounts in thousands)

	Years Ended December 31,		
	2021	**2020**	**2019**
Cash flows from operating activities			
Net income (loss)	$ (6,333)	$ (5,829)	$ 20,950
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Depreciation and amortization	21,628	18,581	13,834
Loss on rental assets and other fixed assets	1,521	864	568
Gain on sale of former rental assets	(65)	(94)	(68)
Provision for sales revenue returns and doubtful accounts	11,094	10,486	17,177
Provision for rental revenue adjustments	—	2,579	2,233
Provision for inventory losses	2,062	1,283	972
Stock-based compensation expense	10,943	8,203	9,129
Deferred income taxes	14,444	(82)	2,873
Change in fair value of earnout liability	(11,596)	1,053	810
Changes in operating assets and liabilities:			
Accounts receivable	(6,127)	(8,177)	(16,707)
Inventories	(10,775)	7,591	(10,336)
Income tax receivable	705	928	(321)
Prepaid expenses and other current assets	(8,104)	31	(2,693)
Operating lease right-of-use asset	(16,087)	(2,970)	(5,856)
Other noncurrent assets	96	2,296	(2,064)
Accounts payable and accrued expenses	(6,476)	(5,830)	3,202
Accrued payroll	10,231	870	(5,188)
Warranty reserve	(668)	1,823	3,041
Deferred revenue	1,613	(203)	2,724
Income tax payable	(1,141)	319	429
Operating lease liability	16,668	3,291	6,716
Other noncurrent liabilities	—	—	(832)
Net cash provided by operating activities	23,633	37,013	40,593
Cash flows from investing activities			
Purchases of marketable securities	(9,987)	(22,751)	(58,686)
Maturities of marketable securities	19,256	14,545	91,350
Investment in intangible assets	(132)	(255)	(254)
Investment in property and equipment	(5,482)	(4,385)	(3,143)
Production and purchase of rental equipment	(18,453)	(12,957)	(3,117)
Proceeds from sale of former assets	153	163	194
Payment for acquisition, net of cash acquired	—	—	(70,401)
Net cash used in investing activities	(14,645)	(25,640)	(44,057)

See accompanying notes to the consolidated financial statements.

Inogen, Inc.
Consolidated Statements of Cash Flows (continued)
(amounts in thousands)

	Years Ended December 31,		
	2021	**2020**	**2019**
Cash flows from financing activities			
Proceeds from stock options exercised	13,699	332	3,109
Proceeds from employee stock purchases	1,948	2,084	2,748
Payment of employment taxes related to release of restricted stock	(647)	(350)	(928)
Net cash provided by financing activities	15,000	2,066	4,929
Effect of exchange rates on cash	(426)	486	(62)
Net increase in cash and cash equivalents	23,562	13,925	1,403
Cash and cash equivalents, beginning of period	211,962	198,037	196,634
Cash and cash equivalents, end of period	$ 235,524	$ 211,962	$ 198,037
Supplemental disclosures of cash flow information			
Cash paid (received) during the period for income taxes, net of refunds received	$ 1,544	$ (713)	$ 239
Supplemental disclosure of non-cash transactions			
Accrued value of earnout related to acquisition	—	—	25,749
Property and equipment in account payable and accrued liabilities	353	55	66

See accompanying notes to the consolidated financial statements.

1. Nature of business

Inogen, Inc. (Company or Inogen) was incorporated in Delaware on November 27, 2001. The Company is a medical technology company that primarily develops, manufactures and markets innovative portable oxygen concentrators (POCs) used to deliver supplemental long-term oxygen therapy to patients suffering from chronic respiratory conditions. Traditionally, these patients have relied on stationary oxygen concentrator systems for use in the home and oxygen tanks or cylinders for mobile use, which the Company calls the delivery model. The tanks and cylinders must be delivered regularly and have a finite amount of oxygen, which requires patients to plan activities outside of their homes around delivery schedules and a finite oxygen supply. Additionally, patients must attach long, cumbersome tubing to their stationary concentrators simply to enable mobility within their homes. The Company's proprietary Inogen One® systems concentrate the air around the patient to offer a single source of supplemental oxygen anytime, anywhere with a single battery and can be plugged into an outlet when at home, in a car, or in a public place with outlets available. The Company's Inogen One systems reduce the patient's reliance on stationary concentrators and scheduled deliveries of tanks with a finite supply of oxygen, thereby improving patient quality of life and fostering mobility.

The Company incorporated Inogen Europe Holding B.V., a Dutch limited liability company, on April 13, 2017. On May 4, 2017, Inogen Europe Holding B.V. acquired all issued and outstanding capital stock of MedSupport Systems B.V. (MedSupport) and began operating under the name Inogen Europe B.V. The Company merged Inogen Europe Holding B.V. and Inogen Europe B.V. on December 28, 2018. Inogen Europe B.V. is the remaining legal entity. Inogen completed the acquisition of New Aera, Inc. (New Aera) on August 9, 2019.

2. Summary of significant accounting policies

Basis of presentation

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

Basis of consolidation

The consolidated financial statements include the accounts of Inogen, Inc. and its wholly owned subsidiary. All intercompany balances and transactions have been eliminated.

Accounting estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Management bases these estimates and assumptions upon historical experience, existing and known circumstances, authoritative accounting pronouncements and other factors that management believes to be reasonable. Significant areas requiring the use of management estimates relate to revenue recognition, warranty reserves and expense, determining the stand-alone selling price (SSP) and service period of performance obligations, rental asset valuations and write-downs, accounts receivable allowances for bad debts, returns and adjustments, impairment of long-lived assets, stock-based compensation expense, income taxes, fair value of acquired intangible assets and goodwill and fair value of earnout liabilities. Actual results could differ from these estimates.

Revenue

The Company generates revenue primarily from sales and rentals of its products. The Company's products consist of its proprietary line of oxygen concentrators, non-invasive ventilators, and related accessories. Other revenue, which is included in sales revenue on the statements of comprehensive income (loss), primarily comes from service contracts, replacement parts and freight revenue for product shipments.

Sales revenue

Revenue is recognized upon transfer of control of promised products or services to customers in an amount that reflects the consideration the Company expects to receive in exchange for those products or services. Revenue from product sales is generally recognized upon shipment of the product but is deferred for certain transactions when control has not yet transferred to the customer.

The Company's product is generally sold with a right of return and the Company may provide other incentives, which are accounted for as variable consideration when estimating the amount of revenue to recognize. Returns and incentives are estimated at the time sales revenue is recognized. The provision for estimated returns is calculated based on historical data and future expectations. Sales revenue incentives within the Company's contracts are estimated based on the most likely amounts expected on the related sales transactions and recorded as a reduction to revenue at the time of sale in accordance with the terms of the contract. Accordingly, revenue is recognized net of allowances for estimated returns and incentives.

For a fixed price, the Company also offers a lifetime warranty for direct-to-consumer sales for its oxygen concentrators. Lifetime warranties are only offered to patients upon the initial sale of oxygen concentrators directly from the Company and are non-transferable. Lifetime warranties are considered to be a distinct performance obligation that are accounted for separately from its sale of oxygen concentrators with a standard warranty of three years.

The revenue is allocated to the distinct lifetime warranty performance obligation based on a relative SSP method. The Company has vendor-specific objective evidence of the selling price for its equipment. To determine the selling price of the lifetime warranty, the Company uses its best estimate of the SSP for the distinct performance obligation as the lifetime warranty is neither separately priced nor is the selling price available through third-party evidence. To calculate the selling price associated with the lifetime warranties, management considers the profit margins of service revenue, the average estimated cost of lifetime warranties and the price of extended warranties. Revenue from the distinct lifetime warranty is deferred after the delivery of the equipment and recognized based on an estimated mortality rate over five years, which is the estimated performance period of the contract based on the average patient life expectancy.

Revenue from the sale of the Company's repair services is recognized when the performance obligations are satisfied and collection of the receivables is probable. Other revenue from the sale of replacement parts is generally recognized when product is shipped to customers.

Freight revenue consists of fees associated with the deployment of products internationally and domestically when expedited freight options are requested or when minimum order quantities are not met. Freight revenue is generally recognized upon shipment of the product but is deferred if control has not yet transferred to the customer. Shipping and handling costs for sold products and rental assets shipped to the Company's customers are included on the consolidated statements of comprehensive income (loss) as part of cost of sales revenue and cost of rental revenue, respectively.

The payment terms and conditions of customer contracts vary by customer type and the products and services offered. For certain products or services and customer types, the Company requires payment before the products or services are delivered to the customer. The timing of sales revenue recognition, billing and cash collection results in billed accounts receivable and deferred revenue in the consolidated balance sheet.

Contract liabilities primarily consist of deferred revenue related to lifetime warranties on direct-to-consumer sales revenue when cash payments are received in advance of services performed under the contract. The contract with the customer states the final terms of the sale, including the description, quantity, and price of each product or service purchase. The increase in deferred revenue related to lifetime warranties for the years ended December 31, 2021 and December 31, 2020 was primarily driven by $6,764 and $5,258, respectively, of payments received in advance of satisfying performance obligations, partially offset by $5,866 and $5,908 of revenues recognized that were included in the deferred revenue balances as of December 31, 2020 and December 31, 2019, respectively. Deferred revenue related to lifetime warranties was $17,976 and $17,078 as of December 31, 2021 and December 31, 2020, respectively, and is classified within deferred revenue – current and noncurrent deferred revenue in the consolidated balance sheets.

The Company elected to apply the practical expedient in accordance with Accounting Standards Codification (ASC) 606—*Revenue Recognition* and did not evaluate contracts of one year or less for the existence of a significant financing component. The Company does not expect any revenue to be recognized over a multi-year period with the exception of revenue related to lifetime warranties.

The Company's sales revenue is primarily derived from thesale of its oxygen concentrator products to individual consumers, home medical equipment providers, distributors, the Company's private label partner and resellers worldwide. Sales revenue is classified into two areas: business-to-business sales and direct-to-consumer sales. The following table sets forth the Company's sales revenue disaggregated by sales channel and geographic region:

(amounts in thousands)	Years ended December 31,		
Revenue by region and category	**2021**	**2020**	**2019**
Business-to-business domestic sales	$ 91,371	$ 96,423	$ 106,428
Business-to-business international sales	79,460	62,147	77,960
Direct-to-consumer domestic sales	140,899	121,619	156,158
Total sales revenue	$ 311,730	$ 280,189	$ 340,546

Rental revenue

The Company recognizes equipment rental revenue over the non-cancelable lease term, which is one month, less estimated adjustments, in accordance with Accounting Standards Codification (ASC) 842—*Leases*. The Company has separate contracts with each patient that are not subject to a master lease agreement with any third-party payor. The Company evaluates the individual lease contracts at lease inception and the start of each monthly renewal period to determine if it is reasonably certain that the monthly renewal option and the bargain renewal option associated with the potential capped free rental period would be exercised. Historically, the exercise of the monthly renewal and bargain renewal option is not reasonably certain at lease inception and at most subsequent monthly lease renewal periods. If the Company determines that the reasonably certain threshold for an individual patient is met at lease inception or at a monthly lease renewal period, such determination would impact the bargain renewal period for an individual lease. The Company would first consider the lease classification issue (sales-type lease or operating lease) and then appropriately recognize or defer rental revenue over the lease term, which may include a portion of the capped rental period. The Company deferred $0 associated with the capped rental period as of December 31, 2021 and December 31, 2020.

