



2024 Annual Report



Dear Inogen Investor,

2024 was a remarkable year for our business. We made great strides in delivering on our mission to improve the lives of patients suffering from respiratory conditions around the world, while significantly advancing the financial profile and condition of the Company. I am truly proud of what our team has accomplished, and believe it is only the beginning of Inogen's return to growth, profitability, and position as a leader in respiratory therapies.

Our priorities as a Company remain steadfast: drive top-line growth, advance our path to profitability, and continue to expand our innovation pipeline to serve patients and providers.

Regarding growth, there were numerous commercial achievements between our channels in 2024. Primarily, as a Company we returned to growth, delivering a 6% revenue improvement over our 2023 results. This success was driven by strong commercial execution in our business-to-business channels, which grew by over 25% domestically and internationally. The job is not finished, and we will continue to rebuild and expand our relationships with our partners.

Building on our organic efforts to drive top-line growth, we entered a significant collaboration with Yuwell Medical. This collaboration is expected to allow Inogen to enter the large and rapidly growing Chinese respiratory market, while expanding Inogen's product portfolio with a high-quality and dependable stationary oxygen concentrator. We are excited about what this collaboration means for our business, and believe it reinforces our long-term growth profile and shortens our pathway to profitability.

During the year we continued to experience pressure in our direct-to-consumer channel. This was largely the result of our downsized salesforce; a decision we made to drive efficiency in that channel.

Our rental channel was similarly pressured, as we continued to see a greater number of patients entering service with private insurance plans. Returning our direct-to-consumer and rental channels to growth remains a key focus of our plan to drive growth and leverage in our business.

On our second priority to advance towards profitability, we made significant improvements during the year. We generated two quarters of Adjusted EBITDA profitability; and we believe these quarters serve as proof points for the capability of our business to generate leverage. While there are steps to be taken to reach consistent profitability, we will continue to prioritize efficiency and diligently manage our expense profile.

Turning to our innovation pipeline, we continued our cadence of new product development and commercialization, while improving our existing portfolio.

In December, we received FDA 510(k) clearance for our Simeox airway clearance device. This was the culmination of a long process by our clinical and regulatory teams following our acquisition of Physio-Assist in 2023. Simeox expands Inogen's capabilities beyond POCs and furthers our offerings as a broader respiratory care provider. Our focus has now shifted to commercializing Simeox, and our plans to pursue reimbursement in the United States.

A number of new innovations to our existing product categories were also introduced during the year. We launched our latest POC, the Rove 4. Its light weight and 6 hours of battery life represent Inogen's core principle of allowing patients to retain mobility. We also launched several updates for our Inogen Connect app, expanding the ease-of-use and accessibility of our devices.

Inogen remains committed to delivering the highest quality, most accessible, and dependable respiratory devices on the market. We look forward to continuing to provide updates on our progress and thank you for your support.



Kevin Smith
Chief Executive Officer, President and Director

BOARD OF DIRECTORS

Kevin Smith
*Chief Executive Officer, President
and Director*

Elizabeth Mora
*Former Chief Administrative Officer,
Charles Stark Laboratory*

Glenn Boehnlein
*Vice President, Chief Financial Officer,
Stryker Corporation*

Kevin King
*Former Chief Executive Officer, President,
iRhythm Technologies, Inc.*

Mary Katherine Ladone
*Former Senior Vice President, Corporate
Development, Strategy and Investor
Relations, Hill-Rom Holdings, Inc.*

Heather Rider
*Former Vice President, Global Human
Resources, Cymer, Inc.*

Mira Sahney
*Former President of the Pelvic Health
Operating Unit at Medtronic*

CORPORATE EXECUTIVE OFFICERS

Kevin Smith
*Chief Executive Officer, President
and Director*

Michael Bourque
*Executive Vice President, Chief Financial
Officer and Corporate Treasurer*

Kevin P. Smith
*Executive Vice President, General Counsel,
Secretary and Business Development*

Gregoire Ramade
*Executive Vice President,
Chief Commercial Officer*

ANNUAL REPORT ON FORM 10-K

Stockholders may receive a copy of our annual report on Form 10-K, including the financial statements and financial statement schedules, free of charge upon the written request of any such person. All such requests shall be sent to Inogen, Inc., Investor Relations Department, 859 Ward Drive, Suite 200, Goleta, California 93111.

CORPORATE HEADQUARTERS

Inogen, Inc.
859 Ward Drive, Suite 200
Goleta, California 93111
T: (805) 562-0500
www.inogen.com

COMMON STOCK LISTING

Nasdaq Global Select Market
Ticker Symbol: INGN

ANNUAL MEETING OF STOCKHOLDERS

May 14, 2025 at 10:00 a.m. (Pacific Time)

Stockholders can attend the virtual Annual Meeting by accessing www.virtualshareholdermeeting.com/INGN2025

REGISTRAR AND TRANSFER AGENT

For questions regarding your account, changes of address or the consolidation of accounts, please contact Inogen's transfer agent:

Computershare Investor Services
P.O. Box 43078
Providence, RI 02940-3078
T: (877) 373-6374 (U.S.)
T: (781) 575-2879 (International)
www.computershare.com/investor

LEGAL COUNSEL

Covington & Burling LLP
One International Place, Suite 1020
Boston, MA 02110-2600

INDEPENDENT AUDITORS

Deloitte & Touche LLP
Los Angeles, California

INVESTOR RELATIONS

Inogen, Inc.
Investor Relations Department
859 Ward Drive, Suite 200
Goleta, California 93111

INTERNET ADDRESS INFORMATION

Visit us online at www.inogen.com for more information about Inogen. The 2024 Annual Report is available online by visiting <http://investor.inogen.com>

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This 2024 Annual Report contains forward-looking statements 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 information concerning our possible or assumed future results of operations, business strategies, financing plans, competitive position, industry environment, potential growth opportunities and market growth expectations, hiring plans, productivity improvements, new product launches, 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. Given these uncertainties, you should not place undue reliance on any forward-looking statements. In particular, Inogen, Inc. ("Inogen") cannot predict its future revenues or operating results or its future rates of revenue growth, if any. Inogen's business, revenues, and operating results as well as its rate of revenue growth, if any, will be subject to numerous risks and uncertainties, including (among others) risks arising from the possibility that Inogen will not realize anticipated revenue; the impact of reduced reimbursement rates, including in connection with competitive bidding and the Centers for Medicare and Medicaid Services (CMS) rules; risks related to reimbursement coding of our products and regulatory approvals; the possible loss of key employees, customers, or suppliers; and intellectual property risks if Inogen is unable to secure and maintain patent or other intellectual property protection for the intellectual property used in its products. In addition, Inogen's business is subject to numerous additional risks and uncertainties, including, among others, risks relating to market acceptance of its products; its ability to successfully launch new products and applications; competition; its sales, marketing and distribution capabilities; its planned sales, marketing, and research and development activities; interruptions or delays in the supply of components or materials for, or manufacturing of, its products; seasonal variations in customer operations; unanticipated increases in costs or expenses, including the impact of expense inflation; cyber-based attacks or network security breaches; and risks associated with international operations. In addition, investors in Inogen should review the more detailed discussions of risks and uncertainties affecting our business described under the caption "Risk Factors" in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 28, 2025 and supplemented in our subsequent Quarterly Reports on Form 10-Q. Except as required by law, we assume no obligation to update these forward-looking statements publicly, 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.



Inogen, Inc.
859 Ward Drive, Suite 200
Goleta, California 93111

www.inogen.com

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 Ended December 31, 2024

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the Transition Period From to

Commission file number: 001-36309

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

Delaware
State or other jurisdiction of
incorporation or organization

859 Ward Drive
Goleta, California
Address of principal executive offices

33-0989359
I.R.S. Employer
Identification No.

93111
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. ☒

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

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

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

The aggregate market value of the 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 \$192.8 million. Shares of common stock held by each executive officer and director and by each other person who may be deemed to be an affiliate of the Registrant, have been excluded from this computation. The determination of affiliate status for this purpose is not necessarily a conclusive determination for other purposes.

The number of shares of the registrant's Common Stock outstanding as of February 21, 2025 was 26,529,544.

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 2025 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, 2024.

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

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, results of operations, and operating and other expenses;
- the impact of expense inflation on the components we use in our products, and the impact of inflation of the ability of our customers to afford our products;
- the potential for future supply chain constraints;
- our assessment and expectations regarding reimbursement rates, future rounds of competitive bidding, Centers for Medicare and Medicaid Services, or CMS, changes to Home Use of Oxygen national coverage determination and how those changes are implemented, and future changes in rental revenue;
- our ability to develop new products, improve our existing products, and increase the value of our products;
- our expectations regarding the timing of new products and product improvement launches as well as product features and specifications;
- our expectations with respect to our cost reduction initiatives;
- our expectations regarding regulatory approvals and government and third-party payor coverage and reimbursement;
- the ability of our competitors to introduce products to the market that may be lower priced than ours, may have more product features than ours, or are otherwise more accepted by the market, including our home medical equipment providers;
- our ability to attract key talent to the Company, and to retain key employees;
- our ability to efficiently integrate Physio-Assist and our ability to obtain reimbursement coverage for the Physio-Assist products in the U.S.;
- expectations with respect to market share, 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 and our ongoing efforts to reduce average unit costs for our systems;
- our expectations regarding the productivity of our sales and marketing teams;
- our expectations with respect to our European and U.S. facilities and our expectations with respect to our contract manufacturer in Europe;
- our expectations, and changing regulations regarding tariffs that are or may be 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 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; and
- 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.

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 and other documents 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 G3,” “G4,” “G5,” “Oxygen.Anytime.Anywhere,” “Intelligent Delivery Technology,” “Inogen At Home,” “Inogen Rove,” and the Inogen design, are registered trademarks with the United States Patent and Trademark Office of Inogen, Inc. We own pending applications for the marks “Rove,” “Inogen Rove 4,” “Inogen Rove 6,” and “VOXI” with the United States Patent and Trademark Office. We own trademark registrations for the mark “Inogen” in Argentina, Australia, Bermuda, Canada, Chile, China, Columbia, Ecuador, Hong Kong, South Korea, Malaysia, Mexico, Europe (European Union Registration), the United Kingdom, Iceland, India, Israel, Japan, Kuwait, New Zealand, Norway, Dominican Republic, Paraguay, Peru, Philippines, Turkey, Singapore, South Africa, Switzerland, and Uruguay. We own pending applications for the mark “Inogen” in Indonesia, Taiwan, Thailand, the UAE and Vietnam. We own a trademark registration for the mark “イノジェン” in Japan. We own trademark registrations for the marks “印真” and “艾根” 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 trademark registrations 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 marks “Inogen Rove 4” and “Inogen Rove 6” 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 pending applications for the marks “Inogen Rove 4” and “Inogen Rove 6” in Canada. We own trademark registrations for the Inogen design in Bolivia and China. We own a trademark registration for the mark “إنوجن” in Saudi Arabia. We own a pending application for the Inogen One G5 design in Brazil. Other service marks, trademarks, and trade names referred to in this Annual Report on Form 10-K are the property of their respective owners. “PHYSIOASSIST,” the Physio-Assist logo, “SIMEOX,” “SIMEOX PRO,” “HOME SIMEOX,” “SIMESOFT,” “PHYSIOWEB,” “PHYSIODATA,” “PHYSIOSERVICES,” and the Pissenlit logo are registered trademarks of Inogen’s wholly-owned subsidiary Physio-Assist. Physio-Assist owns trademark registrations for the mark “PHYSIOASSIST” in Europe (European Union Registration), France, Japan, United Kingdom, and USA. Physio-Assist owns trademark registrations for the Physio-Assist logo in China, Europe (European Union Registration), France, Japan, South Korea, United Kingdom, and USA. Physio-Assist owns trademark registrations for the mark “SIMEOX” in Europe (European Union Registration), France, Japan, Russia, United Kingdom, and USA. Physio-Assist owns pending applications for the mark “SIMEOX” in Argentina, Canada, Colombia, Mexico, Norway, and Switzerland. Physio-Assist owns trademark registrations in France for the marks “PHYSIOASSIST,” “SIMESOFT,” “SIMEOX,” “HOME SIMEOX,” “SIMEOX PRO,” “PHYSIOWEB,” “PHYSIODATA,” “PHYSIOSERVICES,” the Physio-Assist logo, and the Pissenlit logo.

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

ITEM 1. BUSINESS

General

Inogen, Inc. is a medical technology business that primarily focuses on respiratory health. We develop, manufacture, and market innovative respiratory health products, including portable oxygen concentrators, or POCs, used to deliver supplemental long-term oxygen therapy to patients suffering from chronic respiratory conditions and the Simeox[®] product for airway clearance treatment. Our proprietary Inogen One[®] and Inogen Rove[®] systems concentrate the air around the patient to offer a source of supplemental oxygen 24 hours a day, seven days a week with a battery and can be plugged into an outlet when at home, in a car, or in a public place with outlets available. While often used concomitantly with stationary oxygen concentrators and oxygen compressed gas tanks, our POCs are designed to 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. Our Simeox product is a technology-enabled airway clearance and mucus management device predominantly aimed at serving patients with bronchiectasis, which is a condition that presents as the lung's bronchi are damaged and widened in patients with cystic fibrosis, chronic obstructive pulmonary disease, or other chronic respiratory diseases.

Corporate history

We were incorporated in Delaware on November 27, 2001. On February 14, 2014, we completed an initial public offering of common stock and began trading on the Nasdaq Global Select Market, trading under the ticker symbol "INGN".

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., or 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., or New Aera, on August 9, 2019. On September 14, 2023, we completed the acquisition of all of the issued and outstanding capital stock of Physio-Assist SAS, or Physio-Assist, and its wholly-owned subsidiary PhysioAssist GmbH.

The market

Chronic obstructive pulmonary disease

We are focused on oxygen therapy and other opportunities in the global respiratory care market. We believe that our portable oxygen therapy solutions can help patients with chronic respiratory conditions, including patients with chronic obstructive pulmonary disease, or COPD.

COPD is a group of lung diseases including chronic bronchitis and emphysema. The main cause of COPD is smoking, but other factors like air pollution, secondhand smoke and dust, as well as fumes and chemicals can cause COPD. There is currently no cure for COPD, and it is a progressive and debilitating disease that is characterized by a gradual loss of lung function and airflow limitation that is not fully reversible. The symptoms of COPD can range from chronic cough and sputum production to insufficient levels of oxygen in the blood and severe shortness of breath.

COPD has a huge impact on patients and the healthcare system. According to a report published by the Forum of International Respiratory Societies in 2022, an estimated 200 million people in the world have COPD. The Centers for Disease Control and Prevention, or CDC, in the United States estimates that prevalence of COPD among adults 18 years or older was approximately 6.1% based on CDC data of age-adjusted prevalence of COPD from 2011 to 2021. COPD is a major cause of disability and the sixth leading cause of death according to the CDC. In terms of economic impact, the total economic cost from COPD in the United States was projected to be approximately \$49 billion in 2020 with close to 925,000 COPD emergency department visits in 2020.

A peer-reviewed article in the New England Journal of Medicine has stated that long-term oxygen therapy has been shown to help COPD patients who have severely low blood oxygen or hypoxemia. Hypoxemic patients are unable to convert oxygen found in the air into the bloodstream in an efficient manner. Over time it can lead to a lack of oxygen in organs and tissues, known as hypoxia, and acute respiratory failure. As COPD progresses into later stages, patients may need long-term oxygen therapy as part of their treatment. Other diseases including cystic fibrosis or congestive heart failure may lead to lower oxygen in the bloodstream and may also benefit from long-term oxygen therapy.

Oxygen therapy

Inogen created its first POCs with a goal of creating products that allow patients the chance to remain ambulatory while managing the impact of their disease. Traditionally, oxygen patients have relied on stationary oxygen concentrator systems for use in the home and oxygen tanks or cylinders for mobile use, which we refer to as the delivery model. The tanks and cylinders must be delivered regularly and contain 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 to enable mobility within their homes.

We believe the following factors have hindered the market acceptance of POCs:

- to obtain POCs, many patients are dependent on home medical equipment providers, which may have significant investments in the physical distribution infrastructure to support the delivery model for stationary devices and therefore may be disincentivized to encourage adoption of POCs;
- 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;
- due to the nature of the capped reimbursement structure, patients' lack of ability to use their insurance benefits to switch from oxygen tanks or liquid deliveries to POCs; and
- constrained manufacturing costs of conventional POCs, driven by home medical equipment provider preference for products that have lower upfront equipment cost.

Bronchiectasis

We expanded our addressable market opportunity into the bronchiectasis market with the acquisition of Physio-Assist in September 2023. Physio-Assist developed and manufactures Simeox, a technology-enabled airway clearance device with a proven efficacy and safety profile. Simeox has been on the market in Europe and several other markets since prior to the acquisition and was cleared in December 2024 by the FDA for use in the United States. The device is used to treat a condition in the lungs known as bronchiectasis, where the lung's bronchi become damaged and widened. Bronchiectasis is often present in cystic fibrosis and COPD patients. Simeox is used in pulmonary rehabilitation centers, as well as by patients at home. Simeox has expanded our product offering to serve COPD and other chronic respiratory disease patients who suffer from bronchiectasis with an innovative, non-invasive, and next generation airway clearance solution.

We believe that Inogen can potentially access a large growing bronchiectasis market opportunity in the U.S. following receipt of 510(k) clearance for the Simeox 200 device in December 2024. We intend to commercialize Simeox through the purchase of the product initially, followed by recurring sales of device disposables. We will begin efforts to obtain reimbursement coverage in the first quarter of 2025 for the Simeox product in the U.S.

Business strategy

We believe there is an opportunity to grow portable oxygen therapy usage and develop the market further to help patients with chronic conditions breathe better and help providers improve patient outcomes. Our strategy for expanding our business and growing the market includes:

1. **Grow our core business.** We believe we have an opportunity to drive penetration of POC-based oxygen therapy versus other oxygen therapy modalities. We also believe that we have the opportunity to grow by expanding the countries and regions where our products are marketed and sold.
2. **Enhance our business through innovation.** We are committed to the ongoing innovation to meet the needs of patients, providers, and our business-to-business partners to manage lower blood oxygen and shortness-of-breath associated with COPD and other chronic conditions.
3. **Support adoption of Inogen products through clinical evidence and key opinion leaders' advocacy.** We believe that we can develop the market and expand growth opportunities by educating providers and generating clinical evidence. Our clinical approach involves investing in clinical studies and engaging with key opinion leaders, or KOLs, through our Scientific Advisory Board. The KOLs are focused on advocating for the right therapy for patients and changing the behavior of prescribers.

Our products

Our Inogen One and Inogen Rove portable oxygen systems provide patients who require long-term oxygen therapy with a reliable, lightweight solution that we believe allows patients the chance to remain ambulatory while managing the impact of their disease and eliminates dependence on both oxygen tanks and cylinders. We have created a market leading portfolio of POCs.

POC product features

We market our current portable product offerings, the Inogen Rove and Inogen One systems, as ambulatory solutions for long-term oxygen therapy. The Inogen® Rove 4™ can operate up to 96 months when used for up to five hours per day, and the Inogen® Rove 6™ and the Inogen One G5® can operate up to 96 months when used for up to eight hours per day. The Inogen One G4® can operate up to 60 months when used for up to eleven hours per day. Servicing of sieve beds, filters, and accessories can be performed by patients themselves for all of our current portable product offerings. The technology in our Inogen One and Inogen Rove systems are effective for nocturnal use.

All of our portable oxygen 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 250 milliseconds of inspiration, the interval when oxygen has the most effect on lung gas exchange. During periods of sleep, respiratory rates typically decrease. Our 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.

We have also launched Inogen Connect, a wireless connectivity platform for the Inogen One G4, Inogen One G5, Inogen Rove 4 and Inogen Rove 6 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 application, or 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.

We released our latest portable oxygen concentrator, Rove 4, in the U.S. and European Union in October 2024. The Inogen Rove 4 is among the lightest products on the market and has among the highest oxygen production capabilities. The performance parameters around our 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.

Stationary oxygen concentrator

We market our own 5-liter stationary oxygen concentrator, the Inogen At Home, capable of delivering continuous flow of oxygen for the patients who require it. The Inogen At Home is one of the smaller, quieter and lower weight devices in this category. We also supply lower cost third-party manufactured stationary concentrators to our rental patients who require secondary sources of oxygen as a part of their CMS contract or to meet other clinical or payer requirements.

Airway clearance

We added Simeox, an airway clearance device, to our portfolio through the acquisition of Physio-Assist in September 2023. Simeox has been commercialized in Europe and several other markets for several years and was recently cleared by the FDA for use in the United States in December 2024. Simeox uses an innovative technology of oscillating negative pressure to liquify mucus in the bronchi and help patients evacuate it by coughing and/or leveraging postural drainage. A particular advantage of this technology is that it can be used by patients capable of generating productive cough, regardless of the body size, chest wall abnormalities or back pains. The efficacy and safety of Simeox has been demonstrated in 10 clinical trials. It is marketed in Europe under EU Medical Devices Directive 93/42/EEC, or MDD, regulations.

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 \$218.5 million of our 2024 revenue derived from the United States, approximately 38.2% represented sales to traditional home medical equipment providers, distributors (including our private label collaborator) and resellers, 35.7% represented direct-to-consumer sales, and 26.1% represented direct-to-consumer rentals.

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 POCs that employs a direct-to-consumer rental strategy in the United States, meaning we bill Medicare or insurance on the patient's 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 to whom many of our manufacturing competitors sell across their entire homecare businesses.

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

Our direct-to-consumer rental marketing efforts are focused on informing prescribers of the benefits of our products in order to serve patients earlier at the point of diagnosis and prescription while capturing a higher proportion of the life-time value of prescribed oxygen therapy. Our prescriber sales team is focused on accelerating the rental growth and building relationships with prescribers. We believe that these efforts are complementary with our focus on generating clinical evidence in the future and will increase our ability to further expand and develop the market.

Patients who choose to use their Medicare or private insurance benefits typically rent our systems. Those who purchase our products outright are typically patients who are not eligible to use their insurance benefits due to their capped rental status or exercise their personal preferences. 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 different 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.

We work with private payors to become an in-network provider of oxygen therapy solutions where possible, which we expect will reduce patient co-insurance amounts associated with using our products. We believe that additional in-network associations will result in both increased conversion of our initial leads, as well as direct referrals from insurance companies in some cases.

We also sell to resellers and traditional homecare providers in the United States 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. 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 the delivery model for oxygen tanks.

As of December 31, 2024, we employed 356 people in the United States and Europe in our Sales and Marketing organization.