The lease term begins on the date products are shipped to patients and are recorded at amounts estimated to be received under reimbursement arrangements with third-party payors, including Medicare, private payors, and Medicaid. Due to the nature of the industry and the reimbursement environment in which the Company operates, certain estimates are required to record net revenue and accounts receivable at their net realizable values. Inherent in these estimates is the risk that they will have to be revised or updated as additional information becomes available. Specifically, the complexity of many third-party billing arrangements and the uncertainty of reimbursement amounts for certain services from certain payors may result in adjustments to amounts originally recorded. Such adjustments are typically identified and recorded at the point of cash application, claim denial or account review. The Company adjusts revenue for historical trends on revenue adjustments due to timely filings, deaths, hospice, and other types of analyzable adjustments on a monthly basis to record rental revenue at the expected collectible amounts. Accounts receivable is reduced by an allowance for doubtful accounts which provides for those accounts from which payment is not expected to be received although product was delivered and revenue was earned. The determination that an account is uncollectable, and the ultimate write-off of that account occurs once collection is considered to be highly unlikely, and it is written-off and charged to the allowance at that time. Amounts billed but not earned due to the timing of the billing cycle are deferred and recognized in revenue on a straight-line basis over the monthly billing period. For example, if the first day of the billing period does not fall on the first of the month, then a portion of the monthly billing period will fall in the subsequent month and the related revenue and cost would be deferred based on the service days in the following month.

The lease agreements generally contain lease and non-lease components. Non-lease components primarily include payments for supplies. The Company elected the practical expedient to treat the lease and non-lease components as a single lease component.

Rental revenue is recognized as earned, less estimated adjustments. Revenue not billed at the end of the period is reviewed for the likelihood of collections and accrued. The rental revenue stream is not guaranteed, and payment will cease if the patient no longer needs oxygen or returns the equipment. Revenue recognized is at full estimated allowable amounts; transfers to secondary insurances or patient responsibility have no net effect on revenue. Rental revenue is earned for that entire month if the patient is on service on the first day of the 30-day period commencing on the recurring date of service for a particular claim, regardless of whether there is a change in condition or death after that date.

Included in rental revenue are unbilled amounts for which the revenue recognition criteria had been met as of period-end but were not yet billed to the payor. The estimate of net unbilled rental revenue recognized is based on historical trends and estimates of future collectability. In addition, the Company estimates potential future adjustments and write-offs of these unbilled amounts and includes these estimates in the allowance for adjustments and write-offs of rental revenue which is netted against gross receivables.

Product Warranty

The Company generally provides a warranty against defects in material and workmanship. The Company provides a 3-year, 5-year or lifetime warranty on Inogen One systems sold and a 3-year and lifetime warranty on Inogen At Home systems sold. The Tidal Assist® Ventilator (TAV®) system has a 1-year and a 3-year warranty. The Company also offers a lifetime warranty for direct-to-consumer sales of its oxygen concentrators. For a fixed price, the Company agrees to provide a fully functional oxygen concentrator for the remaining life of the patient. Lifetime warranties are only offered to patients upon the initial sale of oxygen concentrators directly from the Company and are non-transferable. The Company's products are subject to regulatory and quality standards. The Company establishes an accrued liability for the estimated warranty costs at the time of revenue recognition, with a corresponding provision to cost of goods sold. The Company evaluates the liability quarterly. Warranty costs are primarily estimated based on product return rates, historical warranty repair costs incurred and historical failure rates. The Company may make further adjustments to the warranty reserve when deemed appropriate, giving additional consideration to length of time the product version has been sold and future expectations of performance based on new features and capabilities. Actual warranty costs could differ materially from the estimated amounts.

Fair value accounting

ASC 820 — *Fair Value Measurements and Disclosures* creates a single definition of fair value, establishes a framework for measuring fair value in U.S. GAAP and expands disclosures about fair value measurements. ASC 820 emphasizes that fair value is a market-based measurement, not an entity-specific measurement, and states that a fair value measurement is to estimate the price at which an orderly transaction to sell an asset or to transfer the liability would take place between market participants at the measurement date under current market conditions. Assets and liabilities adjusted to fair value in the balance sheet are categorized based upon the level of judgment associated with the inputs used to measure their fair value. Level inputs, as defined by ASC 820, are as follows:

Level input	Input definition
Level 1	Inputs are unadjusted, quoted prices for identical assets or liabilities in active markets at the measurement date.
Level 2	Inputs, other than quoted prices included in Level 1, that are observable for the asset or liability through corroboration with market data at the measurement date.
Level 3	Unobservable inputs that reflect management's best estimate of what market participants would use in pricing the asset or liability at the measurement date.

The Company's financial instruments consist of cash and cash equivalents, marketable securities, accounts receivable, accounts payable and accrued expenses. The carrying values of its financial instruments approximate fair value based on their short-term nature.

Fair value of financial instruments

The Company obtained the fair value of its available-for-sale investments, which are not in active markets, from a third-party professional pricing service using quoted market prices for identical or comparable instruments, rather than direct observations of quoted prices in active markets. The Company's professional pricing service gathers observable inputs for all of its fixed income securities from a variety of industry data providers (e.g., large custodial institutions) and other third-party sources. Once the observable inputs are gathered, all data points are considered, and the fair value is determined. The Company validates the quoted market prices provided by its primary pricing service by comparing their assessment of the fair values against the fair values provided by its investment managers. The Company's investment managers use similar techniques to its professional pricing service to derive pricing as described above. As all significant inputs were observable, derived from observable information in the marketplace or supported by observable levels at which transactions are executed in the marketplace, the Company has classified its marketable securities within Level 2 of the fair value hierarchy.

The following table summarizes fair value measurements by level for the assets measured at fair value on a recurring basis for cash, cash equivalents and marketable securities:

	As of December 31, 2021				
(amounts in thousands)	Adjusted cost	Gross unrealized gains	Fair value	Cash and cash equivalents	Marketable securities
Cash	$ 48,817	$ —	$ 48,817	$ 48,817	$ —
Level 1:					
Money market accounts	186,707	—	186,707	186,707	—
Level 2:					
Corporate bonds	9,988	1	9,989	—	9,989
Total	$ 245,512	$ 1	$ 245,513	$ 235,524	$ 9,989

	As of December 31, 2020				
(amounts in thousands)	Adjusted cost	Gross unrealized gains (losses)	Fair value	Cash and cash equivalents	Marketable securities
Cash	$ 52,812	$ —	$ 52,812	$ 52,812	$ —
Level 1:					
Money market accounts	159,150	—	159,150	159,150	—
Level 2:					
Corporate bonds	11,549	(1)	11,548	—	11,548
U.S. Treasury securities	4,107	—	4,107	—	4,107
Agency mortgage-backed securities	3,601	1	3,602	—	3,602
Total	$ 231,219	$ —	$ 231,219	$ 211,962	$ 19,257

The following table summarizes the estimated fair value of the Company's investments in marketable securities, classified by the contractual maturity date of the securities:

(amounts in thousands)	December 31, 2021
Due within one year	$ 9,989
Due in one year through five years	—
Total	$ 9,989

Fair value of derivative instruments and hedging activities

The Company transacts business in foreign currencies and has international sales and expenses denominated in foreign currencies, subjecting the Company to foreign currency risk. The Company has entered into foreign currency forward contracts, generally with maturities of twelve months or less, to reduce the volatility of cash flows primarily related to forecasted revenue denominated in certain foreign currencies. These contracts allow the Company to sell Euros in exchange for U.S. dollars at specified contract rates. Forward contracts are used to hedge forecasted sales over specific months. Changes in the fair value of these forward contracts designed as cash flow hedges are recorded as a component of accumulated other comprehensive income within stockholders' equity and are recognized in the consolidated statements of comprehensive income (loss) during the period which approximates the time the corresponding sales occur. The Company may also enter into foreign exchange contracts that are not designated as hedging instruments for financial accounting purposes. These contracts are generally entered into to offset the gains and losses on certain asset and liability balances until the expected time of repayment. Accordingly, any gains or losses resulting from changes in the fair value of the non-designated contracts are reported in other expense, net in the consolidated statements of comprehensive income (loss). The gains and losses on these contracts generally offset the gains and losses associated with the underlying foreign currency-denominated balances, which are also reported in other income (expense), net.

The Company records the assets or liabilities associated with derivative instruments and hedging activities at fair value based on Level 2 inputs in other current assets or other current liabilities, respectively, in the consolidated balance sheet. The Company had a related receivable of $1,671 and a related payable of $863 as of December 31, 2021 and 2020, respectively.

The Company documents the hedging relationship and its risk management objective and strategy for undertaking the hedge, the hedging instrument, the hedged transaction, the nature of the risk being hedged, how the hedging instrument's effectiveness in offsetting the hedged risk will be assessed prospectively and retrospectively, and a description of the method used to measure ineffectiveness. The Company assesses hedge effectiveness and ineffectiveness at a minimum quarterly but may assess it monthly. For derivative instruments that are designed and qualify as part of a cash flow hedging relationship, the effective portion of the gain or loss on the derivative is reported in other comprehensive income (loss) and reclassified into earnings in the same periods during which the hedged transaction affects earnings. Gains and losses on the derivative representing either hedge ineffectiveness or hedge components excluded from the assessment of effectiveness are recognized in current period earnings.

The Company will discontinue hedge accounting prospectively when it determines that the derivative is no longer effective in offsetting cash flows attributable to the hedge risk. The cash flow hedge is de-designated because a forecasted transaction is not probable of occurring, or management determines to remove the designation of the cash flow hedge. In all situations in which hedge accounting is discontinued and the derivative remains outstanding, the Company continues to carry the derivative at its fair value on the balance sheet and recognizes any subsequent changes in the fair value in earnings. When it is probable that a forecasted transaction will not occur, the Company will discontinue hedge accounting and recognize immediately in earnings gains and losses that were accumulated in other comprehensive income (loss) related to the hedging relationship.

Fair value of accumulated other comprehensive income (loss)

The components of accumulated other comprehensive income (loss) were as follows:

	As of December 31, 2021			
(amounts in thousands)	**Foreign currency translation adjustments**	**Unrealized gains on marketable securities**	**Unrealized gains (losses) on cash flow hedges**	**Accumulated other comprehensive income**
Balance as of December 31, 2020	$ 1,128	$ —	$ (653)	$ 475
Other comprehensive income (loss)	(800)	1	1,793	994
Balance as of December 31, 2021	$ 328	$ 1	$ 1,140	$ 1,469

	As of December 31, 2020			
(amounts in thousands)	**Foreign currency translation adjustments**	**Unrealized gains (losses) on marketable securities**	**Unrealized losses on cash flow hedges**	**Accumulated other comprehensive income (loss)**
Balance as of December 31, 2019	$ 271	$ 6	$ (364)	$ (87)
Other comprehensive income (loss)	857	(6)	(289)	562
Balance as of December 31, 2020	$ 1,128	$ —	$ (653)	$ 475

Comprehensive income (loss) is the total net earnings and all other non-owner changes in equity. Except for net income (loss) and unrealized gains and losses on cash flow hedges, the Company does not have any transactions or other economic events that qualify as comprehensive income (loss).

Fair value of earnout liability

The earnout liability will be adjusted to fair value at each reporting date until settled. At the end of each reporting period after the acquisition date, the arrangement is remeasured at its fair value, with changes in fair value recorded in general and administrative expense.

The Company has obligations to pay up to $31,400 in earnout payments in cash if certain future financial results are met.The earnout liability was valued using Level 3 inputs. The fair value of the earnout was determined by employing a Monte Carlo simulation in a risk-neutral framework. The underlying simulated variable includes recognized revenue. The recognized revenue volatility estimate was based on a study of historical asset volatility for a set of comparable public companies. The model includes other assumptions including the market price of risk, which was calculated as the weighted average cost of capital (WACC) less the long-term risk free rate. The earnout period for recognized revenue is each calendar year beginning with calendar year 2019 and ending on the calendar year in which the earnout consideration equals the earnout cap.

The following table provides quantitative information about Level 3 inputs for fair value measurement of the earnout liability as of December 31, 2021 and December 31, 2020. Significant increases or decreases in these inputs in isolation could result in a significant impact on our fair value measurement:

Simulation input	As of December 31, 2021	As of December 31, 2020
Revenue volatility	15.00 %	35.00 %
WACC	10.50 %	12.00 %
20-year risk free rate	2.02 %	1.45 %
Market price of risk	2.68 %	8.00 %

The reconciliation of the earnout liability measured and carried at fair value on a recurring basis is as follows:

(amounts in thousands)		
Balance as of December 31, 2019	$	26,559
Change in fair value		1,053
Balance as of December 31, 2020	$	27,612
Change in fair value		(11,596)
Balance as of December 31, 2021	$	16,016

The Company recorded $630 and $672 of preacquisition loss recoveries that can be withheld from any earnout amounts payable as of December 31, 2021 and December 31, 2020, respectively.

Cash, cash equivalents, and marketable securities

The Company considers all short-term highly liquid investments with a maturity of three months or less to be cash equivalents. The Company’s marketable debt securities are classified and accounted for as available-for-sale. Cash equivalents are recorded at cost plus accrued interest, which is considered adjusted cost, and approximates fair value. Marketable debt securities are included in cash equivalents and marketable securities based on the maturity date of the security. Short-term investments are included in marketable securities in the current period presentation.

The Company considers investments with maturities greater than three months, but less than one year, to be marketable securities. Investments are reported at fair value with realized and unrealized gains or losses reported in other income (expense), net.

The Company reviews its investments to identify and evaluate investments that have an indication of possible impairment. Factors considered in determining whether a loss is temporary include the length of time and extent to which fair value has been less than the cost basis, the financial condition and near-term prospects of the investee, and the Company's intent and ability to hold the investment for a period of time sufficient to allow for any anticipated recovery in market value. Credit losses and other-than-temporary impairments are declines in fair value that are not expected to recover and are charged to other income (expense), net.

Cash, cash equivalents, and marketable securities consist of the following:

(amounts in thousands)	December 31,	
Cash and cash equivalents	**2021**	**2020**
Cash	$ 48,817	$ 52,812
Money market accounts	186,707	159,150
Total cash and cash equivalents	$ 235,524	$ 211,962
Marketable securities		
Corporate bonds	$ 9,989	$ 11,548
U. S. Treasury securities	—	4,107
Agency mortgage-backed securities	—	3,602
Total marketable securities	$ 9,989	$ 19,257

Accounts receivable

Accounts receivable are customer obligations due under normal sales and rental terms. The Company performs credit evaluations of the customers' financial condition and generally does not require collateral. The allowance for doubtful accounts is maintained at a level that, in management's opinion, is adequate to absorb potential losses related to accounts receivable and is based upon the Company's continuous evaluation of the collectability of outstanding balances. Management's evaluation takes into consideration such factors as past bad debt experience, economic conditions and information about specific receivables. The Company's evaluation also considers the age and composition of the outstanding amounts in determining their net realizable value.

The allowance for doubtful accounts is based on estimates, and ultimate losses may vary from current estimates. As adjustments to these estimates become necessary, they are reported in general and administrative expense for sales revenue in the periods in which they become known. The allowance is increased by bad debt provisions, net of recoveries, and is reduced by direct write-offs.

The Company generally does not allow returns from providers for reasons not covered under its standard warranty. Therefore, provision for returns applies primarily to direct-to-consumer sales. This reserve is calculated primarily based on actual historical return rates under the Company's 30-day return program and is applied to the related sales revenue for the last month of the quarter reported.

The Company also records an estimate for rental revenue adjustments which is recorded as a reduction of rental revenue and net rental accounts receivable balances. These adjustments result from contractual adjustments, audit adjustments, untimely claims filings, or billings not paid due to another provider performing same or similar functions for the patient in the same period, all of which prevent billed revenue from becoming realizable. The reserve is based on historical revenue adjustments as a percentage of rental revenue billed and unbilled during the related period.

When recording the allowance for doubtful accounts for sales revenue, the bad debt expense account (general and administrative expense account) is charged and when recording allowance for sales returns, the sales returns account (contra sales revenue account) is charged.

The Company consistently applies its allowance estimation methodology from period-to-period. The Company's best estimate is made on an accrual basis and adjusted in future periods as required. Any adjustments to the prior period estimates are included in the current period. As additional information becomes known, the Company adjusts its assumptions accordingly to change its estimate of accounts receivable. For the years ended December 31, 2021 and December 31, 2020, the Company had increases of $877 and $575, respectively, in the net rental revenue related to prior years.

Net accounts receivable (gross accounts receivable, net of allowances) balance concentrations by major category as of December 31, 2021 and December 31, 2020 were as follows:

(amounts in thousands)	As of December 31, 2021		As of December 31, 2020	
Net accounts receivable	**$**	**%**	**$**	**%**
Rental (1)	$ 6,011	24.6%	$ 3,794	12.8%
Business-to-business and other receivables (2)	18,441	75.4%	25,923	87.2%
Total net accounts receivable	$ 24,452	100.0%	$ 29,717	100.0%

(1) Rental includes Medicare, Medicaid/other government, private insurance and patient pay.

(2) Business-to business receivables included one customer with an accounts receivable balance of $5,945 and $7,044 as of December 31, 2021 and December 31, 2020, respectively. The customer received extended payment terms through a direct financing plan offered. The Company also has a credit insurance policy in place, which allocated up to $10,000 in coverage as of December 31, 2021 and December 31, 2020 for this customer with a $400 deductible and 10% retention.

The following table sets forth the percentage breakdown of the Company's net accounts receivable by aging category by invoice due date as of December 31, 2021 and December 31, 2020.

(amounts in thousands)	As of December 31, 2021		As of December 31, 2020	
Net accounts receivable by aging category	**$**	**%**	**$**	**%**
Held and Unbilled	$ 848	3.5%	$ 298	1.0%
Aged 0-90 days	22,194	90.8%	28,604	96.2%
Aged 91-180 days	888	3.6%	560	1.9%
Aged 181-365 days	450	1.8%	230	0.8%
Aged over 365 days	72	0.3%	25	0.1%
Total net accounts receivable	$ 24,452	100.0%	$ 29,717	100.0%

The following table sets forth the accounts receivable allowances as of December 31, 2021 and December 31, 2020:

(amounts in thousands)	As of December 31, 2021		As of December 31, 2020	
Allowances - accounts receivable	**$**	**%**	**$**	**%**
Doubtful accounts	$ 52	0.2%	$ 52	0.2%
Rental revenue adjustments	—	0.0%	396	1.3%
Sales returns	810	3.1%	742	2.4%
Total allowances - accounts receivable	$ 862	3.3%	$ 1,190	3.9%

Concentration of credit risk

Financial instruments that potentially subject the Company to concentration of credit risk consist principally of cash, cash equivalents, marketable securities and accounts receivable. At times, cash account balances may be in excess of the amounts insured by the Federal Deposit Insurance Corporation. However, management believes the risk of loss to be minimal. The Company performs periodic evaluations of the relative credit standing of these institutions and has not experienced any losses on its cash and cash equivalents to date. The Company has also entered into hedging relationships with a single counterparty to offset the forecasted Euro-based revenues. The credit risk has been reduced due to a net settlement arrangement whereby the Company is allowed to net settle transactions with a single net amount payable by one party to the other.

Concentration of customers and vendors

The Company primarily sells its products to traditional home medical equipment providers, distributors, and resellers in the United States and in foreign countries on a credit basis. The Company also sells its products direct-to-consumers on a primarily prepayment basis. The Medicare service reimbursement programs represented more than 10% of the Company's total revenue for the year ended December 31, 2021. One single customer represented more than 10% of the Company's total revenue for the year ended December 31, 2020. No single customer represented more than 10% of the Company's total revenue for the year ended December 31, 2019. One single customer and Medicare each represented more than 10% of the Company's net accounts receivable balance with accounts receivable balances of $5,945 and $2,685, respectively, as of December 31, 2021, and two customers each represented more than 10% of the Company's net accounts receivable balance with accounts receivable balances of $8,417 and $7,044, respectively, as of December 31, 2020.

The Company also rents products directly to consumers for insurance reimbursement, which resulted in a customer concentration relating to Medicare's service reimbursement programs. Medicare's service reimbursement programs accounted for 81.9%, 81.5% and 81.1% of rental revenue in 2021, 2020 and 2019, respectively, and based on total revenue were 10.6%, 7.5% and 4.8% for 2021, 2020 and 2019, respectively. Accounts receivable balances relating to Medicare's service reimbursement programs (including held and unbilled, net of allowances) amounted to $2,685 or 11.0% of total net accounts receivable as of December 31, 2021 as compared to $1,882 or 6.3% of total net accounts receivable as of December 31, 2020.

The Company currently purchases raw materials from a limited number of vendors, which resulted in a concentration of three major vendors. The three major vendors supply the Company with raw materials used to manufacture the Company's products. For the year ended December 31, 2021, the Company's three major vendors accounted for 16.3%, 12.1% and 9.9%, respectively, of total raw material purchases. For the year ended December 31, 2020, the Company's three major vendors accounted for 20.7%, 11.7% and 9.3%, respectively, of total raw material purchases.

A portion of revenue is earned from sales outside the United States. Approximately 74.1%, 73.6% and 70.2% of the non-U.S. revenue for the years ended December 31, 2021, 2020 and 2019, respectively, were invoiced in Euros. A breakdown of the Company's revenue from U.S. and non-U.S. sources for the years ended December 31, 2021, 2020 and 2019, respectively, is as follows:

	Years ended December 31,		
(amounts in thousands)	**2021**	**2020**	**2019**
U.S. revenue	$ 278,543	$ 246,340	$ 283,983
Non-U.S. revenue	79,460	62,147	77,960
Total revenue	$ 358,003	$ 308,487	$ 361,943

Inventories

Inventories are stated at the lower of cost and net realizable value. Cost is determined using a standard cost method, including material, labor and manufacturing overhead, whereby the standard costs are updated at least quarterly to reflect approximate actual costs using the first-in, first-out method. The Company records adjustments at least quarterly to inventory for potentially excess, obsolete, slow-moving or impaired items. The Company recorded noncurrent inventory related to inventories that are expected to be realized or consumed after one year of $1,943 and $1,153 as of December 31, 2021 and 2020, respectively. Noncurrent inventories are primarily related to raw materials purchased in bulk to support long-term expected repairs to reduce costs and are classified in other assets. The Company prepaid for raw materials of $15,426 as of December 31, 2021 that were classified in prepaid expenses and other current assets. During the years ended December 31, 2021, 2020 and 2019, $906, $1,970 and $1,043, respectively, of inventory was transferred to rental equipment and was considered a noncash transaction in the production and purchase of rental equipment on the consolidated statements of cash flows. Inventories that are considered current consist of the following:

	December 31,	
(amounts in thousands)	**2021**	**2020**
Raw materials and work-in-progress	$ 21,909	$ 22,318
Finished goods	12,116	3,743
Less: reserves	(2,152)	(1,246)
Inventories, net	$ 31,873	$ 24,815

Property and equipment

Property and equipment are stated at cost. Depreciation and amortization are calculated using the straight-line method over the assets' estimated useful lives as follows:

Rental equipment	1.5-5 years
Manufacturing equipment and tooling	3-5 years
Computer equipment and software	2-3 years
Furniture and equipment	3-5 years
Leasehold improvements	Lesser of estimated useful life or remaining lease term

Expenditures for additions, improvements and replacements are capitalized and depreciated to a salvage value of $0. Repair and maintenance costs on rental equipment are included in cost of rental revenue on the consolidated statements of comprehensive income (loss). Repair and maintenance expense, which includes labor, parts and freight, for rental equipment was $3,387, $2,527 and $2,854 for the years ended December 31, 2021, 2020 and 2019, respectively.

Included within property and equipment is construction in process, primarily related to the design and engineering of tooling, jigs and other machinery. In addition, this item also includes computer software or development costs that have been purchased but have not completed the final configuration process for implementation into the Company's systems. These items have not been placed in service; therefore, no depreciation or amortization was recognized for these items in the respective periods.

Depreciation and amortization expense related to rental equipment and other property and equipment are summarized below for the years ended December 31, 2021, 2020 and 2019, respectively.

	Years ended December 31,		
(amounts in thousands)	**2021**	**2020**	**2019**
Rental equipment	$ 8,860	$ 5,695	$ 6,253
Other property and equipment	3,993	3,882	3,421
Total depreciation and amortization	$ 12,853	$ 9,577	$ 9,674

Property and equipment and rental equipment with associated accumulated depreciation is summarized below as of December 31, 2021 and 2020, respectively.