International

Approximately 34.9% of our total revenue was from outside the United States in 2024. We sell through distributors, resellers, and home medical equipment providers in certain markets within Europe and several other markets. To date, we have sold our products in a total of 65 countries outside the United States through distributors or directly to large “house” accounts, which include gas companies and home oxygen providers. For international sales, 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, 2024, we had 333 people located in the United States who focused on selling our products and providing service and support to distributors and house accounts worldwide and 23 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 2024, 2023 or 2022.

Our wholly-owned subsidiary, Inogen Europe B.V. operates a European customer support site in the Netherlands. 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 Rove 6 concentrators and perform related repair activities using a contract manufacturer, Foxconn, located in the Czech Republic to improve our ability to efficiently service our European customers. Physio-Assist sells its Simeox product throughout Europe and several other markets and manufactures the product in its Montpellier, France location.

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. One customer represented more than 10% of our net accounts receivable balance with a net accounts receivable balance of \$3.3 million as of December 31, 2024. One customer represented more than 10% of our financing receivable balance with a balance of \$6.5 million as of December 31, 2024. Two customers each represented more than 10% of our net accounts receivable balance with net accounts receivable balances of \$8.6 million and \$5.0 million, respectively, as of December 31, 2023.

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 56.3%, 67.7% and 77.0% of rental revenue in 2024, 2023 and 2022, respectively, and accounted for 9.5%, 13.7% and 11.6% of total revenue for 2024, 2023 and 2022, respectively. Accounts receivable balances relating to Medicare’s service reimbursement programs (including held and unbilled receivables, net of allowances) amounted to \$1.1 million or 3.7% of total net accounts receivable as of December 31, 2024 compared to \$2.1 million, or 4.9%, of total accounts receivable as of December 31, 2023.

Customer support

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, 2024, we had a dedicated customer service team that was trained on our products, a clinical support team made up of licensed nurses or respiratory therapists, a patient intake team, an order intake team, and a dedicated billing services team. We provide our patients with a dedicated 24/7 hotline, allowing 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 needed by the patient or the customer service representative. 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, and safety with our products.

Third-party reimbursement

As a provider of home oxygen, Inogen participates in the Medicare Part B, Supplementary Medical Insurance Program, which was established by the Social Security Act of 1965. For our rental revenue, we rely significantly on reimbursement from Medicare and private payors. Medicare reimbursement has historically been based on fixed fee schedules. 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. Our sales and rental intake teams 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 have contracts with Medicaid, Medicare Advantage, government and private payors that qualify us as an in-network provider for these payors. As a result, many patients can rent or purchase our systems at the same patient obligation as other in-network oxygen suppliers. 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 rely significantly on reimbursement from Medicare, Medicaid and private payors, including Medicare Advantage plans and patients for our rental revenue. For the year ended December 31, 2024, approximately 56.3% of our rental revenue was derived from Medicare's traditional fee-for-service reimbursement programs.

Medicare revenue, including patient co-insurance and deductible obligations, represented 9.5% of our total revenue in the year ended December 31, 2024 and 13.7% of our total revenue in the year ended December 31, 2023.

For additional discussion of the impact of Medicare on our business, see "Risk Factors" herein.

Manufacturing and raw materials

We have been developing and refining the manufacturing of our oxygen concentrator systems since 2004. While nearly all of our manufacturing and assembly processes were originally outsourced, assembly of the compressors, sieve beds, and concentrators 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 typically enter into master service agreements with our major vendors for these components that specify supply requirements, quality and delivery terms. In certain cases, these agreements can be terminated by either party upon relatively short notice. We expect to maintain our assembly operations for our products at our facility in Plano, Texas. We also manufacture the Simeox device in a leased facility in Montpelier, France.

We use lean manufacturing practices to maximize manufacturing efficiency and eliminate waste. We rely on third-party manufacturers to supply components of our products. We have elected to source certain key components from single sources of supply where we deem it appropriate. 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. In order to help mitigate against the risks related to a single source of supply, for certain components, we have initiated second sourcing initiatives to qualify alternative suppliers and develop contingency plans for responding to disruptions. This initiative has also resulted in reduced component costs. For additional discussion of potential risks related to our manufacturing and raw materials, please see the risk factor entitled "*Reduction or interruption in our supply of components and products may adversely affect our manufacturing operations and related product sales.*"

We currently manufacture our oxygen concentrators in a leased building in Plano, Texas and have a design facility at our Corporate Headquarters in Goleta, California, that we have registered with the Food and Drug Administration, or FDA, and maintain a Quality Management system for which we have obtained International Standards Organization, or ISO, 13485 certification. We also manufacture the Simeox device in a leased facility in Montpelier, France.

Our entire organization is responsible for quality management. Our Quality Assurance and Regulatory Affairs departments oversee quality management 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 addition, we continue to operate the quality management system of Physio Assist as we move to fully integrate the systems, with its system also certified to ISO 13485:2016 by IMQ, its notified body.

As of December 31, 2024, we had 187 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 the respiratory market. We use a combination of research and development staff along with third party resources to develop our products. As of December 31, 2024, 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, digital health, and manufacturing automation. The team is augmented with expertise and resources of our third-party partners specialized in medical device development. Our current research and development efforts are focused primarily on increasing functionality, improving design for ease-of-use, and reducing the total cost of ownership of our products, as well as developing our next-generation oxygen concentrators and further developing the Simeox product line. We have leveraged our 87 issued patents and intend to continue to seek ways to innovate to develop products and functionality improvements that enhance patient quality of life and to reduce costs through manufacturing and design improvements.

Competition

The long-term oxygen therapy market is a highly competitive industry. We compete with a number of manufacturers and distributors of 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. Some of our competitors are large, well-capitalized companies with greater resources and other advantages than we have.

Our significant manufacturing competitors are Caire Medical (a subsidiary of NGK Spark Plug), DeVilbiss Healthcare (a subsidiary of Drive Medical), O2 Concepts, Precision Medical, Gas Control Equipment (a subsidiary of Colfax), Nidek Medical, 3B Medical, SysMed, iRhythm Technologies, Inc., and Belluscura. Respiroics (a subsidiary of Koninklijke Philips N.V.) announced in early 2024 that it was leaving the U.S. portable oxygen concentrator market until further regulatory assessments but continues to have product in the market. This is not an exhaustive list of competitors. 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 Viamed 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.

Government regulation

Inogen's products, including the Inogen One and Rove systems, Inogen At Home systems, Simeox, 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 marketed safety reporting.

FDA's classification of medical devices and pre-market clearance and approval requirements

FDA classifies medical devices 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. Most Class I devices and some Class II devices are exempt from pre-market review requirements. Class I devices are subject to the “general controls” of the Food, Drug, and Cosmetic Act, or FDCA, which include establishment registration and device listing, quality system requirements, labeling requirements, medical device reporting, and reporting of corrections and removals. Most Class II devices and some Class I devices require FDA clearance of a 510(k) pre-market notification prior to marketing. In addition to the general controls, Class II devices are subject to “special controls,” such as performance standards and guidance documents, as identified in the classification regulation for the device type. Class III devices require FDA approval of a pre-market approval application, or PMA, demonstrating reasonable assurance of safety and effectiveness of the device, prior to commercial distribution. Class III devices are those deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices. Class III devices are subject to the general controls and any conditions of approval in the PMA approval order, which can include post-market study requirements. Novel devices that have not been classified are automatically classified into Class III. For such devices that are low-to moderate-risk, the manufacturer can submit a De Novo classification request to classify the device into Class I or Class II.

510(k) clearance pathway

When a 510(k) clearance is required, we must submit a pre-market notification to the FDA demonstrating that our proposed device is substantially equivalent to a legally marketed predicate device. By law, FDA is supposed to make a decision on a 510(k) within 90 calendar days of accepting the submission for review; however, 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 is not substantially equivalent to a legally marketed predicate device, the FDA will issue a not substantially equivalent, or NSE, order. For a device that is the subject of an NSE, marketing authorization needs to be obtained through a new pre-market review submission (i.e., a 510(k), De Novo, or PMA) before the device can be commercially distributed. We obtained 510(k) clearance for the original Inogen One system on May 13, 2004. We market the 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. We obtained 510(k) clearance for the Rove 4 system on December 9, 2022 and 510(k) clearance for the Rove 6 system on June 30, 2023. We obtained 510(k) clearance for the Simeox airway clearance system on December 23, 2024.

De Novo authorization pathway

The De Novo authorization pathway, also referred to as “Evaluation of Automatic Class III Designation”, entails a request to the FDA to classify novel devices of low to moderate risk into Class II or Class I. De Novo authorization is intended as a potential pathway for devices for which the 510(k) process is not an available pathway because there is no legally marketed predicate device to which to claim substantial equivalence. 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, which can then serve as a predicate device for future 510(k) pre-market notification submissions.

Pre-market approval pathway

A pre-market approval application must be submitted to the FDA if the device cannot be cleared or authorized through the 510(k) or De Novo process. The pre-market approval application process is more demanding than the 510(k) pre-market notification process. A pre-market approval application must be supported by extensive data, generally including but not limited to, technical information, preclinical testing, clinical trials, manufacturing information, and labeling to demonstrate reasonable assurance 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 and De Novo authorization. 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 the risks of the device do not outweigh the potential benefits to the subjects participating in the study 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 a non-significant risk device and, as such, eligible for abbreviated IDE requirements. Clinical trials for significant risk and non-significant risk devices require approval by the appropriate institutional review board(s), or IRB(s), that is responsible for oversight of the study. We, the FDA or the IRB 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.

We have sponsored clinical studies and real-world data analyses that recently resulted in several publications in the areas of the following: use of POCs, impact of oxygen treatment modality and patient mobility on mortality and healthcare resource utilization, as well as the impact of ventilatory support in addition to oxygen therapy on exercise tolerance in patients with COPD. We have also sponsored clinical studies on the Simeox device through Physio-Assist both prior to and since the acquisition. We continue to invest in clinical research activities to support new product development, as well as expansion of the uses of its products and services.

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 regulations, which require device manufacturers to comply with both design control requirements and good manufacturing practice requirements (such as requirements for purchasing controls, document controls, production and process controls, labeling and packaging controls, control of nonconforming product, complaint handling, corrective and preventative actions, storage, handling, distribution, and servicing);
- labeling regulations (including FDA's Unique Device Identification requirements), the FDA's prohibitions against the promotion of devices 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 corrections and removals of distributed devices (including repairs, modifications, adjustments, relabeling, destruction, or inspection of a device without physical removal) if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health; and
- post-market surveillance regulations, which apply, upon FDA order, to certain devices to help address important public health questions regarding the safety and effectiveness of a device.

After a device receives 510(k) clearance or De Novo authorization, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, will require submission and clearance of a new 510(k). After a device receives PMA approval, all changes affecting the safety or effectiveness of the device must be reviewed and approved through a PMA supplement. 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 additional enforcement action, including 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, import detention, 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 inspections and audits by the FDA, certain other regulatory agencies and authorities and our notified body. We have been periodically audited by these organizations and none have identified any major observations with our manufacturing facilities or Good Manufacturing Policies. 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 2027. 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. If we were found not to be in compliance with applicable state regulations regarding licensure requirements, 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, among others. 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, as amended, or the False Claims Act, provides that the federal government, and under certain circumstances a private party or whistleblower, may bring claims against a person who knowingly presents or causes to be presented a false or fraudulent request for payment to the federal government or uses a false statement or false record to get a claim approved. Violations of the False Claims Act can result in penalties up to \$28,619 for each claim, plus three times the amount of damages that the federal government sustained. Moreover, a claim including items or services resulting from a violation of the Federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. The Company is not aware of any pending claims against it under the False Claims Act.

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, or OIG, to seek civil monetary penalties, or 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 we have processes in place to manage our discount and incentive programs, 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 \$50,000 for each wrongful act 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 anti-kickback and self-referral laws similar and statutes similar to the Federal Anti-Kickback Statute and False Claims Act that apply to DMEPOS suppliers regardless of the payor source, and violations of such laws could result in fines, penalties and restrictions on our ability to operate in these jurisdictions. The Company is not aware of any pending claims against it under such state laws.

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 most healthcare providers, health plans and healthcare clearinghouses, which are referred to as “covered entities.” Among the standards that 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, 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, and the Breach Notification Standards, which establish standards for notification in the event of a breach of unsecured individually identifiable health 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. 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 subject to significant civil and criminal penalties for failure to comply with applicable standards. 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.

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.

Physician Payments Sunshine 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 Physician Payments Sunshine Act, enacted as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, 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 Promotes Opioid Recovery and Treatment for Patients and Communities Act enacted in 2018, extended 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 \$211,000 per year (or up to an aggregate of \$1.4 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.

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.

In the European Union, medical devices are regulated by the European Union Medical Devices Regulation (EU) 2017/745, or MDR, which became applicable on May 26, 2021 and replaced the EU MDD, with the EU MDD still applying to certain products that were approved under that process. The MDR and its associated guidance documents and harmonized standards to regulate the design, manufacture, clinical trials, labeling and adverse event reporting for medical devices. Devices that comply with the requirements of the MDR will be entitled to bear the European Conformity Marking, or CE Mark, indicating that the device conforms to the essential requirements of the MDR and, accordingly, can be commercially distributed throughout the Member States of the European Union, and additional Members States of the European Economic Area, or EEA, (i.e., Norway, Lichtenstein and Iceland). The method of assessing conformity under the MDR 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 designated by a Member State country to conduct the conformity assessment. This third-party assessment may consist of an audit of the manufacturer's quality system by reference to ISO 13485, 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 the EEA. We have completed the necessary conformity assessment procedure required to allow us to affix the CE Mark to our oxygen therapy products and to commercialize our devices in the EEA, through the EU MDD and MDR processes. Our ISO 13485 certification was first issued on April 21, 2005, and our EC-Certificate was first issued on March 16, 2007. We received the CE Mark for our oxygen therapy products under the MDR on December 12, 2022.

Following the United Kingdom's exit from the European Union, known as "Brexit", the MDR does not apply in the United Kingdom (except for Northern Ireland, which under the Northern Ireland Protocol is bound by certain EU laws). The medical device legislative framework in the United Kingdom is set out in the Medical Devices Regulations 2002, as amended. These Regulations are based on the previous medical device directives of the EU (including the MDD) but have been amended so that they function properly now the United Kingdom is no longer part of the European Union. The Medical Devices Regulations 2002 have introduced several changes including (but not limited to) replacing the CE mark with a UK Conformity Assessed, or UKCA, marking (although CE marks will be recognized potentially up until June 2030), requiring manufacturers outside of the United Kingdom to appoint a "UK Responsible Person" if they place devices on the Great Britain market and more wide-ranging UK device registration requirements.

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 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 program.

In Australia, we must appoint an agent sponsor who will interact on our behalf with the Therapeutics Goods Administration, or 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 systems, sell counterfeit versions of our products, or obtain and use information that we regard as proprietary.

Patents

As of December 31, 2024, we had 32 pending patent applications and 87 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 2023 acquisition of Physio-Assist 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 Physio-Assist 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, Inogen Rove 4, Inogen Rove 6, 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.

A fourth category of patents and patent applications relates to the Simeox device and related airway clearance technologies and systems that were acquired as part of the Physio-Assist acquisition in 2023. These patents and patent applications provide coverage for the aspects of the Simeox device and potential improvements and adaptations that may be implemented into the device or similar devices in the future.

Trademarks

We own a number of United States registered trademarks that we use in our business. In addition, many of our trademarks are also registered for use in certain foreign countries where we have determined it is commercially advantageous to do so. We utilize our trademarks to represent the quality and goodwill of our products and company and monitor for any unauthorized use of our trademarks, taking action where we deem appropriate and necessary.

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, 2024, we had 766 full and part-time employees worldwide, consisting of 356 employees in sales, marketing, clinical and client services, 187 employees in operations, manufacturing, quality assurance, manufacturing engineering, and repair, 185 employees in general administration and 38 employees in research and development. 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 based on our foundational values of (1) We always do what is right, (2) Invest in people, and (3) Treat people right. This is activated through our five cultural pillars which are (1) Create Trust, (2) Inspire Initiative, (3) Achieve Together, (4) Invite Diversity, and (5) Make a Difference. Onboarding, leadership development and regular engagement surveys create a sustainable ecosystem for these values and culture pillars to thrive.

Additionally, 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 U.S. 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.

Talent acquisition and development

As noted above we seek strong talent with subject matter expertise and provide competitive wages. We also promote from within and encourage Inogen 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. We have a strong leadership and manager program and standardized cultural onboarding for all associates.

Diversity, equity, inclusion, belonging and accessibility (DEIBA)

Diversity, equity, inclusion, belonging and accessibility 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. Our DEIBA Taskforce and Inclusion Ambassador network help guide these efforts through programming and feedback to build a community of psychological safety and inclusion. Internal communications and celebration are further proof points for our efforts as we routinely measure employee engagement in these categories.

We maintain an equitable, market-based compensation architecture and proactively align our benefits, policies and practices with the philosophies, values, and culture pillars. Inclusive leadership programming and onboarding programs further support these efforts across the organization.

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." We perform an annual affirmative action review by job role, and we have a process which identifies pay or promotion discrepancies and ensures that we are equitable in our actions and decisions. Even in the case of reductions in force adverse impact analyses are completed to objectively test and inform our decisions. 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 our management systems, preventative training, problem solving safety committees, 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.

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, or 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 65 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, 2024, 2023, and 2022, substantially all of our long-lived assets were located within the United States. See Note 2 to our 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 historically experienced higher sales revenue 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. As more home medical equipment, or 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.

Corporate and available information

We were incorporated in Delaware in November 2001. Our principal executive offices are located at 859 Ward Drive, Suite 200, Goleta, California 93111. 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 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 provides certain information about our executive officers as of February 21, 2025.

Name	Age	Position
Kevin R. M. Smith	54	Chief Executive Officer, President and Director
Michael Bourque	62	Executive Vice President, Chief Financial Officer and Corporate Treasurer
Kevin P. Smith	54	Executive Vice President, General Counsel, Secretary & Business Development
Gregoire Ramade	55	Executive Vice President, Chief Commercial Officer

Kevin R. M. Smith has served as our President, Chief Executive Officer, and as a director since November 2023. Previously, Mr. Smith served as the CEO, President and Executive Director at Sirtex Medical, a medical device company, from October 2019 to October 2023, after serving as interim CEO from April 2019 to October 2019 and Executive Vice President of Sales & Marketing, Americas from August 2017 to April 2019. Mr. Smith also served as interim President and Chief Executive Officer from 2021 to 2022 and as a Director from February 2020 to June 2023 at OncoSec Medical, Inc., a biotechnology company. In his previous roles, Mr. Smith served as Executive Vice President of Business Development at Gel-e, Inc., as Chief Commercial Officer at Sensium Healthcare, as Global Vice President of Sales & Marketing at Teleflex, and in various sales and marketing roles in medical device companies. Mr. Smith holds an MBA in Global Management from University of Phoenix and a B.S. in Marketing from the University of Kentucky.

Michael Bourque has served as our Executive Vice President, Chief Financial Officer and Corporate Treasurer since March 2024. Most recently, Mr. Bourque served as Chief Financial Officer and Treasurer of Chase Corporation from February 2021 to February 2024. He also served as Chief Financial Officer of Keystone Dental from April 2019 to September 2020, as Senior Vice President, Chief Financial Officer and Treasurer of Analogic Corporation, and as Vice President of Finance for Axcelis Technologies. Mr. Bourque received a B.S. in Accounting from Bentley University and is a Certified Public Accountant.

Kevin P. Smith has served as our Executive Vice President, General Counsel, Secretary and Business Development since July 2024. Most recently, Mr. Smith served as General Counsel and Executive Vice President, Business Development of Sirtex Medical, a medical device company, from October 2018 to June 2024. In his prior roles, Mr. Smith served as Vice President and Associate General Counsel at Flexion Therapeutics, as General Counsel for the Danaher Life Sciences Platform, and in several senior legal leadership positions within Novartis Pharmaceuticals in Switzerland and Massachusetts. Before moving in-house, Mr. Smith worked for multinational law firms in New York, Silicon Valley, and London. Mr. Smith earned his B.S. in Mechanical Engineering from Rensselaer Polytechnic Institute and his J.D. from Albany Law School.

Gregoire Ramade has served as our Chief Commercial Officer since January 2024 and served as our Senior Vice President of International Sales from November 2023 to January 2024. Prior to joining the Company, Mr. Ramade served as Senior Vice President and Chief Commercial Officer of VapoTherm, Inc. from October 2020 to October 2023 and as Vice President, International Sales and Worldwide Marketing of VapoTherm since May 2016. Mr. Ramade previously served as Vice President of Global Marketing and Business Development at Becton Dickinson Medical-Pharmaceutical Systems, as Senior Marketing Director, Home Healthcare Solution at Philips Healthcare, and as Marketing Director EMEA Product Manager of Consumable Masks and Accessories at Philips Respironics. Mr. Ramade holds a B.A. in International Business with a minor in Economics from the American University of Paris and an MBA in International Business and Marketing from the Ecole Nationale des Ponts et Chaussées School of International Management.

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 need to continue to enhance our existing products and develop and market new products;
- potential acquisitions of, or investments in, other companies;
- the complex and lengthy reimbursement process we depend upon for a significant portion of our revenue;
- increases in our operating costs;
- economic impacts that affect customer and consumer spending as well as demand for our products;
- public health threats and epidemics;
- 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;
- consolidation in the healthcare industry;
- healthcare reform measures;
- 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;
- potential failure to maintain or obtain new private payor contracts and future reductions in reimbursement rates from private payors;
- the possibility of non-payment of our HME providers, distributors, private label partners and resellers;
- our international sales and manufacturing activities;
- warranty or product liability claims or other litigation;
- our dependence on the services of our senior executives and other key technical personnel;
- variance in our financial condition and results of operations;
- the market opportunities for our products; and
- our ability to maintain effective internal controls.

Risks related to the regulatory environment:

- extensive federal, state, and international regulations related to our business by numerous government agencies, including the FDA and the MDR;
- the potential need to seek additional clearances or approvals for our products; and
- potential FDA, state, or international regulatory enforcement action and other penalties.

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 our common stock:

- the volatility of the trading price of our common stock;
- potential sales of a large number of shares of our common stock; and
- anti-takeover provisions in our charter documents and under Delaware law.

Risks related to our business and strategy***We operate in a highly competitive industry and we may be unable to compete effectively.***

The respiratory market, including long-term oxygen therapy market, is highly competitive. We compete with a number of manufacturers and distributors of 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.