(amounts in thousands)	December 31,	
Property and equipment	**2021**	**2020**
Rental equipment, net of allowances of $1,290 and $575, respectively	$ 59,073	$ 46,953
Other property and equipment	31,522	27,071
Property and equipment	90,595	74,024
Accumulated depreciation		
Rental equipment	33,355	30,283
Other property and equipment	18,314	15,511
Accumulated depreciation	51,669	45,794
Property and equipment, net		
Rental equipment, net of allowances of $1,290 and $575, respectively	25,718	16,670
Other property and equipment	13,208	11,560
Property and equipment, net	$ 38,926	$ 28,230

Long-lived assets

The Company accounts for the impairment and disposition of long-lived assets in accordance with ASC 360— *Property, Plant, and Equipment.* In accordance with ASC 360, long-lived assets to be held are reviewed for events or changes in circumstances that indicate that their carrying value may not be recoverable. During the twelve months ended December 31, 2021, the Company determined that an impairment indicator was present as a result of the court order to dismiss the Company's preliminary injunction related to the Department of Health and Human Services and the Centers for Medicare and Medicaid Services lawsuit. The relevant long-lived asset grouping was evaluated for impairment. An undiscounted cash flow analysis demonstrated sufficient undiscounted cash flows in excess of the asset group's carrying value. Estimates and significant assumptions included in the long-lived asset impairment analysis included identification of the asset group and undiscounted cash flow projections. The Company concluded that its definite-lived intangible assets and long-lived assets were not impaired based on the results of the quantitative analyses performed. No impairments were recorded as of December 31, 2021 or 2020.

Goodwill and intangible assets

Goodwill is tested for impairment on an annual basis as of October 1. Interim testing of goodwill for impairment is also required whenever an event occurs or circumstances change that would more likely than not reduce the fair value of a reporting unit or asset below its carrying amount. The Company periodically reviews the carrying value of long-lived assets to determine whether or not impairment to such value has occurred. If the carrying amount of goodwill exceeds the implied estimated fair value, an impairment charge to current operations is recorded to reduce the carrying value to the implied estimated fair value. There were no accumulated impairment losses as of December 31, 2021 or 2020.

The Company will first assess qualitative factors to determine whether it is more likely than not that the fair value is less than its carrying amount. If, based on a review of qualitative factors, it is more likely than not that the fair value is less than its carrying amount, the Company will use a quantitative approach, and calculate the fair value and compare it to its carrying amount. If the fair value exceeds the carrying amount, there is no indication of impairment. If the carrying amount exceeds the fair value, an impairment loss is recorded equal to the difference.

The Company performed an assessment of qualitative factors and determined that no events or circumstances existed that would lead to a determination that it is more likely than not that the fair value of indefinite-lived assets were less than the carrying amount. As such, a quantitative analysis was not required to be performed as of December 31, 2021 or December 31, 2020.

Finite-lived intangible assets are amortized over their useful lives and are tested for recoverability whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. Technology and customer relationships are amortized using the straight-line method.

Business combinations

The results of operations of the businesses acquired by the Company are included as of the acquisition date. The purchase price of an acquisition is allocated to the underlying assets acquired and liabilities assumed based upon their estimated fair values at the date of acquisition. To the extent the purchase price exceeds the fair value of the net identifiable tangible and intangible assets acquired and liabilities assumed, such excess is allocated to goodwill. The Company may adjust the preliminary purchase price allocation, as necessary, for up to one year after the acquisition closing date if it obtains more information regarding asset valuations and liabilities assumed. Acquisition-related expenses are recognized separately from the business combination and are expensed as incurred.

Leases

The Company determines if an arrangement is a lease at inception. Operating leases are included in operating lease right-of-use (ROU) assets, operating lease liability – current, and operating lease liability – noncurrent on the consolidated balance sheets.

ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. The Company uses an incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments as the rate implicit in each lease is generally not readily determinable. The operating lease ROU asset also includes any lease payments made to the lessor at or before the commencement date and excludes lease incentives. Lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

The Company has lease agreements with lease and non-lease components. The Company elected the practical expedient to treat the lease and non-lease components as a single lease component. Additionally, the Company elected the practical expedient to not record leases with an initial term of twelve months or less on the consolidated balance sheets.

Loss contingencies

The Company is involved in various lawsuits, claims, investigations, and proceedings that arise in the ordinary course of business. The Company records a liability when it believes that it is both probable that a loss has been incurred and the amount can be reasonably estimated. Significant judgment is required to determine both probability and the estimated amount. The Company reviews at least quarterly and adjusts accordingly to reflect the impact of negotiations, settlements, rulings, advice of legal counsel, and updated information.

Research and development

Research and development costs are expensed as incurred.

Advertising costs

Advertising costs, which approximated $35,183, $34,180 and $40,251 during the years ended December 31, 2021, 2020 and 2019, respectively, are expensed as incurred, excluding the production costs of direct response advertising. Advertising costs are included in sales and marketing expense in the accompanying consolidated statements of comprehensive income (loss).

Income taxes

The Company accounts for income taxes in accordance with ASC 740— *Income Taxes*. Under ASC 740, income taxes are recognized for the amount of taxes payable or refundable for the current period and deferred tax liabilities and assets are recognized for the future tax consequences of transactions that have been recognized in the Company's consolidated financial statements or tax returns. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is provided when it is more likely than not that some portion, or all, of the deferred tax asset will not be realized.

The Company accounts for uncertainties in income taxes in accordance with ASC 740-10— *Accounting for Uncertainty in Income Taxes*. ASC 740-10 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. This accounting standard also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition.

The Company recognizes interest and penalties on taxes, if any, within its income tax provision on its consolidated statements of comprehensive income (loss).

Accounting for stock-based compensation

The Company accounts for its stock-based compensation in accordance with ASC 718— *Compensation—Stock Compensation*, which establishes accounting for share-based awards, exchanged for employee services and requires companies to expense the estimated fair value of these awards over the requisite employee service period. Stock–based compensation cost for stock options and employee stock purchase plan are determined at the grant date using the Black-Scholes option pricing model. Stock-based compensation cost for stock incentive awards is based on the number of shares ultimately expected to vest, estimated at each reporting date based on management's expectations regarding the relevant performance criteria. The value of the award that is ultimately expected to vest is recognized as expense on a straight-line basis over the employee's requisite service period.

As part of the provisions of ASC 718, the Company is required to estimate potential forfeitures of stock grants and adjust compensation cost recorded accordingly. The estimate of forfeitures will be adjusted over the requisite service period to the extent that actual forfeitures differ, or are expected to differ, from such estimates. Changes in estimated forfeitures will be recognized through a cumulative catch-up adjustment in the period of change and will also impact the amount of stock compensation expense to be recognized in future periods.

Foreign currency

The functional currency of the Company's international subsidiary is the local currency. The financial statements of the subsidiary are translated to U.S. dollars using month-end exchange rates for assets and liabilities and average exchange rates for revenue, cost of revenue, operating expense and provision for income taxes. Translation gains and losses are recorded in accumulated other comprehensive income (loss) as a component of stockholders' equity. Foreign exchange transaction gains and losses resulting from the conversion of the transaction currency to functional currency are reflected as a component of foreign currency exchange gains or losses in other income (expense) in the consolidated statements of comprehensive income (loss).

Government grants

The Company may receive cash payments from government grants during a public health emergency (PHE). The Company considers the nature and substance of the government grant and records the cash payment in accordance with the terms and conditions of the grant. Income is deferred until all considerations required for receiving the grant are met and is recognized in the consolidated statements of comprehensive income (loss) based on the nature of the terms and conditions of the grant. In 2020, the Company received a grant of $6,200 from the Public Health and Social Services Emergency Fund (Relief Fund), which was among the provisions of the Coronavirus Aid, Relief, and Economic Security Act (CARES) Act signed into law on March 27, 2020. During 2020, the Company recorded $5,300 in other income, which was associated with lost revenues from the COVID-19 PHE, and a $900 benefit in general and administrative expense due to COVID-19 PHE related costs incurred in the period.

Earnings (loss) per share

Earnings (loss) per share (EPS) is computed in accordance with ASC 260— *Earnings per Share* and is calculated using the weighted-average number of common shares outstanding during each period. Diluted EPS assumes the conversion, exercise or issuance of all potential common stock equivalents (which can include dilution of outstanding stock options, restricted stock units and restricted stock awards) unless the effect is to reduce a loss or increase the income per share. For purposes of this calculation, common stock subject to repurchase by the Company, options, and other dilutive awards are considered to be common stock equivalents and are only included in the calculation of diluted earnings (loss) per share when their effect is dilutive.

Basic earnings (loss) per share is calculated using the Company's weighted-average outstanding common shares. Diluted earnings (loss) per share is calculated using the Company's weighted-average outstanding common shares including the dilutive effect of stock awards as determined under the treasury stock method.

The computation of EPS is as follows:

(amounts in thousands, except share and per share amounts)	Years ended December 31, 2021	2020	2019
Numerator—basic and diluted:			
Net income (loss)	$ (6,333)	$ (5,829)	$ 20,950
Denominator:			
Weighted-average common shares - basic common stock(1)	22,490,027	21,980,326	21,821,104
Weighted-average common shares - diluted common stock	22,490,027	21,980,326	22,241,064
Net income (loss) per share - basic common stock	$ (0.28)	$ (0.27)	$ 0.96
Net income (loss) per share - diluted common stock(2)	$ (0.28)	$ (0.27)	$ 0.94
Denominator calculation from basic to diluted:			
Weighted-average common shares - basic common stock(1)	22,490,027	21,980,326	21,821,104
Stock options and other dilutive awards	166,258	64,471	419,960
Weighted-average common shares - diluted common stock	22,656,285	22,044,797	22,241,064
Shares excluded from diluted weighted-average shares:			
Stock options	151,344	467,378	53,888
Restricted stock units and restricted stock awards	167,237	292,795	169,305
Shares excluded from diluted weighted-average shares	318,581	760,173	223,193

(1) Unvested restricted stock units and restricted stock awards are not included as shares outstanding in the calculation of basic earnings per share. Vested restricted stock units and restricted stock awards are included in basic earnings per share if all vesting and performance criteria have been met. Performance-based restricted stock units and restricted stock awards are included in the number of shares used to calculate diluted earnings per share as long as all applicable performance criteria are met, and their effect is dilutive. Restricted stock awards are eligible to receive all dividends declared on the Company's common shares during the vesting period; however, such dividends are not paid until the restrictions lapse.

(2) Due to net losses for the years ended December 31, 2021 and December 31, 2020, diluted loss per share is the same as basic.

The computations of diluted net income (loss) attributable to common stockholders excluded common stock options, restricted stock units, and restricted stock awards, which were anti-dilutive for the year December 31, 2019.

Business segments

The Company operates and reports in only one operating and reportable segment – development, manufacturing, marketing, sales, and rental of respiratory products. Management reports financial information on a consolidated basis to the Company's chief operating decision maker.

Recently adopted accounting pronouncements

In December 2019, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2019-12,*Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes.* The new guidance simplifies the accounting for income taxes by removing certain exceptions to the general principles in Topic 740. The new guidance also improves consistent application of and simplifies U.S. GAAP for other areas of Topic 740 by clarifying and amending the existing guidance. The Company adopted this standard on January 1, 2021, and adoption of this standard did not have a material impact on the Company's consolidated financial statement presentation or results.

3. Goodwill and other identifiable intangible assets

Goodwill

The changes in the carrying amount of goodwill for the years ended December 31, 2021 and 2020 were as follows:

(amounts in thousands)	
Balance as of December 31, 2019	$ 32,954
Translation adjustment	211
Balance as of December 31, 2020	$ 33,165
Translation adjustment	(186)
Balance as of December 31, 2021	$ 32,979

As of December 31, 2021, the Company hadno accumulated impairment losses related to goodwill.