The market is subject to rapid change resulting from technological advances, innovations and scientific discoveries. In the product lines in which we compete, we face a range of competitors from large companies with multiple business lines to small, specialized manufacturers that offer a limited selection of niche products. Development by other companies of new or improved products, processes, technologies, or the introduction of reprocessed products or low-cost versions of products similar to ours may make our existing or planned products less competitive. In addition, we face competition from providers of alternative medical therapies, such as pharmaceutical companies.

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 of our 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 our 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.

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.

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 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. For the years ended December 31, 2024, 2023, and 2022, sales revenue to our top 10 customers accounted for approximately 33.3%, 25.2% and 30.5%, respectively, of our total revenue. Medicare's service reimbursement programs represented more than 10% of our total revenue for the years ended December 31, 2023 and 2022. 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 collaborator. We have also experienced a decline in sales from other HME providers and these providers have communicated to us that they continue to be subject to capital constraints. 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.

Reduction or interruption in our supply of components and products may adversely affect our manufacturing operations and related product sales.

We obtain some components, subassemblies and completed products included in our products from single source suppliers or from a limited group of manufacturers or suppliers. In some cases, components required to manufacture and assemble our products 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 or limitation on availability could cause significant production delays or stoppages, an inability to meet customer demand, substantial loss in revenue, and have 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 oxygen concentrator systems and our Simeox product. 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, or due to acts of terrorism, hostilities, military conflict or war, including the conflict between Israel and Hamas and the war in Ukraine;
- 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 supply problems in the future. For example, we saw supply chain disruptions in the second half of 2021 as well as in 2022 and 2023, primarily associated with semiconductor chips used in our batteries and printed circuit boards. However, we recognize that there could be supply shortages for other components used in our products. While we have taken steps to attempt to mitigate the impact of potential supply shortages, the previously experienced shortages have had, and any future shortage may have, a negative impact on our ability to manufacture products as these chips are used across all of our portable oxygen concentrators in our batteries and printed circuit boards.

In addition, 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 all of our third-party suppliers. These third-party suppliers, therefore, are not obligated to perform services or supply products to us for any specific period, in any specific quantity or at any specific price, except as may be provided in a particular purchase order. We do not maintain large volumes of inventory from most of these suppliers and could be at risk if we are such suppliers are unwilling or unable to supply us or if these suppliers demand significant price increases.

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 and innovative products ourselves. Product development requires significant financial, technological and other resources. While we expended \$21.6 million, \$20.8 million and \$21.9 million for the years ended December 31, 2024, 2023, and 2022, 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.

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 may expand through acquisitions of, collaborations with, 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.

As part of our business strategy, we regularly explore potential acquisitions of, collaborations with, or investments in complementary products, technologies or businesses. We do not have an extensive history of acquiring or entering into collaborations with other companies and cannot assure you that we will successfully identify suitable acquisition candidates or collaboration partners, 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, collaboration 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, collaborations or investments, which could negatively impact our financial condition, stockholder equity, and stock price. The acquisition, collaboration 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, collaborations and other strategic investments involve significant risks and uncertainties, including:

- the potential failure to achieve the expected benefits of the combination, acquisition or collaboration;
- 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 any 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 any acquired products;
- the potential to become involved in intellectual property litigation related to such acquisitions, collaborations or strategic investments; and
- the inability to maintain uniform standards, controls, policies, and procedures.

Any acquisition, collaboration or investment could expose us to unknown liabilities. Moreover, we cannot assure you that we will realize the anticipated benefits of any acquisition, collaboration 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. In addition, we may be required to take charges or write-downs in connection with acquisitions. In particular, acquisitions of businesses engaged in the development of new products may give rise to developed technology and/or in-process research and development assets. To the extent that the value of these assets decline, we may be required to write down the value of the assets. Also, in connection with certain asset acquisitions, we may be required to take an immediate charge related to acquired in-process research and development assets. Any of these events could result in charges, which could be substantial and which could adversely affect our results of operations.

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, 2024, 2023 and 2022, approximately 17.0%, 20.3% and 15.0%, 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.

In addition, 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, a private insurance company that processes Medicare claims for durable medical equipment, which could cause substantial delays in the collection of our Medicare accounts receivable as well as related amounts due under supplemental insurance plans.

The government has significant resources to audit and ensure oversight of suppliers who care for patients covered by various government healthcare programs. Healthcare providers and suppliers of certain durable medical equipment product categories may be subjected to increased scrutiny from these audit programs. If a government auditor ascribes a high billing error rate to one or more of our locations, it would result 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.

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. As a result, increases in our operating costs including personnel-related costs could adversely affect our financial condition and results of operations.

An economic recession, downturn, period of inflation, or economic uncertainty in our key markets may adversely affect customer and consumer spending as well as demand for our products.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. Global economic conditions, geopolitical instability, and other macroeconomic factors, including inflation, supply chain disruptions, interest rate and foreign currency rate fluctuations, and volatility in the capital markets could negatively impact our business, financial condition, and results of operations. The health of our business and the demand for our products are affected by changes in the overall global economy. Our general business strategy may be adversely affected by unfavorable economic events or unstable market conditions. Unfavorable economic conditions may lead customers and consumers to delay or reduce purchases of our products and/or strain our suppliers. Consumer demand for our products may not reach our targets, or may decline, when there is an economic downturn or uncertainty in our key markets and our customers could be delayed in making payments for our products. Our sensitivity to economic cycles and any related fluctuation in customer and consumer demand could have a material adverse effect on our business, financial condition, and results of operations.

Macroeconomic conditions may also impact our global supply chain, primarily through constraints on raw materials and electronic components. These constraints on raw materials and electronic components may also impact companies outside of our direct industry, which could result in a competitive supply environment causing higher costs, requiring us to commit to minimum purchase obligations as well as make upfront payments to our suppliers. These disruptions may impact our ability to produce and supply products in quantities necessary to satisfy customer demand, which could negatively impact our results of operations. Highly competitive and constrained supply chain conditions may increase our cost of sales, which may adversely impact our operations.

Public health crises have had, and may continue to have, an adverse effect on certain aspects of our business, results of operations, financial condition, and cash flows. The nature and extent of future impacts are highly uncertain and unpredictable.

Public health outbreaks, epidemics, pandemics of contagious or infectious diseases 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, we previously experienced declines in total demand during portions of the COVID-19 pandemic and the related public health emergency, which we believe were due to these and related factors.

In addition, while we and our contract manufacturer were able to keep our manufacturing facilities open during the COVID-19 pandemic, there can be no assurance that we would be able to keep such facilities open indefinitely during a future public health emergency.

Changes to reimbursement rates, payment methodologies, or coverage policies for our products by government or commercial payors may 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.

On December 29, 2022, the Consolidated Appropriations Act of 2023 (Pub. L. 117-328) was signed into law. Included in this law was a provision deferring for two years, until January 1, 2025, the Statutory Pay-as-You-Go, or PAYGO, Medicare payment reductions. This law also extended the DME 75/25 blended rates in non-competitive bidding areas and extended the COVID-19 public health emergency, or PHE, telehealth waivers until the end of 2024. We cannot currently determine if, or to what extent, our business, results of operations, financial condition or liquidity will ultimately be impacted by mandated sequestration triggers under the PAYGO Act, or if or when the mandated sequestration will occur. Medicare's service reimbursement programs accounted for 56.3%, 67.7% and 77.0% of rental revenue for the years ended December 31, 2024, 2023 and 2022, respectively, and based on total revenue were 9.5%, 13.7% and 11.6% for the years ended December 31, 2024, 2023 and 2022, respectively.

Government and other third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for medical products and services. Reimbursement levels may be decreased in the future. Additionally, future legislation, regulation, or reimbursement policies of third-party payors may otherwise adversely affect our ability to operate our rental business in a profitable manner and affect the demand for and price levels of our products.

Various pieces of legislation contain provisions that directly impact reimbursement for the durable medical equipment products provided by us:

- There were significant U.S. reimbursement and policy changes associated with the COVID-19 PHE that impacted oxygen therapy and other durable medical equipment. The Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, allowed the U.S. Department of Health and Human Services, or 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, signed into law 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. The COVID-19 PHE expired on May 11, 2023.
- Congress suspended the 2% Medicare sequestration payment reduction that applies to all Medicare providers and suppliers due to the COVID-19 PHE beginning May 1, 2020. Congress extended the suspension through March 31, 2022. The sequestration payment reduction resumed with a 1% reduction to rates from April 1, 2022 until June 30, 2022, and the full 2% Medicare sequestration resumed on July 1, 2022.
- The CARES Act established a provider relief fund of \$100 billion for providers and suppliers to prevent, prepare for, and respond to the COVID-19 PHE. As a Medicare supplier, we also received funds of \$6.2 million in the second quarter of 2020. The Paycheck Protection Program and Health Care Enhancement Act was also signed into law on April 24, 2020 and provided additional funding of \$484 billion to programs enacted under the CARES Act. Of the \$484 billion, \$75 billion was additional funding for healthcare providers to reimburse healthcare related expenses and lost revenues attributable to COVID-19 PHE.
- On April 6, 2020, CMS issued an Interim Final Rule, or 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, CMS waived the face-to-face requirements and stated it would not enforce clinical indications for home oxygen, among other respiratory products.

- The first Trump administration also issued a number of regulatory waivers to increase the flexibility in durable medical equipment, prosthetics, orthotics and supplies, or DMEPOS, suppliers' ability to service patients quickly and without the normal requirements. For example, the patient signature for proof of delivery for DMEPOS was waived when signatures could not be collected during the COVID-19 PHE. In addition, CMS increased Medicare contractors' ability to waive replacement product requirements, automatically extended expiring accreditations for a 90-day time period, granted contractors flexibility regarding appeals, and suspended most medical reviews of claims. Both the IFR and temporary regulatory changes show significant flexibility from CMS to improve access for oxygen and other DMEPOS items during the COVID-19 PHE. These changes were retroactive to early March 2020. In August 2020, CMS resumed the prior authorization program for certain DMEPOS.
- CMS issued a final rule in December 2021 (CMS-1738-F) to establish payment amounts that were to be effective after the COVID-19 PHE for DMEPOS products and services covered under Medicare.
- 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 reduced Medicare rates following the PHE in the current areas that are considered non-rural but not covered by a former CBA, as those areas previously received 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 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 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 delayed the implementation date for the revised national coverage determination until January 3, 2023.
- On March 11, 2021, the American Rescue Plan Act of 2021, or ARP, became federal law. The ARP, among other things, increased spending without offsets to other federal programs. The Statutory PAYGO Act of 2010 requires deficit neutrality overall in the laws enacted by Congress and imposes automatic spending reductions at the end of the year if such laws increase the deficit when they are added together. Any legislation enacted after February 12, 2010, that affects direct spending and/or revenues is subject to Statutory PAYGO. The Congressional Budget Office previously estimated that a Statutory PAYGO sequester in fiscal year 2022 resulting from the ARP passage would cause a 4% reduction in Medicare spending.

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 OIG has recommended that states review Medicaid reimbursement for durable medical equipment, or 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.

In addition, 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 required 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, 2024, approximately 56.3% of our rental revenue was derived from Medicare's traditional fee-for-service reimbursement programs. Under Medicare reimbursement programs, there are three general categories relevant to our products, including (1) former competitive bidding areas, or CBAs, (2) rural areas, and (3) non-former CBAs in non-rural areas.

Former CBAs:

The U.S. list price for our stationary oxygen rentals (HCPCS E1390) is \$260 per month and the U.S. list price for our oxygen generating portable equipment, or OGPE, rentals (HCPCS E1392) is \$70 per month. The average Medicare reimbursement rates in former CBAs in the prior six years are outlined in the table below for E1390 and E1392 using a simple average of rates in each CBA, 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, or 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, in a proposed rule published November 4, 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.

Average Medicare reimbursement rates in former CBAs	E1390	E1392
As of January 1, 2025	\$ 96.11	\$ 47.11
As of January 1, 2024	\$ 93.41	\$ 45.78
As of January 1, 2023	\$ 90.77	\$ 44.49
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-F) to establish payment methodologies to be effective after the COVID-19 PHE for DMEPOS products and services covered under Medicare.

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.

Rural Areas:

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 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, 2025	\$ 173.32	\$ 51.63
As of January 1, 2024	\$ 168.96	\$ 51.18
As of January 1, 2023	\$ 164.48	\$ 50.44
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

Non-former CBAs in non-rural areas:

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 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. In December 2022, Congress' Consolidated Appropriations Act extended the higher 75/25 blended rates in non-CBAs until December 31, 2023. As of January 1, 2024, the rates in former non-CBAs were reduced to the former CBA rates listed in the table above. Rates in rural areas continue to be based upon a 50/50 blended rates, consistent with CMS' December 2021 final rule described above.

Average Medicare reimbursement rates in non-former CBAs, non-rural areas	E1390	E1392
As of January 1, 2025	\$ 96.42	\$ 47.51
As of January 1, 2024	\$ 93.61	\$ 46.12
As of January 1, 2023	\$ 125.41	\$ 46.49
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.

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 9.5% of our total revenue in the year ended December 31, 2024 and 13.7% in the year ended December 31, 2023.

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. 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, 2024 and December 31, 2023. Our capped patients as a percentage of total patients on service was approximately 16.6% as of December 31, 2024 and 13.1% as of December 31, 2023. The percentage of capped patients may fluctuate over time as new patients come on service, patients come off 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 or 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 confirm the continued medical necessity of the item at least annually by procuring an updated prescription from the physician. We must also confirm the patient's continued use of the oxygen through direct confirmation with our patients. 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.

Consolidation in the healthcare industry could have an adverse effect on our revenues and results of operations.

The home medical equipment market is highly competitive, and our products face significant competition from other well-established manufacturers. Numerous initiatives and reforms instituted by legislators, regulators and third-party payors to reduce home medical equipment costs have caused pricing pressures which have resulted in a consolidation trend in the home medical equipment industry as well as among our customers, including home healthcare providers. In the past, some of our competitors, which may include distributors, have been lowering the purchase prices of their products in an effort to attract customers. This in turn has resulted in greater pricing pressures, including pressure to offer customers more competitive pricing terms, exclusion of products from or unfavorable position on provider formularies and the exclusion of certain suppliers from important market segments as group purchasing organizations, independent delivery networks and large single accounts continue to consolidate purchasing decisions for some of our customers. With this consolidation, competition to provide goods and services to industry participants may become more intense. These industry participants may try to use their market power to negotiate price concession for our products. These factors could force us to reduce our prices or could result in a loss of customers.

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 had 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 was a 1% sequestration reduction, and the full 2% sequestration reduction resumed 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. We regularly monitor developments in state requirements applicable to our business and their impact on our operations, products and access to patients. Some states have already enacted legislation that regulate in-state facilities. 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.

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 that approximately 51.8% of our 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 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 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 facility in Plano, Texas 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 are in areas that have and may in the future be harmed or rendered inoperable by natural or man-made disasters, including, but not limited to, pandemic and 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.

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 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. 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;
- 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.

We are exposed to the credit and non-payment risk of our HME providers, distributors, private label collaborators 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 collaborator 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 customer represented more than 10% of our net accounts receivable balance with a net accounts receivable balance of \$3.3 million as of December 31, 2024. One customer represented more than 10% of our financing receivable balance with a balance of \$6.5 million as of December 31, 2024. Two customers each represented more than 10% of our net accounts receivable balance with net accounts receivable balances of \$8.6 million and \$5.0 million, respectively, as of December 31, 2023. Challenging economic conditions 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 collaborators may increase if our business collaborators and their end customers are adversely affected by potential worsening global economic conditions or disruptions to, and volatility in, the credit and financial markets in the United States and worldwide. One or more of these business collaborators 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, 2024, 2023 and 2022, approximately 34.9%, 28.3% and 26.8%, 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 and data protection regulations, such as the European Union General Data Protection Regulation, or 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, including as a result of recessionary effects or inflationary pressures;
- 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 tariffs, 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.

A portion of our international product sales are currently denominated in U.S. dollars. 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, 2024, we experienced a net foreign currency loss of \$0.2 million, and for the years ended December 31, 2023 and 2022, we experienced a net foreign currency gain of \$0.2 million and a loss of \$0.8 million, respectively. 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, 2024. Additional information on our hedging arrangements is also contained in Note 2 – Fair value measurements in the notes to 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, 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, and anti-corruption, including the U.S. Foreign Corrupt Practices Act of 1977, as amended, and similar laws associated with our activities outside of the United States and anti-money-laundering laws could subject us to penalties and other adverse consequences.

We are subject to the U.S. Foreign Corrupt Practices Act of 1977, as amended (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 sixty-five countries around the world where we have conducted activities and have sold 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, agents, representatives, business partners, and third-party intermediaries, such as distributors or resellers, from authorizing, offering or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector.

We leverage various third parties to sell our products and conduct our business abroad. We, our employees, agents, representatives, business partners, and third-party intermediaries 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 employees, agents, representatives, business partners and third-party intermediaries, 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 cannot assure you that all of our employees, agents, representatives, business partners or third-party intermediaries 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.

These laws also require that we keep accurate books and records and maintain internal controls and compliance procedures designed to prevent any such actions. While we have policies and procedures to address compliance with such laws, and while we provide training to all employees, including management, to ensure compliance with the FCPA and other applicable anti-bribery and anti-corruption laws, we cannot assure you that none of our employees, agents, representatives, business partners or third-party intermediaries will take actions in violation of our policies and applicable law, for which we 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, settlements, prosecutions, enforcement action, fines, damages, loss of export privileges and suspension or debarment from government contracts, which could have a material and adverse effect on our reputation, business, operating results and prospects. In addition, responding to any allegation, 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. and applicable foreign 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 and European Union 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. 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 POCs 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, lawsuits, 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.

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.

We have experienced, and may continue to experience, turn-over in our senior executives and other key technical personnel. For example, our executive team underwent significant transition in 2024. If we are unable to continue to successfully navigate this transition, we may be unable to achieve our strategic priorities. In addition, 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. If we are not able to find a qualified permanent replacement for these positions, it could have a material adverse effect on our ability to effectively pursue our business strategy. Executive leadership and key technical personnel transitions can be difficult to manage and could cause disruption to our business. 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 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. In addition, the value to employees of equity awards that vest over time may be significantly affected by decreases in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. We may face challenges in retaining and recruiting such individuals due to sustained declines in our stock price that could reduce the retention value of equity awards. 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, which could result in a material loss of business, substantial legal liability or significant harm to our reputation.

We rely on information technology networks and systems, certain of which are operated by third parties on which we rely, to process, transmit and store electronic, customer, operational, compliance, and financial information; to coordinate and otherwise operate 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, ransomware, and other malware, cybersecurity risks, data security incidents, telecommunication failures, user errors or catastrophic events. Like other companies, we have experienced data security incidents before and have incurred remedial, legal and other costs in connection with these incidents.

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 or those provided by our third-party service providers and vendors 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 other proceedings and our business could be negatively affected. For example, Change Healthcare, a division of UnitedHealthcare, experienced a cyberattack in late February 2024 that caused connection issues with our third-party service provider and a delay in rental revenue collections. In addition, cybersecurity risks and data security incidents could lead to potential unauthorized access to or acquisition of confidential information (including personally identifiable information and protected health information), and data loss, corruption, unavailability, or other unauthorized processing. There is no assurance that we will not experience service interruptions, security breaches, cybersecurity risks and data security incidents, or other information technology failures, whether suffered by us or third parties on which we rely, in the future.

We receive, collect, process, use and store a large amount of information from our customers, our patients and our own employees, including personal information, intellectual property, protected health and other sensitive and confidential information. This data is often accessed by us through transmissions over public and private networks, including the internet. The secure transmission of such information over the Internet and other mechanisms is essential to maintain confidence in our information technology systems yet is vulnerable to unauthorized access and disclosure. We have implemented security measures, technical controls and contractual precautions designed to identify, detect and prevent unauthorized access, alteration, use or disclosure of our customers', patients' and employees' data. The techniques used in these attacks change frequently and may be difficult to detect for periods of time and we may face difficulties in anticipating and implementing adequate preventative measures. Due to the COVID-19 pandemic and related public health emergency, we allowed an increased number of employees to work remotely, and we continue to do so and expect that this hybrid model of work will continue. 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 information technology 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. Cyberattacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. A material cyberattack or security incident could cause interruptions in our operations and could result in a material disruption of our business operations, damage to our reputation, financial condition, results of operations, cash flows and prospects. 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, or the perception that any of these has occurred, could result in legal claims and proceedings, initiated by private parties, investigations or other proceedings by regulatory authorities, and liability or regulatory penalties, 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. We also face risks associated with security breaches affecting third party vendors or customers and others who interact with our data. While we maintain insurance that covers certain security incidents, we may not carry enough insurance or maintain sufficient coverage to compensate for all potential liability.

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 and data protection 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. Complying with these numerous and complex regulations is expensive and difficult, and failure to comply could result in regulatory scrutiny, fines, civil liability or damage to our reputation. For example, the European Union adopted the GDPR which imposes 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 and regulations can be costly and any failure to comply with these regulatory standards could subject us to legal and reputational risks. Misuse of or failure to secure or properly process personal information could also result in violation of data privacy laws and regulations, and any such event, or the perception it has occurred, may result in claims and litigation by private parties, investigations and other 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 and data protection 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, and in certain cases enacted, privacy legislation imposing operational requirements on U.S. companies similar to the requirements reflected in the GDPR. For example, California has passed the California Consumer Privacy Act, or CCPA, which went into effect on January 1, 2020, and among other things, requires new disclosures to California consumers and affords such consumers new abilities to opt out of certain sales of personal information. The CCPA provides civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. In addition, California voters recently passed the California Privacy Rights Act, or CPRA, which modified the CCPA significantly as of January 1, 2023, potentially resulting in further uncertainty and requiring us to incur additional costs and expenses in an effort to comply. It is possible that these laws and regulations may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. Aspects of these laws, and their interpretation and enforcement, remain uncertain. Their effects potentially are far-reaching and may restrict our ability to use personal information in connection with our business operations, require us to modify our data processing practices and policies and incur substantial compliance-related costs and expenses. Congress also 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 legal matters; and fluctuations in foreign currency exchange rates.

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. 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, and (viii) the share of POCs as a percentage of the total oxygen therapy spend 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 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.

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, the Tax Cuts & Jobs Act of 2017 eliminated the option to deduct research and development expenditures currently and instead required taxpayers to capitalize and amortize them over five or fifteen years beginning in 2022. The Inflation Reduction Act of 2022 imposed a 1% excise tax on certain repurchases of stock. Such changes may have a significant impact on our deferred tax assets, income tax provision and effective tax rate. Proposed legislation before the Administration and Congress may make further changes to the U.S. tax law. 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.