Intangible assets

There were no accumulated impairment losses related to the Company's intangible assets as of December 31, 2021 and 2020.Amortization expense for intangible assets for the years ended December 31, 2021, 2020 and 2019 was as follows:

	Years ended December 31,		
(amounts in thousands)	**2021**	**2020**	**2019**
Research and development expense	$ 7,813	$ 7,800	$ 2,914
Sales and marketing expense	181	204	175
General and administrative expense	781	1,000	1,071
Total	$ 8,775	$ 9,004	$ 4,160

The following tables represent the changes in net carrying values of the intangibles as of the respective dates:

(amounts in thousands) **December 31, 2021**	**Average estimated useful lives (in years)**	**Gross carrying amount**	**Accumulated amortization**	**Net amount**
Technology	10	$ 77,700	$ 18,454	$ 59,246
Licenses	10	185	180	5
Patents and websites	5	4,519	3,746	773
Customer relationships	4	1,361	1,361	—
Commercials	2-3	799	676	123
Total		$ 84,564	$ 24,417	$ 60,147

(amounts in thousands) **December 31, 2020**	**Average estimated useful lives (in years)**	**Gross carrying amount**	**Accumulated amortization**	**Net amount**
Technology	10	$ 77,700	$ 10,684	$ 67,016
Licenses	10	185	174	11
Patents and websites	5	4,488	3,015	1,473
Customer relationships	4	1,474	1,351	123
Commercials	2-3	733	559	174
Total		$ 84,580	$ 15,783	$ 68,797

Annual estimated amortization expense for each of the succeeding fiscal years is as follows:

(amounts in thousands)	December 31, 2021
2022	$ 8,484
2023	7,881
2024	7,833
2025	7,783
2026	7,770
Thereafter	20,396
Total	$ 60,147

4. Current liabilities

Accounts payable and accrued expenses as of December 31, 2021 and 2020 consisted of the following:

(amounts in thousands)	December 31, 2021	2020
Accounts payable	$ 10,258	$ 12,520
Accrued inventory (in-transit and unvouchered receipts) and trade payables	12,488	9,023
Accrued litigation settlement	—	8,000
Accrued purchasing card liability	1,488	2,468
Accrued franchise, sales and use taxes	486	449
Other accrued expenses	969	1,252
Accounts payable and accrued expenses	$ 25,689	$ 33,712

Accrued payroll as of December 31, 2021 and 2020 consisted of the following:

(amounts in thousands)	December 31, 2021	2020
Accrued bonuses	$ 8,274	$ 4
Accrued wages and other payroll related items	5,469	3,796
Accrued vacation	2,894	2,642
Accrued employee stock purchase plan deductions	670	649
Accrued payroll	$ 17,307	$ 7,091

5. Leases

The Company has entered into operating leases primarily for commercial buildings. These leases have terms which range from 2 years to 11 years, some of which include options to extend the leases for up to 5 years. There are no economic penalties for the Company to extend the lease, and it is not reasonably certain that the Company will exercise the extension options. Operating lease right-of-use assets and liabilities commencing after January 1, 2019 are recognized at commencement date based on the present value of lease payments over the lease term. The operating leases do not contain material residual value guarantees or material restrictive covenants.

Rent expense, including short-term lease cost, was $4,095, $2,864, and $2,288 for the years ended December 31, 2021, 2020 and 2019, respectively.

Information related to the Company's right-of-use assets and related operating lease liabilities were as follows:

(amounts in thousands)	Year ended December 31, 2021	Year ended December 31, 2020
Cash paid for operating lease liabilities	$ 3,319	$ 2,342
Operating lease cost	3,854	2,622
Non-cash right-of-use assets obtained in exchange for new operating lease obligations	19,417	5,237
Weighted-average remaining lease term	2.8 years	2.8 years
Weighted-average discount rate	2.9 %	3.3 %

Maturities of lease liabilities due in the 12-month period ending December 31,	
2022	$ 3,960
2023	3,962
2024	3,667
2025	2,717
2026	2,708
Thereafter	12,100
	29,114
Less imputed interest	(2,440)
Total lease liabilities	$ 26,674
Operating lease liability - current	$ 3,393
Operating lease liability - noncurrent	23,281
Total lease liabilities	$ 26,674

6. Income taxes

The components of the Company's income (loss) before provision for income taxes are as follows:

	Years ended December 31,		
(amounts in thousands)	**2021**	**2020**	**2019**
United States	$ 7,621	$ (6,464)	$ 22,553
Foreign	1,038	1,184	1,719
Income (loss) before provision for income taxes	$ 8,659	$ (5,280)	$ 24,272

The provision for income taxes consists of the following:

	Years ended December 31,		
(amounts in thousands)	**2021**	**2020**	**2019**
Current tax expense (benefit)			
Federal	$ —	$ (74)	$ (330)
State	271	198	136
Foreign	266	381	560
Total current tax expense	537	505	366
Deferred tax expense (benefit)			
Federal	10,263	309	3,497
State	4,194	(193)	(396)
Foreign	(22)	(72)	(145)
Total deferred tax expense	14,435	44	2,956
Interest and penalties	20	—	—
Provision for income taxes	$ 14,992	$ 549	$ 3,322

The components of deferred tax assets and liabilities consist of the following:

(amounts in thousands)	As of December 31,	
Deferred tax assets (liabilities)	**2021**	**2020**
Accrued expenses	$ 10,575	$ 8,346
Net operating loss and credit carryforward	21,138	20,145
Allowance, reserves and other	2,668	1,381
Stock-based compensation	2,665	3,379
Lease liability	6,507	2,427
Deferred tax assets	43,553	35,678
Property, plant, and equipment	(7,664)	(4,805)
Intangible amortization	(12,389)	(14,292)
Right-of-use asset	(6,077)	(2,139)
Deferred tax liabilities	(26,130)	(21,236)
Valuation allowance	(17,423)	—
Total	$ —	$ 14,442

Reconciliation of the federal statutory income tax rate to the effective income tax rate for the years ended December 31, 2021, 2020 and 2019 is as follows:

	Years ended December 31,		
	2021	**2020**	**2019**
U.S. Statutory rate	21.00 %	21.00 %	21.00 %
State income taxes, net of federal benefit	-1.39 %	-3.86 %	3.70 %
Stock-based compensation	-21.72 %	-16.80 %	-0.81 %
R&D credit, net of reserve	-5.95 %	-8.11 %	-8.97 %
Change in fair value	-28.19 %	-4.19 %	0.70 %
Nondeductible compensation	7.04 %	—	—
Valuation allowance	201.69 %	—	—
Other	0.63 %	1.57 %	-1.94 %
Effective income tax rate	173.11 %	-10.39 %	13.68 %

The Company operates in several taxing jurisdictions, including U.S. federal, multiple U.S. states and the Netherlands. The statute of limitations has expired for all tax years prior to 2018 for federal and prior to 2016 for various state tax purposes. However, the net operating loss generated on the Company's federal and state tax returns in prior years may be subject to adjustments by the federal and state tax authorities.

As of December 31, 2021, the Company had $60,239 and $26,193 of federal and state net operating loss carryforwards, respectively, and $52,443 of the total federal net operating loss carryforwards have an indefinite life while the remaining federal and state net operating loss carryforwards begin to expire in 2033 and 2028, respectively, if not utilized. As of December 31, 2021, the Company had federal and California research and development credit carryforward of $4,365 and $4,327, respectively. The federal credit will begin to expire in 2022; the California credit has indefinite carryforward.

Utilization of the Company's net operating loss and tax credit carryforwards may be subject to annual limitations arising from ownership change limitations provided by the Internal Revenue Code and similar state provisions. Such annual limitations could result in the expiration of the net operating loss and tax credit carryforwards before their utilization.

The Company recognizes deferred tax assets to the extent it believes these assets are more likely than not to be realized. In making such a determination, the Company considers all available positive and negative evidence, including future reversals of existing taxable temporary differences, projected future taxable income, tax-planning strategies, and results of recent operations. The amount of deferred tax assets considered realizable is subject to adjustment in future periods if estimates of future taxable income are reduced. As of December 31, 2021, the Company determined that net deferred tax assets are not more likely than not realizable based on projected future taxable losses primarily due to planned strategic investments in future periods and the impact of the COVID-19 pandemic, including related supply chain impacts on parts availability and cost inflation. Accordingly, the Company recorded a valuation allowance of $17,423 as of December 31, 2021. The Company's valuation allowance may increase or decrease during the next 12 months based on future operating results.

The Company recognizes interest and penalties on taxes, within its income tax provision on its consolidated statements of comprehensive income (loss).

Included in the balance of unrecognized tax benefits as of December 31, 2021, 2020 and 2019, were $2,078, $1,932 and $1,889, respectively, of tax benefits that, if recognized, would affect the effective tax rate. The Company believes that there will be no significant increases or decreases to unrecognized tax benefits within the next 12 months.

A reconciliation of the beginning and ending amount of unrecognized tax benefit is as follows:

(amounts in thousands)	December 31,		
Reconciliation of liability for unrecognized tax benefits	**2021**	**2020**	**2019**
Balance at beginning of period	$ 1,932	$ 1,889	$ 1,294
Additions based on tax positions related to current year	146	70	595
Reductions based on tax positions related to prior year	—	(181)	—
Additions based on tax positions related to prior year	—	154	—
Balance at end of period	$ 2,078	$ 1,932	$ 1,889

7. Stockholders' equity

Common stock

Each share of common stock is entitled toone 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 other classes of stock outstanding.

Preferred stock

Pursuant to the amended and restated certificate of incorporation filed by the Company in connection with the completion of its initial public offering, the Company's board of directors is authorized to issue up to 10,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, redemption rights, liquidation preferences, sinking fund terms and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of common stock. The issuance of preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing change in the Company's control or other corporate action. As of December 31, 2021 and 2020, no shares of preferred stock were issued or outstanding, and the board of directors has not authorized or designated any rights, preferences, privileges and restrictions for any class of preferred stock.

Dividends

There were no dividends declared during the years ended December 31, 2021, 2020 and 2019.

Stock incentive plans

The Company has a 2012 Equity Incentive Plan (2012 Plan) under which the Company granted options to purchase shares of its common stock. As of December 31, 2021, options to purchase 71,452 shares of common stock remained outstanding under the 2012 Plan. The 2012 Plan was terminated in connection with the Company's initial public offering in February 2014, and accordingly, no new options are available for issuance under this plan. The 2012 Plan continues to govern outstanding awards granted thereunder.

The Company has a 2014 Equity Incentive Plan (2014 Plan) that provides for the grant of incentive stock options, within the meaning of Section 422 of the Internal Revenue Code, to the Company's employees and any parent and subsidiary corporation's employees, and for the grant of nonstatutory stock options, restricted stock, restricted stock units, restricted stock awards, stock appreciation rights, performance units and performance shares to its employees, directors and consultants and its parent and subsidiary corporations' employees and consultants.

As of December 31, 2021, awards with respect to757,401 shares of the Company's common stock were outstanding, and1,481,328 shares of common stock remained available for issuance under the 2014 Plan. The shares available for issuance under the 2014 Plan will be increased by any shares returned to the 2012 Plan and the 2014 Plan as a result of expiration or termination of awards (provided that the maximum number of shares that may be added to the 2014 Plan pursuant to such previously granted awards under the 2012 Plan is 2,328,569 shares). The number of shares available for issuance under the 2014 Plan also is increased annually on the first day of each fiscal year by an amount equal to the least of:

- 895,346 shares;
- 4% of the outstanding shares of common stock as of the last day of the Company's immediately preceding fiscal year; or
- such other amount as the Company's board of directors may determine.

For 2021, no additional shares were added to the 2014 Plan share reserve pursuant to the provision described above.

Stock options

Options typically expire betweenseven and ten years from the date of grant and vest over one to four-year terms. Options have been granted to employees, directors and consultants of the Company, as determined by the board of directors, at the deemed fair market value of the shares underlying the options at the date of grant.

The activity for stock options under the Company's stock plans for the years ended December 31, 2021, 2020 and 2019 is as follows:

	Options	Price per share	Weighted-average exercise price	Remaining weighted-average contractual terms (in years)	Per share average intrinsic value
Outstanding as of December 31, 2018	1,127,336	$0.75-$83.30	$ 34.89	3.84	$ 89.28
Exercised	(109,291)	0.75-58.95	28.45		
Forfeited	(37,161)	38.54-58.95	44.58		
Outstanding as of December 31, 2019	980,884	0.75-83.30	35.24	2.84	34.07
Vested and exercisable as of December 31, 2019	929,825	0.75-83.30	34.73	2.81	34.64
Vested and expected to vest as of December 31, 2019	977,589	0.75-83.30	35.21	2.84	34.11
Outstanding as of December 31, 2019	980,884	0.75-83.30	35.24	2.84	34.07
Exercised	(18,626)	1.17-44.19	17.81		
Forfeited	(6,779)	44.19-56.72	48.23		
Outstanding as of December 31, 2020	955,479	0.75-83.30	35.49	1.85	11.81
Vested and exercisable as of December 31, 2020	955,479	0.75-83.30	35.49	1.85	11.81
Vested and expected to vest as of December 31, 2020	955,479	0.75-83.30	35.49	1.85	11.81
Outstanding as of December 31, 2020	955,479	0.75-83.30	35.49	1.85	11.81
Exercised	(486,038)	0.75-46.66	28.19		
Forfeited	(10,000)	83.30	83.30		
Outstanding as of December 31, 2021	459,441	1.17-83.30	42.18	1.36	4.31
Vested and exercisable as of December 31, 2021	459,441	1.17-83.30	42.18	1.36	4.31
Vested and expected to vest as of December 31, 2021	459,441	$1.17-$83.30	$ 42.18	1.36	$ 4.31

The total intrinsic value of options exercised during the years ended December 31, 2021, 2020, and 2019 was $14,524, $494, and $7,910, respectively. As of December 31, 2021, all stock-based compensation expense for options granted under the Plans was recognized.

Stock incentive awards

The Company grants restricted stock units (RSUs) and restricted stock awards (RSAs) under the 2014 Plan (Stock Awards). The Stock Awards vest either based solely on the satisfaction of time-based service conditions or on the satisfaction of time-based service conditions combined with performance criteria. Stock Awards are subject to forfeiture if the holder's services to the Company terminate before vesting.

Stock Awards granted with only time-based service vesting conditions generally vest over afour-year service period, as defined in the terms of each award. Stock Awards that vest based on the satisfaction of time-based service conditions combined with performance criteria generally vest over a three-year service and performance period, based on performance criteria established at the time of the award. The portion of the Stock Award that is earned may equal or be less than the targeted number of shares subject to the Stock Award depending on whether the performance criteria are met.

Stock Awards activity for the years ended December 31, 2021, 2020 and 2019 is summarized below:

Restricted stock units	Time-based	Performance and time-based	Total	Weighted-average grant date fair value per share
Unvested restricted stock units as of December 31, 2018 (1)	58,589	$ 8,739	67,328	$ 115.16
Granted	87,902	—	87,902	75.56
Vested	(24,680)	(4,366)	(29,046)	123.53
Forfeited/canceled	(12,835)	(1,239)	(14,074)	102.89
Unvested restricted stock units as of December 31, 2019 (1)	108,976	3,134	112,110	$ 83.48
Unvested and expected to vest restricted stock units outstanding as of December 31, 2019			103,087	$ 83.22
Unvested restricted stock units as of December 31, 2019	108,976	3,134	112,110	$ 83.48
Granted	210,622	88,458	299,080	43.52
Vested	(49,636)	—	(49,636)	83.31
Forfeited/canceled	(24,500)	(3,134)	(27,634)	70.60
Unvested restricted stock units as of December 31, 2020 (1)	245,462	88,458	333,920	$ 49.29
Unvested and expected to vest restricted stock units outstanding as of December 31, 2020			246,420	$ 49.82
Unvested restricted stock units as of December 31, 2020	245,462	88,458	333,920	$ 49.29
Granted	240,044	88,902	328,946	56.01
Vested	(109,504)	—	(109,504)	52.79
Forfeited/canceled	(86,836)	(78,248)	(165,084)	46.88
Unvested restricted stock units as of December 31, 2021 (1)	289,166	99,112	388,278	$ 54.81
Unvested and expected to vest restricted stock units outstanding as of December 31, 2021			331,358	$ 54.98

Restricted stock awards	Time-based	Performance and time-based	Total	Weighted-average grant date fair value per share
Unvested restricted stock awards outstanding as of December 31, 2018 (1)	36,937	47,821	84,758	$ 115.80
Granted	54,853	40,166	95,019	86.10
Vested	(13,627)	(15,732)	(29,359)	115.37
Forfeited/canceled	(7,093)	(9,627)	(16,720)	109.11
Unvested restricted stock awards outstanding as of December 31, 2019 (1)	71,070	62,628	133,698	$ 95.74
Unvested and expected to vest restricted stock awards outstanding as of December 31, 2019			79,473	$ 90.31
Unvested restricted stock awards outstanding as of December 31, 2019	71,070	62,628	133,698	$ 95.74
Vested	(28,994)	—	(28,994)	89.37
Forfeited/canceled	—	(29,273)	(29,273)	110.27
Unvested restricted stock awards outstanding as of December 31, 2020 (1)	42,076	33,355	75,431	$ 93.96
Unvested and expected to vest restricted stock awards outstanding as of December 31, 2020			44,159	$ 85.90
Unvested restricted stock awards outstanding as of December 31, 2020	42,076	33,355	75,431	$ 93.96
Vested	(15,728)	—	(15,728)	91.17
Forfeited/canceled	(15,932)	(27,726)	(43,658)	98.05
Unvested restricted stock awards outstanding as of December 31, 2021 (1)	10,416	5,629	16,045	$ 87.12
Unvested and expected to vest restricted stock awards outstanding as of December 31, 2021			15,532	$ 90.08

(1) Outstanding restricted stock units and restricted stock awards are based on the maximum payout of the targeted number of shares.

As of December 31, 2021, the unrecognized compensation cost related to unvested employee restricted stock units and restricted stock awards was $13,685, excluding estimated forfeitures. This amount is expected to be recognized over a weighted-average period of 2.5 years.

Employee stock purchase plan

The Company's 2014 Employee Stock Purchase Plan (ESPP) provides for the grant to all eligible employees an option to purchase stock under the ESPP, within the meaning Section 423 of the Internal Revenue Code. The ESPP permits participants to purchase common stock through payroll deductions of up to 15% of their eligible compensation, which includes a participant's base straight time gross earnings, incentive compensation, bonuses, overtime and shift premium, but exclusive of payments for equity compensation and other similar compensation. A participant may purchase a maximum of 1,500 shares during a purchase period. Amounts deducted and accumulated by the participant are used to purchase shares of the Company's common stock at the end of each six-month period. The purchase price of the shares will be 85% of the lower of the fair market value of the Company's common stock on the first trading day of each offering period or on the exercise date. The offering periods are currently approximately six months in length beginning on the first business day on or after March 1 and September 1 of each year and ending on the first business day on or after September 1 and March 1 approximately six months later.

As of December 31, 2021, a total of569,866 shares of common stock were available for sale pursuant to the ESPP.

The number of shares available for sale under the ESPP is increased annually on the first day of each fiscal year equal to the least of:

- 179,069 shares;
- 1.5% of the outstanding shares of the Company's common stock on the last day of the Company's immediately preceding fiscal year; or
- such other amount as may be determined by the administrator.

For 2021, no additional shares were added to the ESPP share reserve pursuant to the provision described above.

Stock-based compensation

Stock-based compensation expense recognized for the years ended December 31, 2021, 2020 and 2019, was as follows:

(amounts in thousands)	**Years ended December 31,**		
Stock-based compensation expense by type of award:	**2021**	**2020**	**2019**
Stock option plan awards	$ —	$ 709	$ 2,977
Restricted stock units and restricted stock awards	10,229	6,717	5,413
Employee stock purchase plan	714	777	739
Total stock-based compensation expense	$ 10,943	$ 8,203	$ 9,129

Employee stock-based compensation expense was calculated based on awards of stock options, restricted stock units and restricted stock awards ultimately expected to vest based on the Company's historical award cancellations. The employee stock-based compensation expense recognized for the years ended December 31, 2020 and 2019 has been reduced for estimated forfeitures of stock option plan awards at a rate of 7.3% and 7.3%, respectively. The employee stock-based compensation expense recognized for the years ended December 31, 2021, 2020 and 2019 has been reduced for estimated forfeitures of restricted stock at a rate of 4.1%, 4.7% and 4.4%, respectively. ASC 718 – *Compensation-Stock Compensation* requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

For the years ended December 31, 2021, 2020 and 2019, respectively, stock-based compensation expense recognized under ASC 718, included in cost of revenue, research and development expense, sales and marketing expense, and general and administrative expense was as follows:

	Years ended December 31,		
(amounts in thousands)	**2021**	**2020**	**2019**
Cost of revenue	$ 1,106	$ 698	$ 890
Research and development	1,276	969	1,100
Sales and marketing	2,388	2,208	1,755
General and administrative	6,173	4,328	5,384
Total stock-based compensation expense	$ 10,943	$ 8,203	$ 9,129

Valuation assumptions

The employee stock-based compensation expense is recognized under ASC 718. Stock-based compensation cost for stock awards is based on the number of shares ultimately expected to vest, estimated at each reporting date based on management's expectations regarding the relevant performance criteria. The value of the award that is ultimately expected to vest is recognized as expense on a straight-line basis over the employee's requisite service period for stock awards with a time-based service condition and on a graded vesting basis over the employee's requisite service period for stock awards with performance and time-based service conditions.

Stock-based compensation cost for stock options and employee stock purchase plan are determined at the grant date using the Black-Scholes option pricing model. During the years ended December 31, 2021, 2020 and 2019, the Company did not grant any stock option awards.

The following table displays the assumptions that have been applied to estimate the fair value of the Company's shares to be issued under the ESPP using the Black-Scholes option pricing model.

	2021	**2020**	**2019**
Expected term (years)	0.50	0.50	0.50
Risk free interest rate	0.07-0.12%	0.12-1.75%	1.75-2.53%
Expected dividend yield	None	None	None
Volatility	44.59-83.92%	47.00-83.92%	44.00-47.00%

401(k) retirement savings plan

The Company maintains a 401(k) retirement savings plan for the benefit of eligible employees. Under the terms of this plan, eligible employees are able to make contributions to the plan on a tax-deferred basis. The Company matched employees' contributions from January 1, 2017 through June 30, 2020. The Company suspended its 401(k) match, effective July 1, 2020; however, matching contributions were reinstated on June 21, 2021. The Company contributed $479, $455, and $871, net of forfeitures, to the 401(k) plan for the years ended December 31, 2021, 2020 and 2019, respectively.

8. Commitments and contingencies

Purchase obligations

The Company had approximately $111,100 of outstanding purchase orders due within one year with its outside vendors and suppliers as of December 31, 2021.

Warranty obligation

The following table identifies the changes in the Company's aggregate product warranty liabilities for the years ended December 31, 2021, 2020 and 2019, respectively:

	December 31,		
(amounts in thousands)	**2021**	**2020**	**2019**
Product warranty liability at beginning of period	$ 14,394	$ 12,571	$ 9,530
Accruals for warranties issued	9,168	9,462	8,131
Adjustments related to preexisting warranties (including changes in estimates)	(597)	(754)	1,433
Settlements made (in cash or in kind)	(9,239)	(6,885)	(6,523)
Product warranty liability at end of period	$ 13,726	$ 14,394	$ 12,571

Legislation and HIPAA

The healthcare industry is subject to numerous laws and regulations of federal, state and local governments. These laws and regulations include, but are not necessarily limited to, matters such as licensure, accreditation, government healthcare program participation requirements, reimbursement for patient services, and Medicare and Medicaid fraud and abuse. Government activity has continued with respect to investigations and allegations concerning possible violations of fraud and abuse statutes and regulations by healthcare providers. Violations of these laws and regulations could result in exclusion from government healthcare programs together with the imposition of significant fines and penalties, as well as significant repayments for patient services previously billed.