We operate in multiple taxing jurisdictions and certain revenue streams may be subject to sales and use tax. Any 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. We believe that our sales of concentrators and accessories may be subject to sales and use tax in certain states, but that there are exemptions from sales and use tax in most states. There can be no assurance, however, that these states would 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.

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, limitations under federal or state law could impact our ability to use our deferred tax assets. Finally, future changes in tax laws could limit our ability to obtain the future tax benefits represented by our deferred tax assets. See Note 7 – Income taxes in the notes to our consolidated financial statements in this Annual Report on Form 10-K for additional information and factors that could impact our ability to realize the deferred tax assets.

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. 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 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 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 safety reporting, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, would be likely to 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 510(k) clearance, authorization 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 legally marketed predicate device 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 or De Novo authorizations with respect to those products or do so in a timely fashion.

The FDA can delay, limit or deny clearance, authorization, 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 comply with 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, authorizations, or approvals, which, if not granted, would prevent us from selling such modified products.

Any modification we make to our 510(k)-cleared products that could significantly affect their safety or effectiveness, or would constitute a major change in intended use requires the submission and clearance of a new 510(k) pre-market notification, authorization of a De Novo application or, possibly, approval of a pre-market approval application. 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 may make similar determinations regarding modifications to our 510(k) products in the future. If the FDA disagrees with our determinations and requires us to submit new 510(k) pre-market 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 and/or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory penalties or fines.

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, import detentions, 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 existing 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, FDA could take additional actions, such as adverse publicity, or enforcement action, including issuance of 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 any subsequent 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 or our contract 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 and our contract manufacturers are required to comply with the FDA's Quality System Regulation, or QSR, which governs the design, manufacture, packaging, labeling, storage, repair and servicing of our devices. The FDA inspects entities for compliance with the QSR through periodic announced and unannounced inspections of manufacturing facilities. We and our contract manufacturers have been, and anticipate in the future being, subject to such inspections. Although we believe our manufacturing facilities and those of our contract 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 contract manufacturers are found to be in violation of applicable laws and regulations, or we or our contract manufacturers fail to take prompt and satisfactory corrective action in response to an adverse inspection, the FDA could take enforcement action, including, among others, the following sanctions:

- adverse publicity, untitled letters, warning letters, import detentions, 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 pre-market approval of new products or modified products;
- withdrawing 510(k) clearances or other 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.

In the European Union, medical devices are regulated by the MDR. The MDR is applicable in all European Union Member States and in the additional Member States of the European Economic Area and therefore applies in most of the major countries in Europe. The MDR and its associated guidance documents and harmonized standards regulate the design, manufacture, clinical trial, labeling and adverse event reporting for medical devices. Devices must comply with the MDR before they can be commercially distributed throughout the EEA. The method of assessing conformity under the MDR varies based on the class of the product, and typically requires a combination of self-assessment by the manufacturer and a third-party assessment by a "notified body." The EU MDR does not apply in Great Britain (England, Scotland and Wales) and the commercialization of medical devices in that territory must comply with rules set out in domestic legislation including the UK Medical Devices Regulations 2002. Devices that are validly CE marked under the EU MDR or UKCA marked under the UK Medical Devices Regulations 2002 may be placed on the market or put into service in Great Britain. The commercialization of medical devices in the UK are also subject to additional national requirements (e.g., registration and where the manufacturer is not established in the UK, the appointment of a UK Responsible Person).

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

We sell our products in multiple international countries and overseas regions outside of the United States through our wholly-owned subsidiaries, distributors and directly to large "house" accounts. In order to market our products in the European Union or other foreign jurisdictions, we are required to 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. Devices that do not satisfy these requirements cannot be placed on the market or put into service in the relevant jurisdictions, subject to limited exceptions.

The foreign regulatory approval process, including with respect to MDR and other jurisdictions, 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 or fail to comply with the applicable regulatory requirements 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 IRBs before collecting or analyzing such data. If the FDA disagrees with our interpretation, we may be subject to regulatory enforcement including, among others, 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 IRB(s), 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, regulations, or our clinical protocols, or (ii) 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 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 are required to comply with the FDA's requirements and other applicable laws and regulations, including the prohibition against 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, 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, the Health Information Technology for Economic and Clinical Health Act, and implementing regulations could result in significant penalties.

Numerous federal and state laws and regulations, including the Federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, and the Health Information Technology for Economic and Clinical Health Act, or 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. Under the HITECH Act, both covered entities and business associates are subject to significant civil and criminal penalties for failure to comply with the Privacy Standards and Security Standards under HIPAA.

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.

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.

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.

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 to clarify that a person or entity does not need 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 \$150,000 per year (and up to an aggregate of \$1.0 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 OIG to seek 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 we have processes in place to manage our discount and incentive programs, 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 \$50,000 (subject to annual adjustment for inflation) for each wrongful act 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 of 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 August 8, 2024, sets forth adjusted civil monetary penalty amounts that apply to penalties assessed on or after August 8, 2024, 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 sell our products in countries and regions outside the United States through our wholly-owned subsidiaries, 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.

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 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 prior authorization 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 prior authorization 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 prior authorization decision would be two business days. CMS will issue additional sub-regulatory guidance on these timelines in the future. If our products become 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 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.

Our patents may not adequately protect our products from third party competitors

We rely on patents and other intellectual property to protect the design and construction of our products from direct competitors. However, we cannot specify whether our patents individually or as a group will 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. 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. 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.

Also, 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.

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. 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.

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.

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 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. 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, we will continue to incur significant legal, accounting and other expenses. In addition, the Sarbanes-Oxley Act of 2002 and rules enforced by the Public Companies Oversight Board, or 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. 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 and maintain 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.

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. During the last twelve months, our common stock traded as high as \$13.33 per share and as low as \$5.08 per share. The trading price of our common stock could continue to be subject to wide fluctuations in price 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.

Price volatility over a given period or a low stock price could result in a number of negative outcomes, including, but not limited to:

- creating potential limitations on the ability to raise capital through the issuance of equity or equity linked securities;
- impacting the value of our equity compensation, which affects our ability to recruit and retain employees;
- impairing goodwill or long-lived assets;
- difficulty complying with the listing standards of Nasdaq; and
- increasing the risk of regulatory proceedings and litigation, including class action securities litigation.

For example, the decline in our stock price caused our market capitalization to fall below its carrying amount (stockholders' equity) during July 2023 and was noted by management to be more than temporary as the quarter progressed. We determined that the goodwill carrying amount exceeded its fair value and, as such, an impairment charge of \$32.9 million was incurred in the quarter ended September 30, 2023.

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 previously disclosed. 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.

Our certificate of incorporation and our amended and restated bylaws designate the Court of Chancery of the Delaware as the exclusive forum for substantially all disputes between us and our stockholders, and our amended and restated bylaws also provide that the federal district courts will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act of 1933, as amended, each of which could limit our stockholders' ability to choose the judicial forum for disputes with us or our directors, officers, stockholders, or employees.

Our thirteenth amended and restated certificate of incorporation, or the certificate of incorporation, filed with the Delaware Secretary of State on February 20, 2014, and our amended and restated bylaws, as amended and restated effective as of October 27, 2022, or the bylaws, provide that, unless we consent in writing to the selection of an alternative forum, referred to as an "Alternative Forum Consent", the Court of Chancery of the State of Delaware will, to the fullest extent permitted by law, be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action or proceeding asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, or other employees to us or our stockholders, (iii) any action or proceeding asserting a claim arising pursuant to any provision of the Delaware General Corporation Law or our certificate of incorporation or bylaws, or (iv) any action asserting a claim governed by the internal affairs doctrine of the State of Delaware. The foregoing shall not apply to any claims under the Securities Exchange Act of 1934, as amended, or the Exchange Act, or the Securities Act of 1933, as amended, or the Securities Act.

Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated bylaws provide that, unless we give an Alternative Forum Consent, the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act against any person in connection with any offering of our securities, including any auditor, underwriter, expert, control person or other defendant. The foregoing shall not apply to any claims under the Exchange Act.

Any person or entity purchasing or otherwise acquiring or holding or owning (or continuing to hold or own) any interest in any of our securities shall be deemed to have notice of and consented to the foregoing provisions of the bylaws and certificate of incorporation. Although we believe these exclusive forum provisions benefit us by providing increased consistency in the application of Delaware law and federal securities laws in the types of lawsuits to which each applies, the exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum of its choosing for disputes with us or any of our current or former directors, officers, stockholders, employees, auditors, underwriters, experts, control persons or others, which may discourage lawsuits with respect to such claims against such defendants. In addition, a stockholder that is unable to bring a claim in the judicial forum of its choosing may be required to incur additional costs in the pursuit of actions which are subject to the exclusive forum provisions described above. Our stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder as a result of our exclusive forum provisions. Further, in the event a court finds either exclusive forum provision contained in our bylaws to be unenforceable or inapplicable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our results of operations.

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, 2024, 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 33.1% 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 certificate of incorporation and 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 any 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 1C. CYBERSECURITY

Introduction: The medical device industry faces unique cybersecurity challenges, given the sensitive nature of the data and the critical role of devices in patient care. Cybersecurity, data privacy, and data protection are critical to our business. In the ordinary course of our business, we collect and store certain confidential information such as information about our employees, contractors, vendors, suppliers, patients and customers. We are committed to implementing robust security measures to protect against potential cyber threats and vulnerabilities that are constantly evolving across the globe.

Risk Management and Strategy: We have processes for assessing, identifying, and managing cybersecurity threats, and cybersecurity is an integral part of our overall enterprise risk management program which is overseen by our Audit Committee and the Board. Our strategy includes a comprehensive cybersecurity framework, utilizing advanced technologies and methodologies, such as cloud migrations and deployment of threat detection tools to effectively mitigate potential risks. Continuous risk assessments help us better refine our strategy, guiding the deployment of technical safeguards and shaping our incident response plans. For acquired companies, our integration strategies prioritize establishing comprehensive timelines for harmonizing information security, data privacy, and cybersecurity practices. This includes a strong focus on aligning employee education programs to ensure a seamless transition and uphold security and privacy standards across our entities.

Our cybersecurity infrastructure is based on a multi-layered defense framework, aligned with the U.S. National Institute of Standards and Technology guidelines. We take a risk-based approach to cybersecurity, which begins with the identification and evaluation of cybersecurity risks or threats that could affect our operations, finances, legal or regulatory compliance, or reputation. The scope of our evaluation encompasses risks that may be associated with both our internally managed IT systems and key business functions and sensitive data operated or managed by third-party service providers, ensuring the service providers adhere to our security standards, thereby safeguarding our integrated operations. The strategic migration of our data centers and infrastructure to secure cloud environments, coupled with the implementation of targeted technical cybersecurity measures, underscores our dedication to establishing foundational security across our users, applications, data, systems, and networks.

We have established a comprehensive incident response plan to swiftly address and recover from cybersecurity incidents, minimizing operational impact. We conduct regular trainings and simulations to enhance our team's awareness and preparedness against cyber threats. Biannual penetration testing and regular assessments by external experts validate the effectiveness of our cybersecurity measures. Our proactive approach to addressing identified vulnerabilities affirms the continuous improvement of our security posture.

We have insurance coverage in place for certain potential liabilities and costs relating to 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.

Use of Consultants and Advisors: We engage various third-party cybersecurity service providers to assess and enhance our cybersecurity practices and assist with protection and monitoring of our systems and information, including with respect to, network monitoring, endpoint protection, vulnerability assessments and penetration testing. We engage cybersecurity consultants, auditors, and other third parties to assess and enhance our cybersecurity practices, such as a third-party consulting firm to evaluate our cyber processes including an assessment of our incident response procedures.

We have processes to evaluate third-party service providers and vendors that have access to sensitive systems and company and customer data, which may include due diligence procedures such as assessments of that service provider's cybersecurity posture or a recommendation of specific mitigation controls. Following an assessment, we determine and prioritize service provider risk based on potential threat impact and likelihood, and such risk determinations drive the level of due diligence and ongoing compliance monitoring required for each service provider.

Board Oversight and Management's Role: The Board of Directors, both directly and through the delegation of responsibilities to the Audit Committee oversees the proper functioning of our cybersecurity risk management program to ensures strategic alignment and governance of our cybersecurity efforts at the highest level. All of the Audit Committee members are independent directors. In particular, the Audit Committee assists the Board in its oversight of management's responsibility to assess, manage and mitigate risks associated with our business and operational activities, to administer our various compliance programs, in each case including cybersecurity concerns, and to oversee our information technology systems, processes and data.

Management has implemented risk management structures, policies and procedures, and Management is responsible for our day-to-day cybersecurity risk management. Our Chief Data and Information Officer, or CDIO, is responsible for our day-to-day assessment and management of cybersecurity risks. Our Enterprise Enablement function facilitates a cross-departmental approach, ensuring the executive leadership team receives quarterly updates on cybersecurity from various teams. This strategy promotes a comprehensive stakeholder engagement and enhances management oversight on cybersecurity. The updates cover progress on ongoing cybersecurity initiatives, insights from any potential threats or incidents, outputs and action plans from external vulnerability and penetration tests, and key performance metrics in line with industry standards.

Risks from Material Cybersecurity Threats: Despite ongoing threats like cyber-attacks, phishing, and ransomware, we have not identified any cybersecurity threats that have materially affected or are reasonably anticipated to have a material effect on our business strategy, results of operations or financial condition. Our proactive security measures, alongside those of our third-party vendors, aim to protect our information technology systems and the sensitive data they hold. Although these risks have not yet materially impacted our business, we remain vigilant, continuously monitoring and adapting to evolving cybersecurity threats.

ITEM 2. PROPERTIES

As of December 31, 2024, we lease approximately 18,000 square feet of office space at our corporate headquarters in Goleta, California under a lease that expires in January 2028 and approximately 154,000 square feet of manufacturing and office space in Plano, Texas under a lease that expires in April 2031. In addition, we lease approximately 1,900 square feet of office space in Huntsville, Alabama and Aurora, Colorado with lease terms of three years; approximately 3,700 square feet of office space in De Meern in the Netherlands with a lease term of five years; approximately 3,600 square feet of office and warehouse space in Montpellier, France under leases that expire in June 2029 and October 2032; and approximately 6,000 square feet of office space in Beverly, Massachusetts with a lease term of three years. 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.

We lease approximately 51,000 square feet of manufacturing and office space in Goleta, California under a lease that expires in March 2030. In July 2023, we entered into an Assignment and Assumption of Lease Agreement in which a third party, the Assignee, assumed the rights, title, and interest in the lease, including assumption of lease payments. Commencing February 1, 2024 and ending May 31, 2031, the Assignee assumed responsibility for the monthly lease payments. Notwithstanding the Assignee's assumption of lease payments, we remain the primary obligor under the lease to the landlord.

ITEM 3. LEGAL PROCEEDINGS

We are party to various legal proceedings and investigations arising in the normal course of business. We carry insurance, subject to specified deductibles under the policies, to protect against losses from certain types of legal claims. At this time, we do not anticipate that any of these other proceedings arising in the normal course of business will have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us 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.

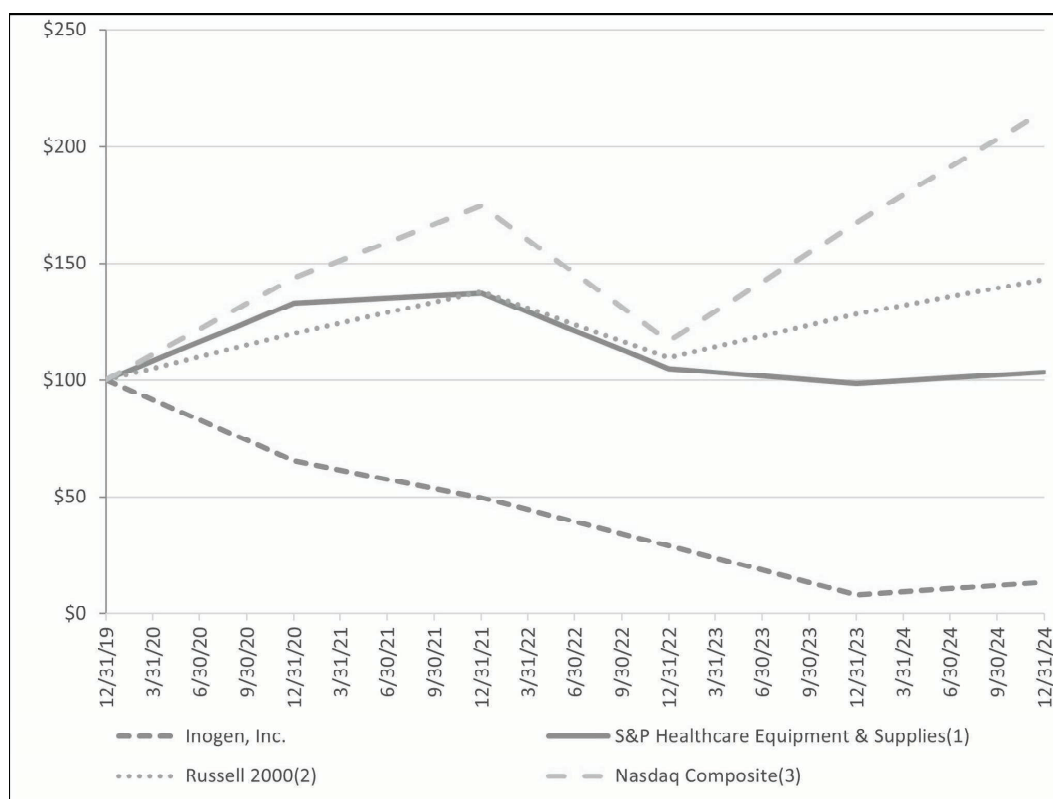
Stock performance graph

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, 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, 2019 to December 31, 2024. This graph assumes an investment of \$100 on December 31, 2019 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



	12/31/19	12/31/20	12/31/21	12/31/22	12/31/23	12/31/24
Inogen, Inc.	\$ 100.00	\$ 65.39	\$ 49.76	\$ 28.85	\$ 8.03	\$ 13.42
S&P Healthcare Equipment & Supplies ⁽¹⁾	100.00	132.91	136.96	104.99	98.45	103.45
Russell 2000 ⁽²⁾	100.00	119.96	137.74	109.59	128.14	142.93
Nasdaq Composite ⁽³⁾	\$ 100.00	\$ 143.64	\$ 174.36	\$ 116.65	\$ 167.30	\$ 215.22

(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 21, 2025, there were 8 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, or 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:

- Critical accounting policies and estimates
- Recent accounting pronouncements
- Macroeconomic environment
- Overview
- Results of operations
- Liquidity and capital resources
- Sources of funds
- Use of funds
- Non-GAAP financial measures

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, or 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 Accounting Standards Codification, or 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 receivables 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 uncollectible, 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.

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. As a result of a decrease in our public stock price that caused our market capitalization to fall below its carrying amount (stockholders' equity) during July 2023 and was noted by management to be more than temporary as the quarter progressed, a quantitative analysis was required to be performed during the quarter ended September 30, 2023. We used a discounted cash flow analysis based on Level 3 inputs and determined that the goodwill carrying amount exceeded its fair value and, as such, an impairment charge of \$32.9 million was incurred in the quarter ended September 30, 2023. Total accumulated impairment losses were \$32.9 million as of December 31, 2023 and 2024. As a result of the Tidal Assist® Ventilator technology intangible asset disposal in 2022, a quantitative analysis was required to be performed as of December 31, 2022 and concluded that there was no impairment.

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 2 – Summary of significant accounting policies in the notes to the consolidated financial statements included in Part IV, Item 15 in this Annual Report on Form 10-K for further discussion.

Macroeconomic environment

While we have worked to improve our global supply chain, challenges and potential disruptions still exist. We have experienced, and may continue to experience, increases in cost and limited availability of certain raw materials, components, and other inputs necessary to manufacture and distribute our products due to constraints and inflation within the global supply chain, as well as increases in wage costs and the cost and time to distribute our products. Uncertainty around inflationary pressures, interest rates, monetary policy, and changes in tariffs and tax laws could potentially cause new, or exacerbate existing, economic challenges that we may face, including the impact of foreign currency fluctuations on our results of operations, or result in an economic downturn or recession, which could negatively impact our business operations and results. Existing and future potential geopolitical dynamics may create economic, supply chain, energy, and other challenges, including disruptions to business operations, which has impacted, and may in the future negatively impact our business. In particular, international conflicts could create instability, have and may further result in sanctions, tariffs, and other measures that restrict international trade and may negatively affect our business operations and results.

For additional information on risk factors that could impact our results, please refer to the sections entitled “Risk Factors” in this Annual Report on Form 10-K.

Overview

We are a medical technology company that primarily develops, manufactures, and markets innovative respiratory market products, including our portable oxygen therapy solutions for patients with chronic respiratory conditions as well as our Simeox product for airway clearance treatment. Our leading portfolio of innovative POCs is designed to deliver high output ratio-to-weight, meaningful sound suppression and has among the longest run times in the industry so that we can meet the needs of patients across a variety of disease states. We are positioned in the market as both a medical technology company and as a home medical equipment provider that is accredited in all 50 states in the United States with a significant patient, prescriber and provider reach. Our products are sold in the United States through direct patient and prescriber sales, as well as resellers and home medical equipment companies, and internationally through distributors and medical equipment companies.

We derive the majority of our revenue from the sale and rental of our Inogen One and Rove systems and related accessories to patients, insurance carriers, home healthcare providers, resellers, and distributors, including our private label collaborator. We sell multiple configurations of our Inogen One®, Rove 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, we intend to:

- *Expand our domestic HME provider and reseller network.* We remain focused on our domestic business-to-business partnerships, including relationships with distributors, key accounts, resellers, our private label collaborator, and traditional HME providers. We offer patient-preferred, low total cost of ownership products to help providers convert their businesses to a non-delivery POC business model. The U.S. market represents a main opportunity for growth as we believe that the POC adoption is still in a low penetration rate.
- *Increase international business-to-business adoption.* We continue to 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 key customers in those markets. We additionally have an Inogen base of operations for sales and customer service in the Netherlands along with sales representatives based in focus European countries, and use a contract manufacturer, Foxconn, located in the Czech Republic to support the majority of our European sales volumes. We are also focused on expanding in the Asia-Pacific region and Latin America where we have added sales representatives to set up new distributors in promising markets.

- *Improve our domestic direct-to-consumer sales and prescriber sales teams and increase productivity.* We are continuing to focus on the patient first initiative, which involves cross-training of sales representatives to execute cash sales and insurance rental. Additionally, we expect to continue to focus on increased productivity driven by improved sales management discipline, insights-informed tools, and optimized patient lead generation with a downsized direct-to-consumer sales team.
- *Optimize our rental revenues.* We continue to evolve our operating model to focus the enhanced sales teams to drive increased rental revenue by establishing relationships with the prescriber through a consistent cadence of contact. We continue to evaluate our hospital pilot program, which targets hospitals and practitioners to access patients earlier in their care pathway.
- *Invest in our product offerings to develop innovative products and expand clinical evidence.* We incurred \$21.6 million, \$20.8 million and \$21.9 million in 2024, 2023 and 2022, respectively, in research and development expenses, and we intend to continue to make similar investments in the foreseeable future.

We launched the Inogen® Rove 4™, our latest portable oxygen concentrator, in the U.S. and EU markets in October 2024, as well as in the UK in December 2024. The Inogen Rove 4 weighs 2.9 pounds and produces 840 ml per minute of oxygen output with quiet operations at 39 dBA and long battery life at 3 hours for a single battery, 4 hours and 15 minutes on our new intermediate battery, and up to 5 hours and 45 minutes for a double battery, as well as improvements to provide ease-of-use and improvements to design in compliance with MDR standards. The Inogen Rove 4 is our first POC to launch with three battery options.

The Inogen Rove 4 has an 8-year expected service life. The 8-year expected service life also extends to the Inogen One G5® and Inogen® Rove 6™ portable oxygen concentrators. We launched the Inogen One G5 in 2019. The Inogen One G5 is similar to the product specifications of the Inogen Rove 6. We estimate that the Inogen Rove 6 and Inogen One G5 are each 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.

Inogen Connect, our connectivity platform is available on our Inogen Rove 4, Inogen One G4®, Inogen One G5, and Inogen Rove 6 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 plan to also continue to 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 and indications for use.* We are focused on expanding new products that drive benefits to patients, prescribers and our customers with a clinically relevant pipeline. These products would include innovations that strengthen our offerings in COPD, as well as future innovations that differentiate beyond devices to allow patients and clinicians to better manage respiratory disease with advanced portable oxygen concentrators with digital health value added services, expansion of use to hypercapnia, shortness-of-breath, and to other related disease indications.

Our Simeox product is a technology-enabled airway clearance and mucus management device predominantly aimed at serving patients with bronchiectasis which is a condition that presents as the lung's bronchi are damaged and widened in patients with cystic fibrosis or COPD. Simeox is used in pulmonary rehabilitation centers as well as at home. Simeox has been cleared under CE mark in the EU and is currently being sold in Europe and several other markets. In addition, we obtained 510(k) clearance for Simeox in December 2024 and plan to leverage our commercial infrastructure and capabilities to market the device in the United States, while continuing to market it in the other geographies. We intend to commercialize Simeox through the purchase of the product initially, followed by recurring sales of device disposables. We will begin efforts to obtain reimbursement coverage in the first quarter of 2025 for the Simeox product in the U.S.

Results of operations

Comparison of years ended December 31, 2024 and 2023

Revenue

(dollar amounts in thousands)	Years ended December 31,		Change 2024 vs. 2023		% of Revenue	
	2024	2023	\$	%	2024	2023
Sales revenue	\$ 278,756	\$ 251,607	\$ 27,149	10.8%	83.0%	79.7%
Rental revenue	56,949	64,053	(7,104)	-11.1%	17.0%	20.3%
Total revenue	<u>\$ 335,705</u>	<u>\$ 315,660</u>	<u>\$ 20,045</u>	<u>6.4%</u>	<u>100.0%</u>	<u>100.0%</u>

Sales revenue increased \$27.1 million for the year ended December 31, 2024 from the year ended December 31, 2023, an increase of 10.8% from the prior year. The increase was primarily attributable to higher international and domestic business-to-business sales. We sold approximately 157,500 oxygen systems during the year ended December 31, 2024 compared to approximately 130,500 oxygen systems sold during the year ended December 31, 2023, an increase of 20.7%.

Rental revenue decreased \$7.1 million for the year ended December 31, 2024 from the year ended December 31, 2023, or a decrease of 11.1% from the prior year. The decrease in rental revenue was primarily related to a higher mix of lower private-payor reimbursement rates.

(dollar amounts in thousands)	Years ended December 31,		Change 2024 vs. 2023		% of Revenue	
	2024	2023	\$	%	2024	2023
Revenue by region and category						
Business-to-business domestic sales	\$ 83,555	\$ 66,196	\$ 17,359	26.2%	24.9%	21.0%
Business-to-business international sales	117,207	89,401	27,806	31.1%	34.9%	28.3%
Direct-to-consumer domestic sales	77,994	96,010	(18,016)	-18.8%	23.2%	30.4%
Direct-to-consumer domestic rentals	56,949	64,053	(7,104)	-11.1%	17.0%	20.3%
Total revenue	<u>\$ 335,705</u>	<u>\$ 315,660</u>	<u>\$ 20,045</u>	<u>6.4%</u>	<u>100.0%</u>	<u>100.0%</u>

Domestic business-to-business sales increased 26.2% for the year ended December 31, 2024 compared to the year ended December 31, 2023, primarily due to the result of increased demand from new customers and resellers.

International business-to-business sales increased 31.1% for the year ended December 31, 2024 compared to the year ended December 31, 2023, primarily due to an increase in demand from our partners in Europe and new customers. In the year ended December 31, 2024, sales in Europe as a percentage of total international sales revenue slightly decreased to 85.0% versus 85.3% in 2023.

Domestic direct-to-consumer sales decreased 18.8% for the year ended December 31, 2024 compared to the year ended December 31, 2023, primarily driven by lower volume due to lower sales representative headcount, partially offset by increased average selling prices versus the prior year.

Domestic direct-to-consumer rentals decreased 11.1% for the year ended December 31, 2024 compared to the year ended December 31, 2023, primarily related to a higher mix of lower private-payor reimbursement rates.

Cost of revenue and gross profit

(dollar amounts in thousands)	Years ended December 31,		Change 2024 vs. 2023		% of Revenue	
	2024	2023	\$	%	2024	2023
Cost of sales revenue	\$ 148,655	\$ 158,636	\$ (9,981)	-6.3%	44.3%	50.3%
Cost of rental revenue	32,309	30,325	1,984	6.5%	9.6%	9.6%
Total cost of revenue	<u>\$ 180,964</u>	<u>\$ 188,961</u>	<u>\$ (7,997)</u>	<u>-4.2%</u>	<u>53.9%</u>	<u>59.9%</u>
Gross profit - sales revenue	\$ 130,101	\$ 92,971	\$ 37,130	39.9%	38.8%	29.4%
Gross profit - rental revenue	24,640	33,728	(9,088)	-26.9%	7.3%	10.7%
Total gross profit	<u>\$ 154,741</u>	<u>\$ 126,699</u>	<u>\$ 28,042</u>	<u>22.1%</u>	<u>46.1%</u>	<u>40.1%</u>
Gross margin percentage - sales revenue	46.7%	37.0%				
Gross margin percentage - rental revenue	43.3%	52.7%				
Total gross margin percentage	46.1%	40.1%				

Cost of sales revenue decreased \$10.0 million for the year ended December 31, 2024 from the year ended December 31, 2023, a decrease of 6.3%, due primarily to lower premiums paid for raw material components, partially offset by an increase in the numbers of systems sold. The year ended December 31, 2024 included \$0.2 million of material cost premiums associated with open-market purchases of semiconductor chips used in our batteries and POCs compared to \$14.2 million in the year ended December 31, 2023.

Cost of rental revenue increased \$2.0 million for the year ended December 31, 2024 from the year ended December 31, 2023, an increase of 6.5%. The increase in cost of rental revenue was primarily attributable to an increase in service costs. Cost of rental revenue included \$12.6 million of rental asset depreciation for the year ended December 31, 2024 compared to \$12.9 million for the year ended December 31, 2023.

Gross margin on sales revenue increased to 46.7% for the year ended December 31, 2024 from 37.0% for the year ended December 31, 2023. The increase was primarily due to lower material cost premiums associated with open-market purchases of semiconductor chips used in our POCs and operational efficiencies, partially offset by a change in sales mix towards increased business-to-business sales. Total worldwide business-to-business sales revenue accounted for 72.0% of total sales revenue in the year ended December 31, 2024 versus 61.8% in the year ended December 31, 2023.

Gross margin on rental revenue decreased to 43.3% for the year ended December 31, 2024 from 52.7% for the year ended December 31, 2023, primarily due to a higher mix shift of private-payor reimbursement, lower net revenue per rental patient as a result of a decrease in the percentage of patients billed compared to total patients on service, and higher service costs.

Research and development expense

(dollar amounts in thousands)	Years ended December 31,		Change 2024 vs. 2023		% of Revenue	
	2024	2023	\$	%	2024	2023
Research and development expense	\$ 21,610	\$ 20,840	\$ 770	3.7%	6.4%	6.6%

Research and development expense increased \$0.8 million for the year ended December 31, 2024 from the year ended December 31, 2023, representing an increase of 3.7%. This was due primarily to a \$2.3 million increase in amortization costs of intangible assets related to the Physio-Assist acquisition, partially offset by a \$1.6 million decrease in product development costs.

Sales and marketing expense

(dollar amounts in thousands)	Years ended December 31,		Change 2024 vs. 2023		% of Revenue	
	2024	2023	\$	%	2024	2023
Sales and marketing expense	\$ 103,069	\$ 107,091	\$ (4,022)	-3.8%	30.7%	33.9%

Sales and marketing expense decreased \$4.0 million for the year ended December 31, 2024 from the year ended December 31, 2023, a decrease of 3.8%. This was primarily due to decreases of \$8.5 million in consulting fees, \$1.9 million in dues, fees and licenses, and \$1.6 million in credit card and financing fees, partially offset by an increase of \$5.1 million in media and advertising costs, \$1.5 million in personnel-related expenses, and \$0.9 million in travel costs. In the year ended December 31, 2024, we spent \$32.2 million in media and advertising costs versus \$27.1 million in 2023.

General and administrative expense

(dollar amounts in thousands)	Years ended December 31,		Change 2024 vs. 2023		% of Revenue	
	2024	2023	\$	%	2024	2023
General and administrative expense	\$ 72,578	\$ 75,260	\$ (2,682)	-3.6%	21.6%	23.8%

General and administrative expense decreased \$2.7 million for the year ended December 31, 2024, from the year ended December 31, 2023, a decrease of 3.6%, primarily due to decreases of \$3.8 million in the change in fair value of the earnout liability, \$3.4 million in restructuring-related costs, \$2.5 million in chief executive officer transition costs and \$1.6 million in acquisition-related expenses. These decreases were partially offset by increases of \$6.9 million in personnel-related expenses and \$1.1 million in dues, fees and licenses.

Impairment charges

(dollar amounts in thousands)	Years ended December 31,		Change 2024 vs. 2023		% of Revenue	
	2024	2023	\$	%	2024	2023
Goodwill impairment	\$ —	\$ 32,894	\$ (32,894)	-100.0%	0.0%	10.4%

There were no impairment charges for the year ended December 31, 2024. Impairment charges for the year ended December 31, 2023 resulted from a drop in our public stock price, which resulted in impairment charges to goodwill.

Other income, net

(dollar amounts in thousands)	Years ended December 31,		Change 2024 vs. 2023		% of Revenue	
	2024	2023	\$	%	2024	2023
Interest income, net	\$ 5,190	\$ 6,574	\$ (1,384)	-21.1%	1.5%	2.1%
Other income, net	850	468	382	81.6%	0.3%	0.1%
Total other income, net	<u>\$ 6,040</u>	<u>\$ 7,042</u>	<u>\$ (1,002)</u>	<u>-14.2%</u>	<u>1.8%</u>	<u>2.2%</u>

Total other income, net decreased \$1.0 million for the year ended December 31, 2024 from the year ended December 31, 2023, a decrease of 14.2%. The decrease was primarily attributable to a decrease of \$1.4 million in interest income due to the lower interest rate environment.

Income tax expense (benefit)

(dollar amounts in thousands)	Years ended December 31,		Change 2024 vs. 2023		% of Revenue	
	2024	2023	\$	%	2024	2023
Income tax expense (benefit)	\$ (588)	\$ 105	\$ (693)	-660.0%	-0.2%	0.0%
Effective income tax rate	1.6%	-0.1%				

Income tax expense (benefit) decreased \$0.7 million for the year ended December 31, 2024 from the year ended December 31, 2023. We continued to record a valuation allowance on the use of deferred tax assets in the current and prior periods. The decrease was attributable to foreign taxes.

Our effective tax rate for the year ended December 31, 2024 increased compared to the year ended December 31, 2023, primarily due to foreign taxes.

Net loss

(dollar amounts in thousands)	Years ended December 31,		Change 2024 vs. 2023		% of Revenue	
	2024	2023	\$	%	2024	2023
Net loss	\$ (35,888)	\$ (102,449)	\$ 66,561	65.0%	-10.7%	-32.5%

Net loss decreased \$66.6 million for the year ended December 31, 2024 from the year ended December 31, 2023, or a decrease of 65.0%. The decrease in net loss was primarily related to lower goodwill impairment, material cost reductions and higher sales revenue.

Comparison of years ended December 31, 2023 and 2022

A discussion of changes in our results of operations during the year ended December 31, 2023 compared to the year ended December 31, 2022 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, 2023, filed with the SEC on March 1, 2024, 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, 2024, we had cash and cash equivalents of \$113.8 million, which consisted of highly liquid investments with a maturity of three months or less. For the years ended December 31, 2024, 2023 and 2022, we received \$0.8 million, \$1.5 million and \$1.7 million, respectively, in proceeds related to stock option exercises and our employee stock purchase plan.

As of December 31, 2024, we had a financing receivable of \$6.5 million, which consisted of \$1.8 million in current assets and \$4.7 million in noncurrent assets. Our credit terms are predominately short term in nature; however, in certain circumstances, we offer extended payment terms to customers who have not met the payment terms of their original contract.

Our principal use of our funds for liquidity and capital resources in the year ended December 31, 2024 consisted of cash used in investing activities of \$17.1 million for additional rental equipment, other property, plant and equipment and intangible assets, partially offset by cash provided by operating activities of \$5.9 million and \$2.8 million for net maturities of marketable securities.

We believe that our current cash, cash equivalents and marketable securities 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 12 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 and integration thereof; 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)

Summary of consolidated cash flows	Years ended December 31,		
	2024	2023	2022
Cash provided by (used in) operating activities	\$ 5,914	\$ (3,234)	\$ (37,532)
Cash used in investing activities	(13,975)	(59,315)	(10,877)
Cash provided by financing activities	265	960	380
Effect of exchange rates on cash	(281)	67	(481)
Net decrease in cash and cash equivalents	<u>\$ (8,077)</u>	<u>\$ (61,522)</u>	<u>\$ (48,510)</u>

(amounts in thousands)

Summary of working capital	December 31,	
	2024	2023
Total current assets	\$ 185,451	\$ 207,067
Total current liabilities	76,686	72,496
Net working capital	<u>\$ 108,765</u>	<u>\$ 134,571</u>

Operating activities

Historically, 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, 2024 consisted primarily of non-cash adjustment items such as depreciation of equipment and leasehold improvements and amortization of intangibles of \$21.0 million, provision for sales returns and doubtful accounts of \$10.9 million, stock-based compensation expense of \$7.4 million, net loss on disposal of rental assets and other assets of \$4.5 million, and change in fair value of earnout liability of \$3.0 million. These adjustment items were partially offset by our net loss of \$35.9 million, and an increase in deferred tax assets of \$1.2 million. The net changes in operating assets and liabilities resulted in a net use of cash of \$4.4 million.

Net cash used in operating activities for the year ended December 31, 2023 consisted primarily of our net loss of \$102.4 million, partially offset by non-cash adjustment items such as impairment charges of \$32.9 million, depreciation of equipment and leasehold improvements and amortization of intangibles of \$18.2 million, provision for sales returns and doubtful accounts of \$10.7 million, stock-based compensation expense of \$7.4 million, change in fair value of earnout liability of \$6.8 million, net loss on disposal of rental assets and other assets of \$4.5 million, provision for inventory obsolescence and other inventory losses of \$2.7 million, and loss on purchase commitments of \$2.1 million. The net changes in operating assets and liabilities resulted in net cash provided of \$14.3 million.

Net cash used in operating activities for the year ended December 31, 2022 consisted primarily of our net loss of \$83.8 million and the non-cash add back for change in fair value of the earnout liability of \$15.4 million, partially offset by non-cash adjustment items such as loss on disposal of intangible asset of \$52.2 million, depreciation of equipment and leasehold improvements and amortization of intangibles of \$23.5 million, provision for sales returns and doubtful accounts of \$13.0 million, stock-based compensation expense of \$12.3 million, net loss on disposal of rental equipment and other fixed assets of \$3.1 million, and provision for inventory obsolescence and other inventory losses of \$2.4 million. The net changes in operating assets and liabilities resulted in a net use of cash of \$44.7 million.

Investing activities

Net cash used in investing activities generally includes the production and purchase of rental assets, property, plant and equipment, acquisitions, and intangibles to support our expanding business as well as maturities (purchases) of marketable securities.

For the year ended December 31, 2024, we invested \$32.7 million in the purchase of marketable securities, \$15.0 million in the production and purchase of rental assets and other property and equipment, and \$2.1 million in intangible assets, partially offset by \$35.5 million we received from maturities of marketable securities.

For the year ended December 31, 2023, we invested \$29.6 million in the Physio-Assist acquisition, net of cash acquired, \$26.9 million in purchase of marketable securities, \$26.5 million in the production and purchase of rental assets and other property and equipment, and \$0.5 million in intangible assets, partially offset by \$24.0 million we received in maturities of marketable securities.

For the year ended December 31, 2022, we invested \$21.2 million in the production and purchase of rental assets and other property and equipment, partially offset by \$10.0 million we received in maturities of marketable securities.

We expend significant manufacturing and production expense in connection with the development and production of our oxygen concentrator and other respiratory care products and, in connection with our rental business, we incur expense in the deployment and maintenance 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 and the issuance of preferred and common stock.

For the year ended December 31, 2024, net cash provided by financing activities consisted of \$0.8 million from the proceeds received from purchases under our employee stock purchase program, partially offset by the payment of employment taxes related to the vesting of restricted stock units of \$0.5 million.

For the year ended December 31, 2023, net cash provided by financing activities consisted of \$1.5 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 \$0.5 million.

For the year ended December 31, 2022, net cash provided by financing activities consisted of \$1.7 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 \$1.4 million.

Sources of funds

Our net cash provided by operating activities in the year ended December 31, 2024 was \$5.9 million compared to net cash used in operating activities of \$3.2 million in the year ended December 31, 2023. As of December 31, 2024, we had cash and cash equivalents of \$113.8 million.

On January 25, 2025, we entered into a securities purchase agreement with Yuwell (Hong Kong) Holdings Limited, an affiliate of Jiangsu Yuyue Medical Equipment & Supply Co., Ltd. Pursuant to the securities purchase agreement, Yuwell (Hong Kong) Holdings Limited has agreed to purchase 2,626,425 shares of the Company's common stock at a price per share of \$10.36, for an aggregate purchase price of approximately \$27.2 million. The transaction closed on February 21, 2025.

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.

Contractual obligations

The following table reflects a summary of our contractual obligations as of December 31, 2024.

(amounts in thousands)	Payments due by period				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Contractual Obligations					
Operating leases - properties and other ⁽¹⁾	\$ 21,126	\$ 3,336	\$ 7,255	\$ 6,271	\$ 4,264
Purchase obligations ⁽²⁾	58,400	58,400	—	—	—
Total	<u>\$ 79,526</u>	<u>\$ 61,736</u>	<u>\$ 7,255</u>	<u>\$ 6,271</u>	<u>\$ 4,264</u>

- (1) We lease manufacturing and office space in Plano, TX, Goleta, CA, Smyrna, TN, Huntsville, AL, Aurora, CO, Beverly, MA, De Meern, Netherlands and Montpellier, France with terms that expire between 2025 and 2031 and miscellaneous office and processing equipment in Texas and California with terms expiring between 2025 and 2028. Included in these amounts are the lease payments assumed by a third party, referred to as the Assignee, based on an Assignment and Assumption of Lease Agreement in which the Assignee assumed the rights, title, and interest in the lease. Commencing February 1, 2024 and ending May 31, 2031, the Assignee assumed responsibility for the monthly lease payments, and we remain the primary obligor under the lease to the landlord.
- (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 and Physio-Assist, we have contingent obligations to pay up to \$31.4 million and \$13.0 million, respectively, 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.

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 loss excluding interest income, interest expense, taxes and depreciation and amortization. Adjusted EBITDA also excludes stock-based compensation, change in fair value of earnout liability, acquisition-related expenses, and restructuring-related and other charges. Below, we have provided a reconciliation of EBITDA and Adjusted EBITDA to our net 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 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, the impact of the change in fair value of the earnout liability, the impact of acquisition-related expenses, the impact of restructuring-related costs, and impairment charges. 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;
- Adjusted EBITDA does not include acquisition-related expenses, whether the acquisition was consummated or not pursued;
- Adjusted EBITDA does not include costs associated with workforce reductions and associated costs and other restructuring-related activities;
- goodwill impairment; 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 financial results, EBITDA and Adjusted EBITDA should be considered alongside other financial performance measures, including U.S. GAAP results.

The following table presents a reconciliation of EBITDA and Adjusted EBITDA to our net loss, the most comparable U.S. GAAP measure, for each of the periods indicated:

<i>(amounts in thousands)</i> Non-GAAP EBITDA and Adjusted EBITDA	Years ended December 31,		
	2024	2023	2022
Net loss (GAAP)	\$ (35,888)	\$ (102,449)	\$ (83,772)
Non-GAAP adjustments:			
Interest income, net	(5,190)	(6,574)	(2,837)
Provision (benefit) for income taxes	(588)	105	504
Depreciation and amortization	21,004	18,152	23,514
EBITDA (non-GAAP)	(20,662)	(90,766)	(62,591)
Stock-based compensation	7,397	7,427	12,283
Acquisition-related expenses	784	2,413	—
Restructuring-related and other charges	—	3,426	—
Impairment charges	—	32,894	—
Change in fair value of earnout liability	3,000	6,822	(15,386)
Loss on disposal of intangible asset	—	—	52,161
Adjusted EBITDA (non-GAAP)	<u>\$ (9,481)</u>	<u>\$ (37,784)</u>	<u>\$ (13,533)</u>

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. 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, 2024 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 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, cash, receivables and payables. 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, 2024, 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 \$9.0 million decline in revenue for the year ended December 31, 2024. 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 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 \$113.8 million as of December 31, 2024, which consisted of highly liquid investments with a maturity of three months or less. 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 our 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, 2024 and December 31, 2023. If overall interest rates had increased or decreased by 1.00% (100 basis points), our interest income would not have been materially affected during the years ended December 31, 2024 or December 31, 2023.