The Company believes that it is in compliance in all material respects with applicable fraud and abuse regulations and other applicable government laws and regulations. Compliance with such laws and regulations can be subject to future government review and interpretation as well as regulatory actions unknown or unasserted at this time. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) was enacted to ensure health insurance portability, reduce healthcare fraud and abuse, guarantee security and privacy of health information, and enforce standards for health information. The Health Information Technology for Economic and Clinical Health Act (HITECH Act), in part, imposes notification requirements of certain security breaches relating to protected health information. The Company believes that it complies in all material respects with the provisions of those regulations that are applicable to the Company's business.

Legal proceedings

Securities class action and derivative lawsuits

On March 6, 2019, plaintiff William Fabbri filed a lawsuit against Inogen, Scott Wilkinson, and Alison Bauerlein, in the United States District Court for the Central District of California on behalf of a purported class of purchasers of the Company's securities. On March 21, 2019, plaintiff Steven Friedland filed a substantially similar lawsuit against the same defendants in the same court. On May 20, 2019, the court issued an order consolidating the two lawsuits under the name *In re Inogen, Inc. Sec. Litig.,* No. 2:19-cv-01643-FMO-AGR, appointing Dr. John Vasil and Paragon Fund Management as lead plaintiffs, and appointing Robbins Geller Rudman & Dowd LLP and Glancy Prongay & Murray LLP as lead plaintiffs' counsel. On July 10, 2019, the lead plaintiffs filed a consolidated amended complaint on behalf of a purported class of purchasers of the Company's common stock between November 8, 2017 and May 7, 2019. The complaint generally alleges that the defendants failed to disclose that: (i) Inogen had overstated the true size of the total addressable market for its portable oxygen concentrators and had misstated the basis for its calculation of the total addressable market; (ii) Inogen had falsely attributed its sales growth to the strong sales acumen of its sales force, rather than to deceptive sales practices; (iii) the growth in Inogen's domestic business-to-business sales to home medical equipment providers was inflated, unsustainable and was eroding direct-to-consumer sales; and (iv) Inogen's decision to focus on sales over rentals of portable oxygen concentrators harmed its ability to serve the Medicare market, in violation of sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended. The complaint seeks compensatory damages in an unspecified amount, costs and expenses, including attorneys' fees and expert fees, prejudgment and post-judgment interest and such other relief as the court deems proper. On January 2, 2020, the court dismissed the consolidated amended complaint with leave to amend. On January 9, 2020, the plaintiffs filed a second amended complaint generally alleging substantially similar claims as those in the previous complaint. On January 23, 2020, the defendants filed a motion to dismiss the second amended complaint. On September 2, 2020, the court denied the defendants' motion to dismiss without prejudice and instructed defendants to file another motion to dismiss if the parties are unable to resolve the issues relating to the second amended complaint. The Company filed its motion to dismiss on October 28, 2020. On August 13, 2021, the court granted Defendants' motion to dismiss, and on September 27, 2021, the court entered judgment dismissing the action in its entirety.

On June 26, 2019, plaintiff Twana Brown filed a shareholder derivative lawsuit against Inogen, Scott Wilkinson, Alison Bauerlein, Benjamin Anderson-Ray, Scott Beardsley, R. Scott Greer, Raymond Huggenberger, Heath Lukatch, Loren McFarland, and Heather Rider in the United States District Court for the Central District of California. The complaint purports to bring claims on behalf of Inogen against the individual defendants for breaches of their fiduciary duties as directors and/or officers of Inogen, unjust enrichment, waste of corporate assets and violations of section 14(a) of the Securities Exchange Act of 1934, as amended. The complaint generally alleges similar claims to the securities class action. The complaint seeks compensatory damages and restitution in an unspecified amount, changes to the Company's corporate governance and internal procedures, costs and expenses, including attorneys' fees and expert fees, and such other relief as the court deems proper. On August 5, 2019, the court issued an order staying the derivative action pending the resolution of the motion to dismiss stage in *In re Inogen, Inc. Sec. Litig.* Between October 7, 2019 and October 31, 2019, three additional shareholder derivative complaints were filed in the United States District Court for the Central District of California based on similar factual allegations. These lawsuits purport to bring claims on behalf of Inogen for breach of fiduciary duty, unjust enrichment, waste of corporate assets, insider trading and misappropriation of information, and violations of section 14(a) of the Securities Exchange Act of 1934, as amended. On January 13, 2020, the court consolidated the four derivative lawsuits before it under the name *In re Inogen, Inc. S'holder Deriv. Litig.*, Lead Case No. 2:19-cv-5568-FMO-AGR and ordered that the consolidated action be stayed pending the resolution of the motion to dismiss stage in *In re Inogen, Inc., Sec. Litig.* On November 10, 2021, the plaintiffs filed a Notice of Voluntary Dismissal Without Prejudice. On February 8, 2022, the court dismissed the California derivative action without prejudice.

On September 13, 2019, plaintiff Dustin Weller filed a shareholder derivative lawsuit against Inogen, Scott Wilkinson, Alison Bauerlein, Benjamin Anderson-Ray, Scott Beardsley, R. Scott Greer, Raymond Huggenberger, Heath Lukatch, Loren McFarland, and Heather Rider in the United States District Court for the District of Delaware captioned *Weller v. Wilkinson, et al*., No. 1:19-cv-01723-MN. On October 17, 2019, plaintiff Sharokh Soltanipour filed a shareholder derivative lawsuit against the same defendants in the same court, captioned *Soltanipour v. Wilkinson, et al*., No. 1:19-cv-1968-MN. The complaints generally allege similar claims to those in *In re Inogen, Inc., S'holder Deriv. Litig.* The complaints purport to bring claims on behalf of Inogen for breach of fiduciary duty, unjust enrichment, waste of corporate assets, abuse of control, gross mismanagement, insider selling and misappropriation of information, violations of section 14(a) of the Securities Exchange Act of 1934, as amended, and for contribution from certain of the individual defendants. The complaints seek compensatory damages in unspecified amounts, changes to the Company's corporate governance and internal procedures, return of compensation, disgorgement of profits from sale of stock, costs and expenses, including attorneys' fees and expert fees, and such other relief as the court deems proper. On May 15, 2020, the court consolidated the two derivative lawsuits before it under the name *In re Inogen, Inc. S'holder Deriv. Litig.*, Lead Case No. 1:19-cv-01723-MN-JLH. On July 8, 2020, the court ordered that the consolidated action be stayed pending the resolution of the motion to dismiss in the securities class action, *In re Inogen, Inc., Sec. Litig*. On November 3, 2021, the court approved the parties' stipulation to voluntarily dismiss the Delaware derivative action without prejudice.

Other litigation

In addition to the lawsuits discussed above, the Company is party to various legal proceedings arising in the normal course of business. The Company carries insurance, subject to specified deductibles under the policies, to protect against losses from certain types of legal claims. At this time, the Company does not anticipate that any of these other proceedings arising in the normal course of business will have a material adverse effect on the Company's business. Regardless of the outcome, litigation can have an adverse impact on the Company because of defense and settlement costs, diversion of management resources, and other factors.

9. Foreign currency exchange contracts and hedging

As of December 31, 2021 and December 31, 2020, the Company's total non-designated and designated derivative contracts had notional amounts totaling approximately $2,318 and $23,253, respectively, and $0 and $16,303, respectively. These contracts were comprised of offsetting contracts with the same counterparty, each expires within one to twelve months. During the years ended December 31, 2021, 2020, and 2019, these contracts had, net of tax, unrealized gains of $3,793, and unrealized losses of $289 and $694, respectively.

The nonperformance risk of the Company and the counterparty did not have a material impact on the fair value of the derivatives. During the years ended December 31, 2021, 2020 and 2019, there were no ineffective portions relating to these hedges and the hedges remained effective through their respective settlement dates. As of December 31, 2021, the Company had thirteen designated hedges and two non-designated hedges. As of December 31, 2020, the Company had seventeen designated hedges and no non-designated hedges.

Schedule II: Valuation and Qualifying Accounts

(amounts in thousands)	Balance at Beginning of Year	Additions	Deletions	Balance at End of Year
Year ended December 31, 2021				
Allowance for doubtful accounts (1)	$ 52	$ 60	$ 60	$ 52
Allowance for sales returns (2)	742	11,034	10,966	810
Allowance for rental asset loss (3)	575	1,153	438	1,290
Year ended December 31, 2020				
Allowance for doubtful accounts (1)	$ 205	$ 187	$ 340	$ 52
Allowance for sales returns (2)	1,163	10,299	10,720	742
Allowance for rental revenue adjustments (4)	411	2,579	2,594	396
Allowance for rental asset loss (3)	395	559	379	575
Year ended December 31, 2019				
Allowance for doubtful accounts (1)	$ 693	$ 612	$ 1,100	$ 205
Allowance for sales returns (2)	890	17,036	16,763	1,163
Allowance for rental revenue adjustments (4)	438	1,762	1,789	411
Allowance for rental asset loss (3)	594	188	387	395

(1) The additions to the allowance for doubtful accounts represent the estimates of bad debt expense based upon factors for which the company evaluates the collectability of accounts receivable, with actual recoveries netted into additions. Deductions are the actual write-offs of the receivables.

(2) The additions to the allowance for sales returns represent estimates of returns based upon historical returns experience, primarily for the direct-to-consumer sales channel. Deductions are the actual returns of products.

(3) The additions to the allowance for rental asset loss represent estimated losses of the Company's rental assets that will potentially be unrecoverable from the patient. Deductions are the actual write-offs of the rental assets.

(4) The additions to the allowance for rental revenue adjustments represent estimates of revenue adjustments that will need to be recorded for billing adjustments on rental revenue, net of recoveries. Deductions are the actual adjustments and write-offs of the rental receivables for such revenue adjustments.

EXHIBIT INDEX

Exhibit Number	Description	Incorporated by Reference From Form	Incorporated by Reference From Exhibit Number	Date Filed
2.1	Agreement and Plan of Merger dated August 6, 2019, by and among Inogen, Inc., Move Merger Sub, Inc., New Aera, Inc. and Gregory J. Kapust, as the entitled holders' agent.	8-K	2.1	08/07/19
3.1	Thirteenth Amended and Restated Certificate of Incorporation of the Registrant.	10-K	3.1	02/25/20
3.2	Amended and Restated Bylaws of the Registrant.	10-K	3.2	02/25/20
4.1	Specimen Common Stock Certificate of the Registrant.	S-1/A	4.1	01/16/14
4.2	Ninth Amended and Restated Investors' Rights Agreement, dated March 12, 2012, by and among the Registrant and the investors named therein, as amended.	S-1/A	4.2	01/16/14
4.3	Amendment No. 2 to Ninth Amended and Restated Investor Rights Agreement, dated December 10, 2018.	10-K	4.3	02/26/19
4.4	Description of Securities.	10-K	4.4	02/25/20
10.1+	Form of Director and Executive Officer Indemnification Agreement.	S-1	10.1	11/27/13
10.2+	2002 Stock Plan, as amended.	S-1	10.2	11/27/13
10.3+	Form of Notice of Stock Option Grant and Stock Option Agreement under the 2002 Stock Plan, as amended.	S-1	10.3	11/27/13
10.4+	2012 Equity Incentive Plan, as amended.	S-1	10.4	11/27/13
10.5+	Form of Stock Option Agreement under the 2012 Equity Incentive Plan.	S-1	10.5	11/27/13
10.6+	2014 Equity Incentive Plan.	S-1/A	10.6	01/28/14
10.7A+	Form of Stock Option Agreement under the 2014 Equity Incentive Plan.	10-Q	10.1	11/07/17
10.7B+	Form of Restricted Stock Unit Agreement – Time-Based under the 2014 Equity Incentive Plan.	10-Q	10.2	11/07/17
10.7C+	Form of Restricted Stock Unit Agreement – Performance-Based under the 2014 Equity Incentive Plan.	10-Q	10.3	11/07/17
10.7D+	Form of Restricted Stock Award Agreement – Time-Based under the 2014 Equity Incentive Plan.	10-Q	10.4	11/07/17
10.7E+	Form of Restricted Stock Award Agreement – Performance-Based under the 2014 Equity Incentive Plan.	10-Q	10.5	11/07/17
10.8+	2014 Employee Stock Purchase Plan.	S-1/A	10.8	01/28/14
10.9+	Executive Incentive Compensation Plan.	S-1	10.9	11/27/13
10.10+	Amended and Restated Employment and Severance Agreement, effective March 1, 2017, between the Registrant and Scott Wilkinson.	10-K	10.11	02/28/17
10.11+	Employment Agreement, dated October 1, 2013, between the Registrant and Alison Bauerlein.	S-1/A	10.12	12/23/13
10.12+	Employment Agreement, dated October 1, 2013, between the Registrant and Matt Scribner.	S-1/A	10.13	12/23/13
10.13+	Employment Agreement, dated October 1, 2013, between the Registrant and Brenton Taylor.	S-1/A	10.14	12/23/13