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 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, 2024. Based upon the evaluation described above, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2024, 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), or 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, 2024 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, 2024 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 subsidiaries (the “Company”) as of December 31, 2024, 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, 2024, 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, 2024, of the Company and our report dated February 28, 2025, 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 28, 2025

ITEM 9B. OTHER INFORMATION

Annual Meeting

Our annual meeting of stockholders will be held at 10:00 a.m. Pacific Time on Wednesday, May 14, 2025, as a virtual meeting. Holders of record at the close of business on Monday, March 17, 2025, will be entitled to vote at the meeting.

Insider Trading Arrangements

During the three months ended December 31, 2024, none of our directors or Section 16 reporting officers adopted or terminated any Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement (as such terms are defined in Item 408 of the SEC's Regulation S-K).

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required 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, 2024, or 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

None.

Inogen, Inc.
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and Financial Statement Schedule

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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 subsidiaries (the "Company") as of December 31, 2024 and 2023, the related consolidated statements of comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2024, 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, 2024 and 2023, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2024, 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, 2024, 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 28, 2025, 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 \$9.9 million at December 31, 2024.

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 28, 2025

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

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

	December 31,	
	2024	2023
Assets		
Current assets		
Cash and cash equivalents	\$ 113,795	\$ 125,492
Marketable securities	—	2,979
Restricted cash	3,620	—
Accounts receivable, net	29,563	42,241
Inventories, net	24,812	21,840
Income tax receivable	538	669
Prepaid expenses and other current assets	13,123	13,846
Total current assets	185,451	207,067
Property and equipment, net	44,400	50,316
Goodwill	9,465	10,057
Intangible assets, net	30,493	34,591
Operating lease right-of-use asset	18,295	20,338
Other assets	8,081	3,825
Total assets	<u>\$ 296,185</u>	<u>\$ 326,194</u>
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable and accrued expenses	\$ 27,153	\$ 30,142
Accrued payroll	17,189	11,066
Warranty reserve - current	9,736	9,628
Operating lease liability - current	2,812	3,653
Earnout liability	13,000	10,000
Deferred revenue - current	6,654	7,980
Income tax payable	142	27
Total current liabilities	76,686	72,496
Long-term liabilities		
Warranty reserve - noncurrent	16,350	13,850
Operating lease liability - noncurrent	16,594	18,270
Deferred revenue - noncurrent	5,747	8,227
Deferred tax liability	6,948	8,539
Total liabilities	122,325	121,382
Commitments and contingencies (Note 9)		
Stockholders' equity		
Common stock, \$0.001 par value per share; 200,000,000 shares authorized; 23,902,338 and 23,324,750 shares issued and outstanding as of December 31, 2024 and 2023, respectively	24	23
Additional paid-in capital	328,174	320,513
Accumulated deficit	(152,837)	(116,949)
Accumulated other comprehensive income (loss)	(1,501)	1,225
Total stockholders' equity	173,860	204,812
Total liabilities and stockholders' equity	<u>\$ 296,185</u>	<u>\$ 326,194</u>

See accompanying notes to the consolidated financial statements.

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

	Years Ended December 31,		
	2024	2023	2022
Revenue			
Sales revenue	\$ 278,756	\$ 251,607	\$ 320,549
Rental revenue	56,949	64,053	56,692
Total revenue	335,705	315,660	377,241
Cost of revenue			
Cost of sales revenue	148,655	158,636	197,805
Cost of rental revenue, including depreciation of \$12,592, \$12,893 and \$11,103, respectively	32,309	30,325	25,903
Total cost of revenue	180,964	188,961	223,708
Gross profit			
Gross profit-sales revenue	130,101	92,971	122,744
Gross profit-rental revenue	24,640	33,728	30,789
Total gross profit	154,741	126,699	153,533
Operating expense			
Research and development	21,610	20,840	21,943
Sales and marketing	103,069	107,091	120,767
General and administrative	72,578	75,260	43,905
Loss on disposal of intangible asset	—	—	52,161
Impairment charges	—	32,894	—
Total operating expense	197,257	236,085	238,776
Loss from operations	(42,516)	(109,386)	(85,243)
Other income (expense)			
Interest income, net	5,190	6,574	2,837
Other income (expense)	850	468	(862)
Total other income, net	6,040	7,042	1,975
Loss before provision (benefit) for income taxes	(36,476)	(102,344)	(83,268)
Provision (benefit) for income taxes	(588)	105	504
Net loss	(35,888)	(102,449)	(83,772)
Other comprehensive income (loss), net of tax			
Change in foreign currency translation adjustment	(2,590)	1,358	(597)
Change in net unrealized losses on foreign currency hedging	(324)	—	(3,130)
Less: reclassification adjustment for net gains included in net loss	324	—	1,990
Total net change in unrealized losses on foreign currency hedging	—	—	(1,140)
Change in net unrealized gains (losses) on marketable securities	(136)	110	25
Total other comprehensive income (loss), net of tax	(2,726)	1,468	(1,712)
Comprehensive loss	\$ (38,614)	\$ (100,981)	\$ (85,484)
Basic net loss per share attributable to common stockholders (Note 2)	\$ (1.52)	\$ (4.42)	\$ (3.67)
Diluted net loss per share attributable to common stockholders (Note 2)	\$ (1.52)	\$ (4.42)	\$ (3.67)
Weighted-average number of shares used in calculating net loss per share attributable to common stockholders:			
Basic shares of common stock	23,654,395	23,176,098	22,852,571
Diluted shares of common stock	23,654,395	23,176,098	22,852,571

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 deficit)	Accumulated other comprehensive income (loss)	Total stockholders' equity
	Shares	Amount				
Balance, December 31, 2021	22,731,586	\$ 23	\$ 299,463	\$ 69,272	\$ 1,469	\$ 370,227
Stock-based compensation	—	—	12,283	—	—	12,283
Employee stock purchases	62,328	—	1,691	—	—	1,691
Restricted stock awards issued, net of forfeitures	(5,134)	—	—	—	—	—
Vesting of restricted stock units	141,728	—	(1,252)	—	—	(1,252)
Shares withheld related to net restricted stock settlement	(3,019)	—	(103)	—	—	(103)
Stock options exercised	14,154	—	44	—	—	44
Net loss	—	—	—	(83,772)	—	(83,772)
Other comprehensive loss	—	—	—	—	(1,712)	(1,712)
Balance, December 31, 2022	22,941,643	\$ 23	\$ 312,126	\$ (14,500)	\$ (243)	\$ 297,406
Stock-based compensation	—	—	7,427	—	—	7,427
Employee stock purchases	136,032	—	1,094	—	—	1,094
Vesting of restricted stock units	192,735	—	(517)	—	—	(517)
Shares withheld related to net restricted stock settlement	(92)	—	(1)	—	—	(1)
Stock options exercised	54,432	—	384	—	—	384
Net loss	—	—	—	(102,449)	—	(102,449)
Other comprehensive income	—	—	—	—	1,468	1,468
Balance, December 31, 2023	23,324,750	\$ 23	\$ 320,513	\$ (116,949)	\$ 1,225	\$ 204,812
Stock-based compensation	—	—	7,397	—	—	7,397
Stock issued	644,854	1	810	—	—	811
Tax withholding related to vesting of restricted stock units	(67,266)	—	(546)	—	—	(546)
Net loss	—	—	—	(35,888)	—	(35,888)
Other comprehensive loss	—	—	—	—	(2,726)	(2,726)
Balance, December 31, 2024	<u>23,902,338</u>	<u>\$ 24</u>	<u>\$ 328,174</u>	<u>\$ (152,837)</u>	<u>\$ (1,501)</u>	<u>\$ 173,860</u>

See accompanying notes to the consolidated financial statements.

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

	Years Ended December 31,		
	2024	2023	2022
Cash flows from operating activities			
Net loss	\$ (35,888)	\$ (102,449)	\$ (83,772)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation and amortization	21,004	18,152	23,514
Loss on rental units and other assets	4,535	4,508	3,095
Gain on sale of former rental assets	(165)	(84)	(154)
Provision for sales revenue returns and doubtful accounts	10,890	10,730	13,024
Provision for inventory losses	233	2,691	2,423
Loss on purchase commitments	448	2,057	—
Stock-based compensation expense	7,397	7,427	12,283
Deferred income taxes	(1,150)	(251)	—
Change in fair value of earnout liability	3,000	6,822	(15,386)
Loss on disposal of intangible asset	—	—	52,161
Impairment charges	—	32,894	—
Changes in operating assets and liabilities:			
Accounts receivable	(5,187)	10,141	(51,337)
Inventories	(3,538)	7,878	(5,601)
Income tax receivable	120	988	(281)
Prepaid expenses and other current assets	2,411	5,583	6,803
Operating lease right-of-use asset	3,854	3,413	3,259
Other noncurrent assets	551	(1,110)	224
Accounts payable and accrued expenses	(3,414)	(9,177)	6,759
Accrued payroll	6,222	(508)	(6,106)
Warranty reserve	2,608	3,565	6,187
Deferred revenue	(3,806)	(3,075)	(1,150)
Income tax payable	115	27	(82)
Operating lease liability	(4,326)	(3,456)	(3,395)
Net cash provided by (used in) operating activities	5,914	(3,234)	(37,532)
Cash flows from investing activities			
Purchases of available-for-sale securities	(32,657)	(26,869)	—
Maturities of available-for-sale securities	35,500	24,000	10,014
Investment in intangible assets	(2,090)	(494)	—
Investment in property and equipment	(3,360)	(5,218)	(3,337)
Production and purchase of rental equipment	(11,643)	(21,299)	(17,885)
Proceeds from sale of former assets	275	198	331
Acquisition of business, net of cash acquired	—	(29,633)	—
Net cash used in investing activities	(13,975)	(59,315)	(10,877)

See accompanying notes to the consolidated financial statements.

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

	Years Ended December 31,		
	2024	2023	2022
Cash flows from financing activities			
Proceeds from stock options exercised	—	384	44
Proceeds from employee stock purchases	811	1,094	1,691
Payment of employment taxes related to release of restricted stock	(546)	(518)	(1,355)
Net cash provided by financing activities	265	960	380
Effect of exchange rates on cash	(281)	67	(481)
Net decrease in cash, cash equivalents and restricted cash	(8,077)	(61,522)	(48,510)
Cash, cash equivalents and restricted cash, beginning of period	125,492	187,014	235,524
Cash, cash equivalents and restricted cash, end of period	<u>\$ 117,415</u>	<u>\$ 125,492</u>	<u>\$ 187,014</u>
Supplemental disclosures of cash flow information			
Cash paid (received) during the period for income taxes, net of refunds received	\$ 375	\$ (703)	\$ 499
Supplemental disclosure of non-cash transactions			
Accrued value of earnout related to acquisition	—	3,178	—
Property and equipment in accounts payable and accrued expenses	197	204	428

See accompanying notes to the consolidated financial statements.

Inogen, Inc.
Notes to the Consolidated Financial Statements
(amounts in thousands, except share and per share amounts)

1. Nature of business

Inogen, Inc. (Company or Inogen) was incorporated in Delaware on November 27, 2001. The Company is a medical technology business that primarily develops, manufactures, and markets innovative respiratory products, such as 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 refers to as the delivery model. The tanks and cylinders must be delivered regularly and contain 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 and Inogen Rove systems concentrate the air around the patient to offer a source of supplemental oxygen anytime, anywhere with a 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 and Inogen Rove 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. On September 14, 2023, the Company completed the acquisition of all of the issued and outstanding capital stock of Physio-Assist SAS (Physio-Assist) and its wholly-owned subsidiary PhysioAssist GmbH.

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 subsidiaries. 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 goodwill, impairment of long-lived assets, stock-based compensation expense, income taxes, fair value of acquired intangible assets and goodwill, financing receivable 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 primarily of its proprietary line of oxygen concentrators, and related accessories. Other revenue, which is included in sales revenue on the statements of comprehensive 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 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 sheets.

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 decrease in deferred revenue related to lifetime warranties for the years ended December 31, 2024 and December 31, 2023 was primarily driven by \$5,088 and \$6,438, respectively, of revenues recognized that were included in the deferred revenue balances, partially offset by \$1,695 and \$3,219, respectively, of payments received in advance of satisfying performance obligations. Deferred revenue related to lifetime warranties was \$9,922 and \$13,315 as of December 31, 2024 and December 31, 2023, 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 the sale 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:

Revenue by region and category	Years ended December 31,		
	2024	2023	2022
Business-to-business domestic sales	\$ 83,555	\$ 66,196	\$ 86,049
Business-to-business international sales	117,207	89,401	101,163
Direct-to-consumer domestic sales	77,994	96,010	133,337
Total sales revenue	<u>\$ 278,756</u>	<u>\$ 251,607</u>	<u>\$ 320,549</u>

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 has not deferred any amounts associated with the capped rental period as of December 31, 2024 and December 31, 2023. 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 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 uncollectible, 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 three-year, five-year or lifetime warranty on Inogen One and Rove systems and a three-year and lifetime warranty on Inogen At Home systems sold. The Company only 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 each reporting period. 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, financing receivable, 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, 2024					
	Adjusted cost	Gross unrealized gains	Fair value	Cash and cash equivalents	Restricted cash
Cash	\$ 23,053	\$ —	\$ 23,053	\$ 23,053	\$ —
Level 1:					
Money market accounts	72,129	—	72,129	68,509	3,620
Level 2:					
Institutional Insured Liquidity Deposit Savings	22,233	—	22,233	22,233	—
Total	<u>\$ 117,415</u>	<u>\$ —</u>	<u>\$ 117,415</u>	<u>\$ 113,795</u>	<u>\$ 3,620</u>

As of December 31, 2023					
	Adjusted cost	Gross unrealized gains	Fair value	Cash and cash equivalents	Marketable securities
Cash	\$ 12,611	\$ —	\$ 12,611	\$ 12,611	\$ —
Level 1:					
Money market accounts	72,368	—	72,368	72,368	—
Level 2:					
Corporate bonds	2,979	—	2,979	—	2,979
U.S. Treasury securities	19,252	136	19,388	19,388	—
Institutional Insured Liquidity Deposit Savings	21,125	—	21,125	21,125	—
Total	<u>\$ 128,335</u>	<u>\$ 136</u>	<u>\$ 128,471</u>	<u>\$ 125,492</u>	<u>\$ 2,979</u>

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 and balance sheet hedges are recorded as a component of accumulated other comprehensive income within stockholders' equity and are recognized in the consolidated statements of comprehensive 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 income (expense), net in the consolidated statements of comprehensive 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 sheets. The Company had a related receivable of \$351 and related payable of \$155 as of December 31, 2024 and December 31, 2023, 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 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 sheets 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 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, 2024		
	Foreign currency translation adjustments	Unrealized losses on marketable securities	Accumulated other comprehensive income (loss)
Balance as of December 31, 2023	\$ 1,089	\$ 136	\$ 1,225
Other comprehensive loss	(2,590)	(136)	(2,726)
Balance as of December 31, 2024	<u>\$ (1,501)</u>	<u>\$ —</u>	<u>\$ (1,501)</u>

	As of December 31, 2023		
	Foreign currency translation adjustments	Unrealized gains on marketable securities	Accumulated other comprehensive income (loss)
Balance as of December 31, 2022	\$ (269)	\$ 26	\$ (243)
Other comprehensive income	1,358	110	1,468
Balance as of December 31, 2023	<u>\$ 1,089</u>	<u>\$ 136</u>	<u>\$ 1,225</u>

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 earnings. Changes in fair value will be recognized in general and administrative expense.

The Company has obligations to pay up to \$13,000 and \$31,400 in earnout payments for the Physio-Assist acquisition and the New Aera acquisition, respectively, in cash if certain future financial and regulatory results are met. The earnout liabilities were valued using Level 3 inputs.

The fair value of the New Aera earnout was determined historically 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 included other assumptions including the market price of risk, which was calculated as the weighted average cost of capital 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. As a result of the earnout requirements not expected to be met for New Aera due to the asset disposal, the Company considered the fair value measurement of the earnout liability to be \$0 as of December 31, 2024 and 2023. Additional information on the loss on disposal of intangible asset contained later in this Note in *Long-lived assets*.

The fair value of the Physio-Assist earnout was valued using a probability weighted expected return methodology and was discounted using a rate and probability that appropriately captures the risk associated with the achievement of one of two milestones related to FDA De Novo authorization or 510(k) clearance for the Simeox Airway Clearance System within four years of the date of the closing of the transaction. Significant increases or decreases in these inputs could result in a significant impact on our fair value measurement. In December 2024, the Company received FDA 510(k) clearance of its Simeox 200 device. Upon clearance, the Company became obligated to make the \$13,000 cash earnout milestone payment. The payment was made within ten business days following the date clearance was received.

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

Balance as of December 31, 2022	\$	—
Addition for acquisition		3,178
Change in fair value		6,822
Balance as of December 31, 2023	\$	10,000
Change in fair value		3,000
Balance as of December 31, 2024	\$	13,000

Cash, cash equivalents, marketable securities and restricted cash

The Company considers all short-term highly liquid investments with a maturity of three months or less to be cash equivalents. Restricted cash and cash equivalents are considered to be legally restricted as to withdrawal or usage. The Company's restricted cash is a legally restricted deposit held as a compensating balance against its corporate credit card balances.

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.

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. Expected credit losses are declines in fair value that are not expected to recover and are charged to other income (expense), net.

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, 2024 and December 31, 2023, the Company had increases of \$2,127 and \$1,055, 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, 2024 and December 31, 2023 were as follows:

	As of December 31, 2024		As of December 31, 2023	
	\$	%	\$	%
Net accounts receivable				
Rental ⁽¹⁾	\$ 4,863	16.4%	\$ 6,401	15.2%
Business-to-business and other receivables ⁽²⁾	24,700	83.6%	35,840	84.8%
Total net accounts receivable	<u>\$ 29,563</u>	<u>100.0%</u>	<u>\$ 42,241</u>	<u>100.0%</u>

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

(2) One customer represented more than 10% of the Company's net accounts receivable balance with a net accounts receivable balance of \$3,288 as of December 31, 2024. Two customers each represented more than 10% of the Company's net accounts receivable balance with net accounts receivable balances of \$8,639 and \$4,994, respectively, as of December 31, 2023.

The following table sets forth the percentage breakdown of the Company's net accounts receivable by aging category and invoice due date as of December 31, 2024 and December 31, 2023.

	As of December 31, 2024		As of December 31, 2023	
	\$	%	\$	%
Net accounts receivable by aging category				
Held and Unbilled	\$ 491	1.7%	\$ 1,388	3.3%
Aged 0-90 days	27,973	94.6%	32,020	75.8%
Aged 91-180 days	633	2.1%	8,222	19.5%
Aged 181-365 days	466	1.6%	574	1.4%
Aged over 365 days	—	0.0%	37	0.0%
Total net accounts receivable	<u>\$ 29,563</u>	<u>100.0%</u>	<u>\$ 42,241</u>	<u>100.0%</u>

The following table sets forth the accounts receivable allowances as of December 31, 2024 and December 31, 2023:

	As of December 31, 2024		As of December 31, 2023	
	\$	%	\$	%
Allowances - accounts receivable				
Doubtful accounts	\$ 458	1.5%	\$ 2,341	5.2%
Sales returns	413	1.4%	479	1.1%
Total allowances - accounts receivable	<u>\$ 871</u>	<u>2.9%</u>	<u>\$ 2,820</u>	<u>6.3%</u>

Concentration of credit risk

Financial instruments that potentially subject the Company to concentration of credit risk consist principally of cash, cash equivalents, marketable securities, financing receivable 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.

Financing receivable

The Company's credit terms are predominately short term in nature from delivery of the product or invoicing. However, in certain circumstances, the Company offers extended payment terms to customers who have not met the payment terms of their original contract. In addition, certain customers may not comply with formal payment terms specified in their written agreements with us. When the period between the transfer of control of the products and payment is expected to be greater than one year, the Company will adjust the promised amount of consideration for the effects of a significant financing component. When contracts contain a significant financing component in which the Company is effectively financing the customer, a portion of the transaction price is recognized as interest income rather than revenue using a discount rate that reflects the rate that would be used in a separate financing transaction between the Company and the customer. The Company exercises judgment to determine an appropriate interest rate considering the customer's credit characteristics and current economic conditions.

Based on an agreement reached on December 31, 2024 with a customer, the Company agreed to a revised payment schedule through 2028 for \$7,500 in outstanding net accounts receivables related to prior year sales. As a result, the receivable was reclassified to a financing receivable. The related net accounts receivable as of December 31, 2023 was \$8,639 for this customer. The current and noncurrent financing receivable related to this agreement was \$1,751 and \$4,747 as of December 31, 2024, respectively, and are classified within prepaid expenses and other current assets and other assets - noncurrent in the consolidated balance sheets.

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 primarily on a prepayment basis. Medicare's service reimbursement programs represented more than 10% of the Company's total revenue for the years ended December 31, 2023 and 2022. One customer represented more than 10% of the Company's net accounts receivable balance with a net accounts receivable balance of \$3,288 as of December 31, 2024. Two customers each represented more than 10% of the Company's net accounts receivable balance with net accounts receivable balances of \$8,639 and \$4,994, respectively, as of December 31, 2023.

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 56.3%, 67.7% and 77.0% of rental revenue in 2024, 2023 and 2022, respectively, and based on total revenue were 9.5%, 13.7% and 11.6% for 2024, 2023 and 2022, respectively. Accounts receivable balances relating to Medicare's service reimbursement programs (including held and unbilled, net of allowances) amounted to \$1,107, or 4.8%, of total net accounts receivable as of December 31, 2024 compared to \$2,059, or 4.9%, of total net accounts receivable as of December 31, 2023.

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, 2024, the Company's three major vendors accounted for 19.6%, 18.4% and 10.2%, respectively, of total raw material purchases. For the year ended December 31, 2023, the Company's three major vendors accounted for 30.8%, 16.1% and 7.9%, respectively, of total raw material purchases.

A portion of revenue is earned from sales outside the United States. Approximately 77.2%, 77.7% and 70.9% of the non-U.S. revenue for the years ended December 31, 2024, 2023 and 2022, 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, 2024, 2023 and 2022, respectively, is as follows:

	Years ended December 31,		
	2024	2023	2022
U.S. revenue	\$ 218,498	\$ 226,259	\$ 276,078
Non-U.S. revenue	117,207	89,401	101,163
Total revenue	<u>\$ 335,705</u>	<u>\$ 315,660</u>	<u>\$ 377,241</u>

Inventories

Inventories are stated at the lower of cost and net realizable value, using the first-in, first-out (FIFO) method. The Company records adjustments to inventory for potentially excess, obsolete, slow-moving or impaired items, and losses on firm purchase commitments as a component of cost of sales in the consolidated statements of comprehensive loss. The Company recorded noncurrent inventory related to inventories that are expected to be realized or consumed after one year of \$1,291 and \$1,225 as of December 31, 2024 and 2023, 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. During the years ended December 31, 2024, 2023 and 2022, \$562, \$2,187 and \$1,221, 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,	
	2024	2023
Raw materials and work-in-progress	\$ 19,224	\$ 18,036
Finished goods	7,633	6,871
Less: reserves	(2,045)	(3,067)
Inventories, net	<u>\$ 24,812</u>	<u>\$ 21,840</u>

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	1.5-8 years
Manufacturing equipment and tooling	3-5 years
Computer equipment and software	2-3 years
Furniture and equipment	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 loss. Repair and maintenance expense, which includes labor, parts and freight, for rental equipment was \$6,413, \$5,143 and \$4,528 for the years ended December 31, 2024, 2023 and 2022, 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, 2024, 2023 and 2022, respectively.

	Years ended December 31,		
	2024	2023	2022
Rental equipment	\$ 12,592	\$ 12,893	\$ 11,103
Other property and equipment	4,082	4,057	3,942
Total depreciation and amortization	<u>\$ 16,674</u>	<u>\$ 16,950</u>	<u>\$ 15,045</u>

Property and equipment and rental equipment with associated accumulated depreciation is summarized below as of December 31, 2024 and 2023, respectively.

	December 31,	
	2024	2023
Property and equipment		
Rental equipment, net of allowances of \$3,744 and \$2,606, respectively	\$ 64,012	\$ 67,804
Other property and equipment	25,123	30,357
Property and equipment	89,135	98,161
Accumulated depreciation		
Rental equipment	32,294	31,023
Other property and equipment	12,441	16,822
Accumulated depreciation	44,735	47,845
Property and equipment, net		
Rental equipment, net of allowances of \$3,744 and \$2,606, respectively	31,718	36,781
Other property and equipment	12,682	13,535
Property and equipment, net	\$ 44,400	\$ 50,316

Long-lived assets

The Company accounts for the impairment and disposition of long-lived assets in accordance with ASC 360 — *Property, Plant, and Equipment*. Long-lived assets are reviewed for indicators of impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. No impairments were recorded for the years ended December 31, 2024 and 2023.

On December 19, 2022, the Company determined to dispose of the technology intangible assets previously acquired from New Aera related to the Tidal Assist Ventilator (TAV) technology by ceasing development of such assets and abandoning the TAV program (the Disposal Determination). Prior to December 19, 2022, the TAV intangible asset was held and used, including ongoing research and development and no significant revenue. The Company made the Disposal Determination based on the Company's assessment that continued development of the assets would not be economically feasible. The assessment considered many factors, including 1) the lack of compatibility and functionality of the technology intangible asset within the Company's existing product portfolio, 2) the lack of commercial potential of such products that were not approved for ventilation Medicare reimbursement and a negative litigation outcome that occurred subsequent to the approved coding process, and 3) the substantial additional investment that would be required in order to attempt to achieve any commercial potential with substantial risk that no benefit would ever be achievable. There had been no significant revenue associated with the sale of products developed from the technology intangible asset acquired from New Aera to date and the Company does not expect any revenue from such products going forward. Upon abandonment, the Company recognized a loss on disposal of \$52,161 in our consolidated statements of comprehensive loss for the year ended December 31, 2022 for intangible assets, inventories, fixed assets, and construction in process associated with the TAV technology. As a result of no future sales, the fair value of the earnout resulted in a benefit of \$13,687 to general and administrative expense during the fourth quarter of 2022.

Goodwill and other identifiable intangible assets

Goodwill represents the excess acquisition cost over the fair value of the net tangible and intangible assets acquired. Goodwill is not amortized and is tested for impairment on an annual basis as of October 1 or 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. 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.

The Company first assesses 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.

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 were approximately \$32,176, \$27,120 and \$33,265 during the years ended December 31, 2024, 2023 and 2022, 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 loss.

Restructuring charges

Restructuring costs include workforce reductions, termination benefits, office downsizing, centralizing manufacturing activities, and equipment relocation. Key assumptions used in calculating the restructuring costs include the terms of, and payments under, agreements to terminate certain contractual obligations and the timing of reductions in workforce.

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 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 subsidiaries is the local currency. The financial statements of the subsidiaries 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), net in the consolidated statements of comprehensive loss.

Loss per share

Loss per share (EPS) is computed in accordance with ASC 260 — *Earnings per Share* and is calculated using the weighted-average number of shares of common stock 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 loss per share when their effect is dilutive.

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

The computation of EPS is as follows:

	Years ended December 31,		
	2024	2023	2022
Numerator—basic and diluted:			
Net loss	\$ (35,888)	\$ (102,449)	\$ (83,772)
Denominator:			
Weighted average shares of common stock - basic common stock ⁽¹⁾	23,654,395	23,176,098	22,852,571
Weighted average shares of common stock - diluted common stock	23,654,395	23,176,098	22,852,571
Net loss per share - basic common stock	\$ (1.52)	\$ (4.42)	\$ (3.67)
Net loss per share - diluted common stock ⁽²⁾	\$ (1.52)	\$ (4.42)	\$ (3.67)
Denominator calculation from basic to diluted:			
Weighted average shares of common stock - basic common stock ⁽¹⁾	23,654,395	23,176,098	22,852,571
Stock options and other dilutive awards	557,197	160,682	115,155
Weighted average shares of common stock - diluted common stock	24,211,592	23,336,780	22,967,726
Shares excluded from diluted weighted average shares:			
Stock options	5,000	104,681	329,586
Restricted stock units and restricted stock awards	375,486	926,859	528,398
Shares excluded from diluted weighted average shares	380,486	1,031,540	857,984

- (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 stock 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, 2024, 2023 and 2022, diluted loss per share is the same as basic loss per share.

Recently issued accounting pronouncements not yet adopted

In December 2023, the Financial Accounting Standards Board (FASB) issued the Accounting Standards Update (ASU) No. 2023-09, *Improvements to Income Tax Disclosures*. The new guidance requires disaggregated information about a reporting entity's effective tax rate reconciliation as well as information on income taxes paid. The standard is intended to benefit investors by providing more detailed income tax disclosures that would be useful in making capital allocation decisions. The ASU is effective for fiscal years beginning after December 15, 2025, and interim periods within those years, with early adoption permitted. The Company is currently evaluating the effect of the new guidance but does not expect it to have a material impact on the Company's consolidated financial statement presentation or results of operations.

In November 2024, the FASB issued ASU 2024-03, *Disaggregation of Income Statement Expenses*, requiring public companies to disaggregate key expense categories such as inventory purchases, employee compensation and depreciation in their financial statements. This aims to improve investor insights into company performance. ASU 2024-03 is effective for fiscal years beginning after December 15, 2024, and interim periods within fiscal years beginning after December 15, 2025, with early adoption permitted. The Company is currently evaluating the impact, if any, adoption will have on its financial position and results of operations.

Recently adopted accounting pronouncements

In November 2023, the FASB issued ASU No. 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*. The new guidance expands annual and interim disclosure requirements for reportable segments, primarily through enhanced disclosures about significant segment expenses. The ASU is effective for fiscal years beginning after December 15, 2023, and for interim periods beginning after December 15, 2024, with early adoption permitted. The Company adopted this standard on January 1, 2024. Upon adoption, the guidance was applied retrospectively to all prior periods presented in the financial statements, and the adoption of this standard did not have a material impact on the Company's consolidated financial statement presentation or results of operations.

3. Acquisitions

On July 10, 2023, the Company entered into a share purchase agreement to acquire Physio-Assist, which is in the business of the design, production, and marketing of medical devices for bronchial decongestion (airway clearance technique) for patients suffering from obstructive respiratory diseases. On September 14, 2023, the Company completed the acquisition of all of the issued and outstanding capital stock of Physio-Assist and its wholly-owned subsidiary PhysioAssist GmbH for a purchase price consisting of \$32,250 in cash consideration and the fair value of a potential earnout of \$3,178 based on future regulatory clearances. The Company incurred acquisition-related expenses of approximately \$1,860 in the twelve months ended December 31, 2023, which were recorded within general and administrative expense.

A potential earnout payment of either \$13,000 (without a clinical trial requirement) or \$11,000 (with a required clinical trial less related development costs) is dependent upon the achievement of one of two milestones related to the FDA De Novo authorization or 510(k) clearance for the Simeox Airway Clearance System within four years of the date of the closing of the transaction. The fair value of the earnout liability was measured using the probability weighted expected return methodology and was discounted using a rate and probability that appropriately captures the risk associated with the obligation. Upon receipt of FDA 510(k) clearance of the Simeox 200 device in December 2024, the Company became obligated to make the \$13,000 cash earnout milestone payment.

Assets and liabilities of the acquired company were recorded at their estimated fair values at the date of acquisition. 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 assets 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. The purchase accounting for this acquisition has been finalized.

The following table summarizes the allocation of the purchase price over the estimated fair value of the assets acquired and liabilities assumed in the acquisition of Physio-Assist:

Cash	\$	2,617
Accounts receivable		184
Inventories		296
Other assets		325
Property and equipment		82
Operating lease right-of-use asset		306
Intangible assets		34,100
Goodwill		9,755
Total assets acquired	\$	47,665
Accounts payable and accrued expenses	\$	1,108
Bank loans		1,922
Other current liabilities		376
Operating lease liability		306
Deferred tax liability - noncurrent		8,525
Total liabilities assumed		12,237
Total identifiable net assets	\$	35,428
Cash consideration	\$	32,250
Fair value of contingent earnout consideration		3,178
Total purchase price	\$	35,428

Included in the acquired intangible assets were \$32,300 of developed technology, \$1,600 of customer relationships, and \$200 related to trade name. The fair value measurements of the intangibles were based primarily on Level 3 inputs. Certain working capital accounts such as accounts receivables, inventories, other current assets, accounts payable and accrued expenses, bank loans and other current liabilities, as well as intangibles and related income tax amounts may be adjusted subsequent to the acquisition as they are realized at different values. These changes would be reflected as measurement period adjustments. All of the bank loans were settled subsequent to the acquisition date and prior to December 31, 2023.

The consolidated financial and operating results reflect the Physio-Assist operations beginning September 14, 2023. The following unaudited pro forma information for the twelve months ended December 31, 2023 and December 31, 2022 presents total revenue and net loss assuming the acquisition of Physio-Assist had occurred as of January 1, 2022.

	Twelve months ended December 31,	
	2023	2022
Total revenue	\$ 318,737	\$ 379,305
Net loss	\$ (105,230)	\$ (87,079)

4. Goodwill and other identifiable intangible assets

Goodwill

The changes in the carrying amount of goodwill for the years ended December 31, 2024 and 2023 were as follows:

Balance as of December 31, 2022	\$ 32,852
Translation adjustment	344
Impairment charge	(32,894)
Acquisition	9,755
Balance as of December 31, 2023	10,057
Translation adjustment	(592)
Balance as of December 31, 2024	<u>\$ 9,465</u>

As a result of a decrease in Company's public stock price that caused the Company's market capitalization to fall below its carrying amount (stockholders' equity) during July 2023 and noted by management to be more than temporary as the quarter progressed, a quantitative analysis was required to be performed during the quarter ended September 30, 2023. The Company used a discounted cash flow analysis based on Level 3 inputs and determined that the goodwill carrying amount exceeded its fair value and, as such, an impairment charge of \$32,894 was incurred in the quarter ended September 30, 2023. Accumulated impairment losses were \$32,894 as of December 31, 2024 and 2023.

Intangible assets

There were no impairment losses related to the Company's intangible assets as of December 31, 2024 and 2023. Amortization expense for intangible assets for the years ended December 31, 2024, 2023 and 2022 was as follows:

	Years ended December 31,		
	2024	2023	2022
Research and development expense	\$ 3,319	\$ 986	\$ 7,813
Sales and marketing expense	798	155	116
General and administrative expense	213	61	540
Total	<u>\$ 4,330</u>	<u>\$ 1,202</u>	<u>\$ 8,469</u>

Intangible assets as of December 31, 2024 and 2023 consisted of the following:

	Average estimated useful lives (in years)	Gross carrying amount	Accumulated amortization	Net amount
December 31, 2024				
Developed technology	10	\$ 31,342	\$ 4,048	\$ 27,294
Licenses	10	159	159	—
Patents and websites	5	3,776	3,752	24
Customer relationships	4-10	2,799	1,447	1,352
Trade name	4	194	63	131
Commercials	3	494	282	212
Internally developed software	3	2,090	610	1,480
Total		<u>\$ 40,854</u>	<u>\$ 10,361</u>	<u>\$ 30,493</u>

	Average estimated useful lives (in years)	Gross carrying amount	Accumulated amortization	Net amount
December 31, 2023				
Developed technology	10	\$ 33,303	\$ 971	\$ 32,332
Licenses	10	185	185	—
Patents and websites	5	4,518	4,429	89
Customer relationships	4	2,974	1,372	1,602
Trade name	4	206	15	191
Commercials	3	494	117	377
Total		<u>\$ 41,680</u>	<u>\$ 7,089</u>	<u>\$ 34,591</u>

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

	December 31, 2024
2025	\$ 4,218
2026	4,087
2027	3,411
2028	3,289
2029	3,289
Thereafter	12,199
Total	<u>\$ 30,493</u>

5. Current liabilities

Accounts payable and accrued expenses as of December 31, 2024 and 2023 consisted of the following:

	December 31,	
	2024	2023
Accounts payable	\$ 16,616	\$ 13,454
Accrued inventory (in-transit and unvouchered receipts) and trade payables	6,917	10,054
Accrued loss on purchase commitments	672	2,057
Other accrued expenses	2,948	4,577
Total accounts payable and accrued expenses	<u>\$ 27,153</u>	<u>\$ 30,142</u>

Accrued payroll as of December 31, 2024 and 2023 consisted of the following:

	December 31,	
	2024	2023
Accrued bonuses	\$ 6,370	\$ 1,110
Accrued wages and other payroll related items	5,570	4,170
Accrued vacation	3,456	3,194
Accrued severance	1,429	2,284
Accrued employee stock purchase plan deductions	364	308
Total accrued payroll	<u>\$ 17,189</u>	<u>\$ 11,066</u>

6. Leases

The Company has entered into operating leases primarily for commercial buildings. These leases have terms which range from three years to 11 years, some of which include options to extend the leases for up to five years. Rent expense, including short-term lease cost, was \$4,227, \$4,017, and \$3,870 for the years ended December 31, 2024, 2023 and 2022, respectively. 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.

In July 2023, the Company entered into an Assignment and Assumption of Lease Agreement in which a third party, referred to as the Assignee, assumed the rights, title, and interest in the lease, including assumption of lease payments. As inducement for the Assignee to enter into the agreement, the Company paid an incentive of \$395, provided for four months of free rent for the period October 1, 2023 through January 31, 2024, and conveyed ownership of certain items of the facility's furniture and equipment. Commencing February 1, 2024 and ending May 31, 2031, the Assignee assumed responsibility for the monthly lease payments. Notwithstanding the Assignee's assumption of lease payments, Inogen remains the primary obligor under the lease to the landlord. The Assignee gained control to the facility on September 29, 2023, and related sublease income was not material.

Lease payments assumed by the Assignee are:

Payments due in the 12-month period ending December 31,

2025	\$ 1,136
2026	1,136
2027	1,136
2028	1,136
2029	1,136
Thereafter	1,609
	<u>\$ 7,289</u>

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

	Year ended December 31, 2024	Year ended December 31, 2023
Cash paid for operating lease liabilities	\$ 4,391	\$ 4,044
Operating lease cost	4,173	3,979
Non-cash right-of-use assets obtained in exchange for new operating lease obligations	1,838	1,781
Weighted-average remaining lease term	3.2 years	2.9 years
Weighted-average discount rate	5.7%	4.5%

Maturities of lease liabilities due in the 12-month period ending December 31,

2025	\$ 3,336
2026	3,649
2027	3,606
2028	3,179
2029	3,093
Thereafter	4,264
	21,127
Less imputed interest	(1,721)
Total lease liabilities	<u>\$ 19,406</u>
Operating lease liability - current	2,812
Operating lease liability - noncurrent	16,594
Total lease liabilities	<u>\$ 19,406</u>

7. Income taxes

The components of the Company's loss before provision (benefit) for income taxes are as follows:

	Years ended December 31,		
	2024	2023	2022
United States	\$ (29,143)	\$ (99,015)	\$ (84,422)
Foreign	(7,333)	(3,329)	1,154
Loss before provision for income taxes	<u>\$ (36,476)</u>	<u>\$ (102,344)</u>	<u>\$ (83,268)</u>

The provision (benefit) for income taxes consists of the following:

	Years ended December 31,		
	2024	2023	2022
Current tax expense			
State	\$ 16	\$ 229	\$ 201
Foreign	406	127	303
Total current tax expense	<u>422</u>	<u>356</u>	<u>504</u>
Deferred tax benefit			
Foreign	(1,010)	(251)	—
Provision (benefit) for income taxes	<u>\$ (588)</u>	<u>\$ 105</u>	<u>\$ 504</u>

The components of deferred tax assets and liabilities consist of the following:

Deferred tax assets (liabilities)	As of December 31,	
	2024	2023
Accrued expenses	\$ 11,167	\$ 10,121
Net operating loss and credit carryforward	43,309	41,195
Allowance, reserves and other	2,753	3,015
Stock-based compensation	5,368	5,809
Lease liability	4,601	5,098
Capitalized R&D under Sec 174	8,544	6,257
Deferred tax assets	75,742	71,495
Property, plant, and equipment	(6,799)	(8,806)
Intangible amortization	(5,018)	(6,528)
Right-of-use asset	(4,340)	(4,732)
Deferred tax liabilities	(16,157)	(20,066)
Valuation allowance	(66,533)	(59,968)
Total	<u>\$ (6,948)</u>	<u>\$ (8,539)</u>

Reconciliation of the federal statutory income tax rate to the effective income tax rate for the years ended December 31, 2024, 2023 and 2022 is as follows:

	Years ended December 31,		
	2024	2023	2022
U.S. Statutory rate	21.00%	21.00%	21.00%
State income taxes, net of federal benefit	1.54%	1.43%	3.53%
Stock-based compensation	-2.35%	-0.66%	-1.02%
R&D credit, net of reserve	1.58%	1.00%	1.32%
Change in fair value	-1.73%	-1.40%	3.88%
Nondeductible compensation	-0.83%	-0.09%	-1.50%
Valuation allowance	-17.83%	-14.80%	-27.75%
Goodwill impairment charge	—	-6.75%	—
Other	0.23%	0.17%	-0.07%
Effective income tax rate	<u>1.61%</u>	<u>-0.10%</u>	<u>-0.61%</u>

The Company operates in several taxing jurisdictions, including U.S. federal, multiple U.S. states, Netherlands, France and Germany. The statute of limitations has expired for all tax years prior to 2021 for federal and prior to 2017 for various state tax purposes. The statute of limitations has expired for all tax years prior to 2022 for France, prior to 2021 for Germany, and prior to 2020 for Netherlands 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, 2024, the Company had \$126,180, \$70,477 and \$15,189 of federal, state and foreign net operating loss carryforwards, respectively. Federal net operating loss carryforwards of \$118,384 have an indefinite life while the remaining federal and state net operating loss carryforwards begin to expire in 2034 and 2028, respectively, if not utilized. Foreign net operating loss carryforwards of \$15,189 also have an indefinite life. As of December 31, 2024, the Company had federal and California research and development credit carryforwards of \$7,471 and \$4,654, respectively. The federal credit will begin to expire in 2025; the California credit has indefinite carryforward. As of December 31, 2024, the Company had a federal foreign tax credit carryforward of \$774. The federal credit will begin to expire in 2027.

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 and foreign 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, 2024 and 2023, the Company determined that net deferred tax assets are not more likely than not realizable based on cumulative three-year pretax losses and recorded a full valuation allowance. The Company's valuation allowance may increase or decrease during the next 12 months based on future operating results. The increase in valuation allowance of \$6,565 is attributable to losses generated in the current year.

As of December 31, 2024, unremitted earnings of the subsidiaries outside of the United States were approximately \$6,552, on which no deferred tax liability has been recorded. The Company's intention is to indefinitely reinvest these earnings outside the United States. Upon distribution of those earnings in the form of a dividend or otherwise, the Company would be subject to both state income taxes and withholding taxes payable to various foreign countries. The amounts of such tax liabilities that might be payable upon repatriation of foreign earnings are not material.

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

Included in the balance of unrecognized tax benefits as of December 31, 2024, 2023 and 2022, were \$2,922, \$2,778 and \$2,366, 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:

Reconciliation of liability for unrecognized tax benefits	December 31,		
	2024	2023	2022
Balance at beginning of period	\$ 2,778	\$ 2,366	\$ 2,078
Additions based on tax positions related to current year	193	400	242
Reductions based on tax positions related to prior year	(82)	(34)	—
Additions based on tax positions related to prior year	33	46	46
Balance at end of period	<u>\$ 2,922</u>	<u>\$ 2,778</u>	<u>\$ 2,366</u>

8. Stockholders' equity

Common stock

Each share of common stock is entitled to one vote. The holders of common stock are also entitled to receive dividends whenever funds are legally available and when declared by the board of directors, subject to the prior rights of holders of 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, 2024 and 2023, 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, 2024, 2023 and 2022.

Stock incentive plans

The Company has a 2014 Equity Incentive Plan (2014 Plan) under which the Company granted restricted stock units, restricted stock awards, performance units, performance shares, and options to purchase shares of its common stock. As of December 31, 2024, awards with respect to 280,193 shares of the Company's common stock were outstanding.