Exhibit Number	Description	Incorporated by Reference From Form	Incorporated by Reference From Exhibit Number	Date Filed
10.14	Multi-Purpose Commercial Building Lease, dated February 1, 2010, between the Registrant and Rockbridge Investments, L.P., as amended.	S-1	10.17	11/27/13
10.15	Lease Agreement, dated May 3, 2012, between the Registrant and Bayview (TX) Holding LLC.	S-1	10.18	11/27/13
10.16	License Agreement, dated July 23, 2007, between the Registrant and Air Products and Chemicals, Inc.	S-1/A	10.19	12/23/13
10.17	Amendment to License Agreement, dated October 23, 2009, between the Registrant and Air Products and Chemicals, Inc.	S-1	10.20	11/27/13
10.18	Amendment No. 2 to License Agreement, dated October 4, 2010, between the Registrant and Air Products and Chemicals, Inc.	S-1	10.21	11/27/13
10.19	Amendment No. 3 to License Agreement, dated March 22, 2011, between the Registrant and Air Products and Chemicals, Inc.	S-1	10.22	11/27/13
10.20	Lease Agreement, dated December 4, 2014, between the Registrant and TCIT Dallas Industrial, Inc.	10-K	10.23	04/27/15
10.21	Second Amendment to lease, dated January 20, 2015, between Registrant and Rockbridge Investments, L.P.	10-Q	10.1	05/12/15
10.22+	Amended and Restated Employment and Severance Agreement, effective January 1, 2017, between the Registrant and Byron Myers.	10-K	10.28	02/28/17
10.23	First Amendment and Expansion of Premises entered into as of November 9, 2015, by and between Registrant and ATLAS 35-75 INDUSTRIAL, LP.	8-K	10.1	11/10/15
10.24*	Private Label Distribution Agreement, effective as of November 12, 2014, between the Registrant and Applied Home Healthcare Equipment LLC, as amended.	10-Q	10.1	11/03/16
10.25*	Addendum to Private Label Distribution Agreement between the Company and Applied Home Healthcare Equipment LLC, as amended.	10-Q	10.1	05/09/17
10.26*	First Amendment to Private Label Distribution Agreement by and between the Company and Applied Home Healthcare Equipment, LLC, dated as of February 21, 2018.	10-Q	10.1	04/30/18
10.27*	Second Amendment to Private Label Distribution Agreement by and between the Company and OxyGo HQ, LLC, formerly known as Applied Home Healthcare Equipment, LLC, dated as of March 1, 2019.	10-Q	10.1	05/07/19
10.28	Lease Agreement by and between the Company, Cleveland American, LLC and Holdings Cleveland American, LLC, dated as of May 31, 2017.	10-Q	10.1	08/07/18
10.29	First Amendment to Lease Agreement between the Company, Cleveland American, LLC and Holdings Cleveland American, LLC, dated as of January 10, 2018.	10-Q	10.2	08/07/18
10.30	Second Amendment to Lease Agreement between the Company, Cleveland American, LLC and Holdings Cleveland American, LLC, dated as of May 1, 2018.	10-Q	10.3	08/07/18
10.31	Lease Agreement, dated June 19, 2019, by and between the Company, and RAF Pacifica Group – Real Estate Fund IV, LLC, APG Hollywood Center, LLC, and APG Airport Freeway Center, LLC.	10-Q	10.1	08/07/19
10.32	Lease Agreement, dated August 29, 2019, by and between the Company, and TCG Industrial Shiloh LLC.	10-Q	10.1	11/05/19

Exhibit Number	Description	Incorporated by Reference From Form	Incorporated by Reference From Exhibit Number	Date Filed
10.33	Lease Agreement Amendment No. 1, dated November 1, 2019, by and between the Company, and TCG Industrial Shiloh LLC.	10-Q	10.2	11/05/19
10.34+	Transition Agreement and Release by and between the Company and Matthew Scribner, dated September 14, 2018.	8-K	10.1	09/17/18
10.35+	Employment and Severance Agreement, dated August 17, 2018, between the Registrant and Bart Sanford.	10-Q	10.2	11/06/18
10.36	Third Amendment to lease, dated July 14, 2020, between Registrant and Rockbridge Investments, L.P.	10-Q	10.1	08/04/20
10.37+	Employment and Severance Agreement, dated August 17, 2020, between the Company and Arron Retterer.	10-Q	10.1	11/04/20
10.38+	Employment and Severance Agreement between the Company and Nabil Shabshab, dated January 22, 2021.	8-K	10.1	01/25/21
10.39+	Transition Agreement and Release by and between the Company and Scott Wilkinson, dated January 22, 2021.	10-K	10.39	02/24/21
10.40	First Amendment to Agreement and Plan of Merger, dated August 6, 2019 between the Company and New Aera, dated January 18, 2021.	10-K	10.40	02/24/21
10.41+	Transition Agreement and Release between the Company and Arron Retterer, dated April 5, 2021.	8-K	10.1	04/07/21
10.42+	Transition Agreement and Release between the Company and Byron Myers, dated April 5, 2021.	8-K	10.2	04/07/21
10.43+	Employment and Severance Agreement between the Company and George Parr, dated April 12, 2021.	10-Q	10.6	05/04/21
10.44+	Employment and Severance Agreement, between the Company and Stanislav Glezer, dated June 21, 2021.	10-Q	10.1	08/04/21
10.45+	Employment and Severance Agreement, between the Company and Jason M. Somer, dated July 12, 2021.	10-Q	10.2	08/04/21
10.46	First Amendment to Lease dated as of June 17, 2021, by and between the Company and RAF Pacifica Group – Real Estate Fund IV, LLC, APG Hollywood Center, LLC and APG Airport Freeway Center, LLC.	10-Q	10.1	11/04/21
10.47*	Private Label Distribution Agreement, by and between the Company and OxyGo HQ Florida, LLC, dated as of September 23, 2021.	10-Q	10.2	11/04/21
10.48+	Transition Agreement and Release, dated September 30, 2021, between the Company and Brenton Taylor.	10-Q	10.3	11/04/21
10.49+	Amended and Restated Employment and Severance Agreement, dated October 11, 2021, between the Company and Stanislav Glezer.	10-Q	10.4	11/04/21
10.50+	Offer Letter by and between the Company and Michael K. Sergesketter, dated December 10, 2021.	8-K	10.1	12/13/21
10.51+	Transition Agreement and Release between the Company and Alison Bauerlein, dated December 10, 2021.	8-K	10.2	12/13/21
10.52+	Consulting Agreement by and between the Company and Raymond Huggenberger, effective December 29, 2021.	8-K	10.1	12/30/21
23.1	Consent of Deloitte & Touche LLP, Independent Registered Public Accounting Firm.	Filed Herewith		
24.1	Powers of Attorney (contained in the signature page to this Annual Report on Form 10-K).	Filed Herewith		

Exhibit Number	Description	Incorporated by Reference From Form	Incorporated by Reference From Exhibit Number	Date Filed
31.1	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Filed Herewith		
31.2	Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Filed Herewith		
32.1~	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Filed Herewith		
101.SCH	XBRL Taxonomy Extension Schema Document			
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document			
101.LAB	XBRL Taxonomy Extension Label Linkbase Document			
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document			
101.DEF	XBRL Taxonomy Extension Definition Document			
104	The cover page of this Annual Report on Form 10-K, formatted in inline XBRL.			

+ Indicates a management contract or compensatory plan.

* Portions of the exhibit have been omitted pursuant to Item 601(b)(10) of Regulation S-K. The Company agrees to furnish to the Securities and Exchange Commission a copy of any omitted portions of the exhibit upon request.

~ The certifications attached as Exhibit 32.1 that accompany this Annual Report on Form 10-K, are deemed furnished and not filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of Inogen, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Annual Report on Form 10-K, irrespective of any general incorporation language contained in such filing.

SIGNATURES

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

INOGEN, INC.
(Registrant)

By: /s/ Nabil Shabshab
Nabil Shabshab
Chief Executive Officer
President
Director
(Principal Executive Officer)

Dated: February 24, 2022

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Nabil Shabshab and Michael Sergesketter, and each of them, as his or her true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his or her substitutes, may lawfully do or cause to be done by virtue thereof.

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

Signature	Title	Date
/s/ Nabil Shabshab Nabil Shabshab	Chief Executive Officer, President and Director *(Principal Executive Officer)*	February 24, 2022
/s/ Michael Sergesketter Michael Sergesketter	Chief Financial Officer *(Principal Accounting and Financial Officer)*	February 24, 2022
/s/ Elizabeth Mora Elizabeth Mora	Chairperson of the Board	February 24, 2022
/s/ Heath Lukatch, Ph.D. Heath Lukatch, Ph.D.	Director	February 24, 2022
/s/ Benjamin Anderson-Ray Benjamin Anderson-Ray	Director	February 24, 2022
/s/ Heather Rider Heather Rider	Director	February 24, 2022
/s/ Loren McFarland Loren McFarland	Director	February 24, 2022
/s/ Kristen Miranda Kristen Miranda	Director	February 24, 2022

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-223280, 333-216352, 333-210175, 333-203842 and 333-194016 on Form S-8 of our reports dated February 24, 2022, relating to the financial statements of Inogen, Inc. (the "Company"), and the effectiveness of the Company's internal control over financial reporting, appearing in this Annual Report on Form 10-K for the year ended December 31, 2021.

/s/ DELOITTE & TOUCHE LLP

Los Angeles, California
February 24, 2022

Exhibit 31.1

CERTIFICATION OF PERIODIC REPORT UNDER SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Nabil Shabshab, certify that:

1. I have reviewed this annual report on Form 10-K of Inogen, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: February 24, 2022

By: /s/ Nabil Shabshab
Nabil Shabshab
Chief Executive Officer
President
Director
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PERIODIC REPORT UNDER SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael Sergesketter, certify that:

1. I have reviewed this annual report on Form 10-K of Inogen, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a–15(f) and 15d–15(f))for the registrant and have:
    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: February 24, 2022

By: /s/ Michael Sergesketter
Michael Sergesketter
Chief Financial Officer
Executive Vice President, Finance
Corporate Treasurer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATIONS OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER PURSUANT TO 18 U.S.C. § 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Nabil Shabshab, the chief executive officer of Inogen, Inc. (the "Company"), certify for the purposes of 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge,

(i) the Annual Report of the Company on Form 10-K for the year ended December 31, 2021 (the "Report"), fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

February 24, 2022

By: /s/ Nabil Shabshab
Nabil Shabshab
Chief Executive Officer
President
Director

I, Michael Sergesketter, the chief financial officer of Inogen, Inc. (the "Company"), certify for the purposes of 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge,

(i) the Annual Report of the Company on Form 10-K for the year ended December 31, 2021 (the "Report"), fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

February 24, 2022

By: /s/ Michael Sergesketter
Michael Sergesketter
Chief Financial Officer
Executive Vice President, Finance
Corporate Treasurer