The Company's stockholders approved the adoption of the Amended and Restated 2023 Equity Incentive Plan (2023 Plan) on June 5, 2024 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. The 2023 Plan became effective on June 7, 2024. The 2014 Plan terminated upon effectiveness of the 2023 Plan and no further awards will be made under the 2014 Plan, but the 2014 Plan will continue to govern awards previously granted under it. The number of shares of common stock reserved for issuance under the 2023 Plan was: (i) 1,600,000 shares, plus (ii) (A) 2,027,790 shares that, as of immediately before the termination or expiration of the 2014 Plan, had been reserved but not issued under any 2014 Plan awards and are not subject to any awards granted under the 2014 Plan, plus (B) any shares subject to awards granted under the 2014 Plan or the 2012 Plan that, after the 2014 Plan is terminated or expired, expire or otherwise terminate without having been exercised or issued in full or are forfeited to or repurchased by the Company due to failure to vest with the maximum number of shares that may be added to the 2023 Plan under subsection (ii) above equal to 2,950,000 shares.

As of December 31, 2024, awards with respect to 1,299,384 shares of the Company's common stock were outstanding, and 2,393,025 shares of common stock remained available for issuance under the 2023 Plan. The shares available for issuance under the 2023 Plan will be increased by any shares returned to the 2014 Plan as a result of expiration or termination of awards.

Pursuant to the Nasdaq inducement grant exception, during the year ended December 31, 2024, the Company issued 225,000 shares of common stock to a certain new hire issuable upon (i) the vesting of a maximum of 75,000 time-based restricted stock units granted, and (ii) the vesting of a maximum of 150,000 share of performance-based restricted stock units granted to induce the employee to accept employment with the Company in accordance with Nasdaq Listing Rule 5635(c)(4).

Stock options

Options typically expire between seven 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, 2024, 2023 and 2022 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, 2021	459,441	\$1.17-\$83.30	\$ 42.18	1.36	\$ 4.31
Exercised	(14,154)	1.17-8.37	3.14		
Forfeited	(15,417)	38.54-44.19	43.27		
Expired	(81,586)	38.54-43.21	40.08		
Outstanding as of December 31, 2022	<u>348,284</u>	<u>1.17-83.30</u>	<u>44.21</u>	<u>0.43</u>	<u>2.07</u>
Vested and exercisable as of December 31, 2022	348,284	1.17-83.30	44.21	0.43	2.07
Vested and expected to vest as of December 31, 2022	348,284	1.17-83.30	44.21	0.43	2.07
Outstanding as of December 31, 2022	348,284	1.17-83.30	44.21	0.43	2.07
Exercised	(54,432)	1.17-8.37	7.03		
Forfeited	(6,019)	8.37-44.19	32.92		
Expired	(267,833)	8.37-83.30	49.10		
Outstanding as of December 31, 2023	<u>20,000</u>	<u>83.30</u>	<u>83.30</u>	<u>0.36</u>	<u>—</u>
Vested and exercisable as of December 31, 2023	20,000	83.30	83.30	0.36	—
Vested and expected to vest as of December 31, 2023	20,000	83.30	83.30	0.36	—
Outstanding as of December 31, 2023	20,000	83.30	83.30	0.36	—
Forfeited	(10,000)	83.30	83.30		
Expired	(10,000)	83.30	83.30		
Outstanding as of December 31, 2024	<u>—</u>	<u>—</u>	<u>—</u>	<u>—</u>	<u>—</u>
Vested and exercisable as of December 31, 2024	—	—	—	—	—
Vested and expected to vest as of December 31, 2024	—	\$ —	\$ —	—	\$ —

The total intrinsic value of options exercised during the years ended December 31, 2024, 2023, and 2022 was \$0, \$735 and \$309, respectively. As of December 31, 2024, all stock-based compensation expense for options granted under the 2014 and 2023 Plans was recognized.

Stock incentive awards

The Company grants restricted stock units (RSUs) and restricted stock awards (RSAs) under the 2014 and 2023 Plans and made one inducement grant of RSUs in 2024 (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 market 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 three-year and four-year service periods, 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 and/or market conditions established at the time of the award. The portion of the Stock Award that is earned may equal or be more or 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, 2024, 2023 and 2022 is summarized below:

		Performance and time-based	Total	Weighted- average grant date fair value per share
Restricted stock units	Time-based			
Unvested restricted stock units as of December 31, 2021 ⁽¹⁾	289,166	99,112	388,278	\$ 54.81
Granted	769,976	164,722	934,698	29.76
Vested	(142,942)	(37,678)	(180,620)	55.04
Forfeited/canceled	(95,259)	(42,959)	(138,218)	45.10
Unvested restricted stock units as of December 31, 2022 ⁽¹⁾	<u>820,941</u>	<u>183,197</u>	<u>1,004,138</u>	\$ 32.72
Unvested and expected to vest restricted stock units outstanding as of December 31, 2022			840,413	\$ 32.37
Unvested restricted stock units as of December 31, 2022	820,941	183,197	1,004,138	\$ 32.72
Granted	1,214,144	621,990	1,836,134	12.29
Vested	(214,644)	(15,618)	(230,262)	35.68
Forfeited/canceled	(674,037)	(442,881)	(1,116,918)	23.62
Unvested restricted stock units as of December 31, 2023 ⁽¹⁾	<u>1,146,404</u>	<u>346,688</u>	<u>1,493,092</u>	\$ 14.67
Unvested and expected to vest restricted stock units outstanding as of December 31, 2023			1,159,877	\$ 14.79
Unvested restricted stock units as of December 31, 2023	1,146,404	346,688	1,493,092	\$ 14.67
Granted	890,300	587,768	1,478,068	7.28
Vested	(500,599)	—	(500,599)	15.70
Forfeited/canceled	(332,722)	(333,262)	(665,984)	14.09
Unvested restricted stock units as of December 31, 2024 ⁽¹⁾	<u>1,203,383</u>	<u>601,194</u>	<u>1,804,577</u>	\$ 8.61
Unvested and expected to vest restricted stock units outstanding as of December 31, 2024			1,381,787	\$ 8.65
		Performance and time-based	Total	Weighted- average grant date fair value per share
Restricted stock awards	Time-based			
Unvested restricted stock awards outstanding as of December 31, 2021 ⁽¹⁾	10,416	5,629	16,045	\$ 87.12
Vested	(4,496)	(5,629)	(10,125)	99.46
Forfeited/canceled	(5,134)	—	(5,134)	74.25
Unvested restricted stock awards outstanding as of December 31, 2022 ⁽¹⁾	<u>786</u>	<u>—</u>	<u>786</u>	\$ 59.55
Unvested and expected to vest restricted stock awards outstanding as of December 31, 2022			748	\$ 60.39
Unvested restricted stock awards outstanding as of December 31, 2022	786	—	786	\$ 59.55
Vested	(786)	—	(786)	59.55
Unvested restricted stock awards outstanding as of December 31, 2023 ⁽¹⁾	<u>—</u>	<u>—</u>	<u>—</u>	\$ —
Unvested and expected to vest restricted stock awards outstanding as of December 31, 2023			—	\$ —

(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, 2024, the unrecognized compensation cost related to unvested employee restricted stock units was \$7,478, excluding estimated forfeitures. This amount is expected to be recognized over a weighted average period of 1.7 years.

Employee stock purchase plan

The Company's 2014 Employee Stock Purchase Plan (ESPP) provides all eligible employees the option to purchase the Company's ordinary shares at a discount through payroll deductions. The expense recognized for shares purchased under the ESPP is equal to the 15% discount the employee receives. In 2024, employees purchased a total of 144,255 shares at an average price of \$5.62 per share. As of December 31, 2024, a total of 585,409 shares of common stock were available for future purchase under the ESPP. For 2024, an additional 179,069 shares were added to the ESPP share reserve.

Stock-based compensation

Stock-based compensation expense recognized for the years ended December 31, 2024, 2023 and 2022, was as follows:

Stock-based compensation expense by type of award:	Years ended December 31,		
	2024	2023	2022
Restricted stock units and restricted stock awards	\$ 6,941	\$ 7,037	\$ 11,748
Employee stock purchase plan	456	390	535
Total stock-based compensation expense	<u>\$ 7,397</u>	<u>\$ 7,427</u>	<u>\$ 12,283</u>

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, 2024, 2023 and 2022 has been reduced for estimate forfeitures of restricted stock at a rate of 8.3%, 5.3% and 4.1%, 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, 2024, 2023 and 2022, 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,		
	2024	2023	2022
Cost of revenue	\$ 579	\$ 540	\$ 1,127
Research and development	474	1,592	1,591
Sales and marketing	1,558	1,598	2,785
General and administrative	4,786	3,697	6,780
Total stock-based compensation expense	<u>\$ 7,397</u>	<u>\$ 7,427</u>	<u>\$ 12,283</u>

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 the employee stock purchase plan is determined at the grant date using the Black-Scholes option pricing model. During the years ended December 31, 2024, 2023 and 2022, 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.

	2024	2023	2022
Expected term (years)	0.50	0.50	0.50
Risk free interest rate	4.33-5.29%	3.51-5.36%	0.07-3.51%
Expected dividend yield	None	None	None
Volatility	52.85-95.80%	47.97-71.53%	47.97-59.21%

For the year ended December 31, 2024, the Company granted certain RSU awards based on achievement of the market condition total shareholder return (TSR) relative to an objectively selected group of industry peers over a three-year period, with payouts ranging from zero to 120 percent of the target award. The fair value of the TSR component of the awards was \$6.94 per share for the 2024 awards determined on the grant date using a Monte Carlo simulation model based on the following assumptions:

	2024
Expected term (years)	3.0
Dividend yield	—
Volatility factor	67.02%
Risk free interest rate	4.40%

9. Commitments and contingencies

Purchase obligations

The Company had approximately \$58,400 of outstanding purchase orders due within one year with its outside vendors and suppliers as of December 31, 2024. The Company has \$672 and \$2,057 accrued within accounts payable and other accrued expenses in the consolidated balance sheet as of December 31, 2024 and 2023, respectively, related to estimated losses for firm commitment contractual obligations under these agreements. Losses on these firm commitment contractual obligations are recognized based upon the terms of the respective agreement and similar factors considered for the write-down of inventory, including expected sales requirements as determined by internal sales forecasts.

Warranty obligation

The following table identifies the changes in the Company's aggregate product warranty liabilities for the years ended December 31, 2024, 2023 and 2022, respectively:

	December 31,		
	2024	2023	2022
Product warranty liability at beginning of period	\$ 23,478	\$ 19,913	\$ 13,726
Accruals for warranties issued	12,076	9,843	10,416
Adjustments related to preexisting warranties (including changes in estimates)	280	5,014	8,234
Settlements made (in cash or in kind)	(9,748)	(11,292)	(12,463)
Product warranty liability at end of period	<u>\$ 26,086</u>	<u>\$ 23,478</u>	<u>\$ 19,913</u>

During the years ended December 31, 2023 and 2022, the Company recorded \$5,014 and \$8,234 of changes in estimates related to preexisting warranties due to data and information that became available during those years. The changes in estimates were primarily due to the increased cost to repair for all products stemming from the current year inflationary environment and increased product failure rates.

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. Compliance with government 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 is not aware of any pending claims against it under the HIPAA and HITECH regulations that are applicable to the Company's business.

Legal proceedings

The Company is party to various legal proceedings and investigations 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.

10. Restructuring charges

For the year ended December 31, 2024, the Company had no restructuring costs. The Company incurred \$3,426 of restructuring costs during the year ended December 31, 2023, primarily in connection with the Company's cost reduction initiatives, which were recorded within general and administrative expense in the consolidated statements of comprehensive loss. The restructuring charges consisted primarily of severance and termination benefits. Other related costs consisted of targeted workforce reductions, office downsizing, centralizing manufacturing activities, and equipment relocation. The Company had \$0 and \$638 of accrued liabilities related to restructuring charges as of December 31, 2024 and 2023, respectively.

11. Foreign currency exchange contracts and hedging

As of December 31, 2024 and December 31, 2023, the Company's total non-designated and designated derivative contracts had notional amounts totaling approximately \$46,288 and \$0, respectively, and \$30,373 and \$0, respectively. These contracts were comprised of offsetting contracts with the same counterparty, each expires within one to two months. During the years ended December 31, 2024 and 2023, these contracts had, net of tax, an unrealized gain or loss of \$0 and during the year ended December 31, 2022, these contracts had, net of tax, an unrealized loss of \$1,140.

The nonperformance risk of the Company and the counterparty did not have a material impact on the fair value of the derivatives. During the year ended December 31, 2024 and December 31, 2023, there were no ineffective portions relating to these hedges and the hedges remained effective through their respective settlement dates. During the year ended December 31, 2022, there were three ineffective portions relating to these hedges. As of December 31, 2024 and December 31, 2023, the Company had no designated hedges and five non-designated hedges.

12. Segments

Operating segments are defined as components of an enterprise engaging in business activities for which separate financial information is available that is regularly evaluated by the Group's chief operating decision makers (CODM). Based on the criteria established by ASC 280 *Segment Reporting*, the Company's CODM has been identified as the executive leadership team (ELT), which includes the Chief Executive Officer, the Chief Financial Officer and several other members of the ELT. The ELT reviews a monthly executive reporting package based on consolidated results of the Company when making decisions about allocating resources and assessing performance. The Company derives revenues from customers through the development, manufacturing, marketing, sales, and rental of respiratory products. The Company considered the following when assessing its segment determination: the similar nature of the Company's products and services that are included together in the oxygen therapy and respiratory care markets; the consistent production processes used to manufacture the Company's products; the same channels used to distribute and sell the Company's products; and the products align and qualify as respiratory durable medical equipment per the regulatory definition. Therefore, the Company determined that it operates and reports in only one operating and reportable segment. The CODM assesses performance for the one operating and reportable segment and decides how to allocate resources based on the segment profit or loss measure and adjusted EBITDA. The measure of segment assets is reported on the balance sheet as "total assets." The CODM determined that the Company's segment profit or loss measure that is most consistent with GAAP measurement principles is net loss to evaluate income and loss generated from segment assets (return on assets). Net Loss for the Company's one operating and reportable segment is reported on the consolidated statements of comprehensive loss. The Company evaluated the monthly executive reporting package and did not identify any significant or other expenses for disclosure that are not already presented on the consolidated statements of comprehensive loss.

13. Subsequent Events

Collaboration Agreement

On January 25, 2025, the Company entered into a Strategic Collaboration Agreement (Collaboration Agreement) with Jiangsu Yuyue Medical Equipment & Supply Co., Ltd. (Yuwell). The collaboration with Yuwell is expected to broaden the Company's product portfolio through distribution of certain respiratory products in the United States and select other territories, expand and enhance Inogen's innovation pipeline through R&D collaboration, and accelerate the entry of the Company's brand into the Chinese market. The Collaboration Agreement will establish guidelines and principles relating to the parties' cooperation with respect to distribution, research and development, licensing, and supply chain optimization. The parties have also entered into two distribution arrangements whereby Inogen will distribute certain products supplied by Yuwell in the United States and specified European countries and Yuwell will distribute certain products supplied by the Company in specified Asia Pacific countries.

Securities Purchase Agreement

On January 25, 2025, the Company entered into a Securities Purchase Agreement (Purchase Agreement) with Yuwell (Hong Kong) Holdings Limited (Investor), a wholly-owned subsidiary of Jiangsu Yuyue Medical Equipment & Supply Co., Ltd., pursuant to which the Investor purchased 2,626,425 shares of the Company's common stock, at a price per share of \$10.36, for an aggregate purchase price of approximately \$27,210 (the Private Placement). The closing of the Private Placement took place on February 21, 2025.

Schedule II: Valuation and Qualifying Accounts

	Balance at Beginning of Year	Additions	Deletions	Balance at End of Year
Year ended December 31, 2024				
Allowance for doubtful accounts ⁽¹⁾	\$ 2,341	\$ 2,101	\$ 3,984	\$ 458
Allowance for sales returns ⁽²⁾	479	8,789	8,855	413
Allowance for rental asset loss ⁽³⁾	2,606	4,082	2,944	3,744
Year ended December 31, 2023				
Allowance for doubtful accounts ⁽¹⁾	\$ 77	\$ 2,273	\$ 9	\$ 2,341
Allowance for sales returns ⁽²⁾	483	8,457	8,461	479
Allowance for rental asset loss ⁽³⁾	2,255	3,290	2,939	2,606
Year ended December 31, 2022				
Allowance for doubtful accounts ⁽¹⁾	\$ 52	\$ 97	\$ 72	\$ 77
Allowance for sales returns ⁽²⁾	810	12,927	13,254	483
Allowance for rental asset loss ⁽³⁾	1,290	2,940	1,975	2,255

- (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.

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
2.2	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
2.3	Share Purchase Agreement dated July 10, 2023, by and among Inogen, Inc. and Mr. Adrien Mithalal, Mr. Jean-Sébastien Lantz, Mrs. Anne Reiser, CAAP Creation, Societe De Capital Risque Provencale Et Corse, Region Sud Investissement, Mérieux Participations 2, Relyens Innovation Santé and certain individual sellers identified herein.	8-K	2.1	07/13/23
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.	8-K	3.1	11/02/22
4.1	Specimen Common Stock Certificate of the Registrant.	S-1/A	4.1	01/16/14
4.2	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+	2014 Equity Incentive Plan.	S-1/A	10.6	01/28/14
10.3A+	Form of Stock Option Agreement under the 2014 Equity Incentive Plan.	10-Q	10.1	11/07/17
10.3B+	Form of Restricted Stock Unit Agreement – Time-Based under the 2014 Equity Incentive Plan.	10-Q	10.2	11/07/17
10.3C+	Form of Restricted Stock Unit Agreement – Performance-Based under the 2014 Equity Incentive Plan.	10-Q	10.3	11/07/17
10.3D+	Form of Restricted Stock Award Agreement – Time-Based under the 2014 Equity Incentive Plan.	10-Q	10.4	11/07/17
10.3E+	Form of Restricted Stock Award Agreement – Performance-Based under the 2014 Equity Incentive Plan.	10-Q	10.5	11/07/17
10.4+	2014 Employee Stock Purchase Plan.	S-1/A	10.8	01/28/14
10.5	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
10.6	Lease Agreement dated August 29, 2019, by and between the Company, and TCG Industrial Shiloh LLC.	10-Q	10.1	11/05/19
10.7	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
10.8+	Employment and Severance Agreement between the Company and Nabil Shabshab, dated January 22, 2021.	8-K	10.1	01/25/21
10.9	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

Exhibit Number	Description	Incorporated by Reference From Form	Incorporated by Reference From Exhibit Number	Date Filed
10.10+	Amended and Restated Employment and Severance Agreement, dated October 11, 2021, between the Company and Stanislav Glezer.	10-Q	10.4	11/04/21
10.11+	Amended and Restated 2023 Equity Incentive Plan.	8-K	10.1	06/07/24
10.11A+	Form of Stock Option Agreement under the Amended and Restated 2023 Equity Incentive Plan.	8-K	10.2	06/07/24
10.11B+	Form of Restricted Stock Unit Agreement (Time-Based) under the Amended and Restated 2023 Equity Incentive Plan.	8-K	10.3	06/07/24
10.11C+	Form of Restricted Stock Unit Agreement (Performance-Based) under the Amended and Restated 2023 Equity Incentive Plan.	8-K	10.4	06/07/24
10.12+	Outside Director Compensation Policy	Filed Herewith		
10.13	Assignment and Assumption of Lease Agreement dated July 13, 2023 between Inogen, Inc. and Sonos, Inc.	8-K	10.1	07/18/23
10.14+	Employment and Severance Agreement by and between the Company and Kevin R.M. Smith, dated November 10, 2023.	8-K	10.1	11/13/23
10.15+	Separation Agreement and Release by and between the Company and Nabil Shabshab, dated November 22, 2023.	8-K	10.1	11/27/23
10.16+	Employment and Severance Agreement by and between the Company and Michael Bourque, dated effective as March 4, 2024.	8-K	10.1	01/24/24
10.17+	Employment Contract by and between the Company and Grégoire Ramade, dated October 5, 2023	10-K	10.44	03/01/24
10.18+	Addendum No. 1 to the Employment Contract dated January 4, 2024, between the Company and Gregoire Ramade.	10-K	10.45	03/01/24
10.19+	Separation Agreement and Release by and between the Company and Stanislav Glezer, dated May 10, 2024	8-K	10.1	05/15/24
10.20+	Employment Contract by and between the Company and Kevin P. Smith, dated effective as of July 22, 2024	8-K	10.1	07/03/24
10.21+	Transition Agreement and Release by and between the Company and Jason M. Somer, dated July 26, 2024	8-K	10.1	07/31/24
10.22	Lease Agreement, dated July 27, 2023, by and between the Company and Townsgate Business Park 2, LLC and Majestic Luna 2, LLC, as tenants-in-common	10-Q	10.5	08/08/23
19.1	Inogen, Inc. Insider Trading Policy	Filed Herewith		
21.1	Subsidiaries of the Registrant	Filed Herewith		
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		
31.1	Certification of Principal 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		

Exhibit Number	Description	Incorporated by Reference From Form	Incorporated by Reference From Exhibit Number	Date Filed
31.2	Certification of Principal 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 Principal Executive Officer and Principal 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		
97.1	Inogen, Inc. Clawback Policy	10-K	97.1	03/01/24
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.			
101.SCH	Inline XBRL Taxonomy Extension Schema with Embedded Linkbase Documents.			
104	The cover page of this Annual Report on Form 10-K, formatted in inline XBRL.			

+ Indicates a management contract or compensatory plan.

~ 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)

Dated: February 28, 2025

By: /s/ Kevin R. M. Smith
Kevin R. M. Smith
Chief Executive Officer
President
Director
(Principal Executive Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Kevin R. M. Smith and Michael Bourque, 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
<u>/s/ Kevin R. M. Smith</u> Kevin R. M. Smith	Chief Executive Officer, President and Director (Principal Executive Officer)	February 28, 2025
<u>/s/ Michael Bourque</u> Michael Bourque	Chief Financial Officer (Principal Accounting and Financial Officer)	February 28, 2025
<u>/s/ Elizabeth Mora</u> Elizabeth Mora	Chairperson of the Board	February 28, 2025
<u>/s/ Glenn Boehnlein</u> Glenn Boehnlein	Director	February 28, 2025
<u>/s/ Kevin King</u> Kevin King	Director	February 28, 2025
<u>/s/ Mary Katherine Ladone</u> Mary Katherine Ladone	Director	February 28, 2025
<u>/s/ Heather Rider</u> Heather Rider	Director	February 28, 2025
<u>/s/ Mira Sahney</u> Mira Sahney	Director	February 28, 2025