

Inogen Inc
Form 10-K
April 27, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the Fiscal Year Ended December 31, 2014

OR

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

For the Transition Period From _____ to _____

Commission file number: 001-36309

INOGEN, INC.

(Exact name of registrant as specified in its charter)

Delaware 33-0989359
(State or other jurisdiction of (I.R.S. Employer
incorporation or organization) Identification No.)

326 Bollay Drive

93117

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Goleta, California
(Address of principal executive offices) (Zip Code))

(805) 562-0500

(Registrant’s telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class Name of each exchange on which registered
Common Stock, \$0.001 par value The 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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of the Registrant’s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company) Smaller reporting company

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 stock held by non-affiliates of the Registrant, based on the closing sale price of the Registrant’s common stock on the last business day of its most recently completed second

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fiscal quarter, as reported on The NASDAQ Global Select Market, was approximately \$135,071,367. Shares of common stock held by each executive officer and director and by each person who owns 5% or more of the outstanding common stock, based on filings with the Securities and Exchange Commission, have been excluded from this computation since such persons may be deemed affiliates of the Registrant. The determination of affiliate status for this purpose is not necessarily a conclusive determination for other purposes.

As of April 15, 2015, the registrant had 19,282,247 shares of common stock, par value \$0.001, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

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INOGEN, INC.

PART I

Forward-Looking Statements

The following discussion and analysis should be read together with our financial statements and the notes to those statements included elsewhere in this Form 10-K. This Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or 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 flow, revenue, sources of revenue and results of operations, operating and other expenses;
- our assessment of the impact from Competitive Bidding and the Centers for Medicare and Medicaid services rules;
- our ability to develop new products, including our fourth-generation portable oxygen concentrator, improve our existing products and increase the value of our products;
- market share expectations, unit sales, business strategies, financing plans, expansion of our business, competitive position, industry environment, potential growth opportunities;
- our expectations regarding the market size, market growth and the growth potential for our business;
- our ability to sustain and manage growth, including our ability to develop new products and enter new markets;
- our expectations regarding the average selling price and manufacturing costs of our products;
- the effects of seasonal trends on our results of operations;
- our expectations regarding our fourth-generation portable oxygen concentrator product; 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," "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. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

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. You should read this Annual Report on Form 10-K completely and with the understanding that our actual future results may be materially different from what we expect.

"Inogen," "Inogen One," "Inogen One G2," "Inogen One G3," "Oxygenation," "Live Life in Moments, not Minutes," "Never Run Out of Oxygen," "Oxygen Therapy on Your Terms," "Oxygen.Anytime.Anywhere," "Reclaim Your Independence," "Intelligent Delivery Technology," "Inogen At Home," and the Inogen design are trademarks or registered trademarks of Inogen, Inc. We have registered the trademark Inogen in Australia, Canada, China, South Korea, Mexico, and in Europe (European Community registration). We have registered the trademark Inogen One in Australia, Canada, China, South Korea, Mexico, and in Europe (European Community registration). We have registered the trademark

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Satellite Conserver in Canada, and China. We have registered the trademark Inogen At Home in Europe (European Community Registration). Other service marks, trademarks, and trade names referred to in this Annual Report on Form 10-K are the property of their respective owners.

In this Form 10-K, “we,” “us” and “our” refer to Inogen, Inc.

Unless otherwise specifically indicated, all amounts herein are expressed in thousands, except for share quantity, per share data, and unit counts. The following discussion of our financial condition and results of operations should be read together with our financial statements and the accompanying notes to those statements included elsewhere in this document. Also, forward-looking statements represent our management's beliefs and assumptions only as of the date of this Form 10-K.

ITEM 1. BUSINESS

General

We are a medical technology company that primarily develops, manufactures and markets innovative portable oxygen concentrators used to deliver supplemental long-term oxygen therapy to patients suffering from chronic respiratory conditions. Traditionally, these patients have relied on stationary oxygen concentrator systems for use in the home and oxygen tanks or cylinders for mobile use, which we call the delivery model. The tanks and cylinders must be delivered regularly and have a finite amount of oxygen, which requires patients to plan activities outside of their homes around delivery schedules and a finite oxygen supply. Additionally, patients must attach long, cumbersome tubing to their stationary concentrators simply to enable mobility within their homes. Our proprietary Inogen One systems concentrate the air around the patient to offer a single source of supplemental oxygen anytime, anywhere with a portable device weighing approximately 4.8 or 7.0 pounds. Our Inogen One G3 and G2 have up to 4.5 and 5 hours of battery life, respectively, with a single battery and can be plugged into an outlet when at home, in a car, or in a public place with outlets available. Our Inogen One systems reduce the patient's reliance on stationary concentrators and scheduled deliveries of tanks with a finite supply of oxygen, thereby improving patient quality of life and fostering mobility.

Although portable oxygen concentrators represent the fastest-growing segment of the Medicare oxygen therapy market, we estimate based on 2013 Medicare data that patients using portable oxygen concentrators represent approximately 5% to 7% of the total addressable oxygen market in the United States. Based on 2013 industry data, we believe we were the leading worldwide manufacturer of portable oxygen concentrators, as well as the largest provider of portable oxygen concentrators to Medicare patients, as measured by dollar volume. We believe we are the only manufacturer of portable oxygen concentrators that employs a direct-to-consumer strategy in the United States, meaning we market our products to patients, process their physician paperwork, provide clinical support as needed and bill Medicare or insurance on their behalf. To pursue a direct-to-consumer 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 that many rely on across their entire homecare business.

Since adopting our direct-to-consumer strategy in 2009 following our acquisition of Comfort Life Medical Supply, LLC, which had an active Medicare billing number but few other assets and limited business activities, we have directly sold or rented our Inogen One systems to more than 66,000 patients, growing our revenue from \$10.7 million in 2009 to \$112.5 million in 2014. In 2014, 22% of our revenue came from our international markets and 35% of our revenue came from oxygen rentals. Our net loss was \$2.6 million in 2009 transitioning to net income of \$6.8 million in 2014.

Our market

Overview of oxygen therapy market

We believe the current total addressable oxygen therapy market in the United States is approximately \$3 billion to \$4 billion, based on 2013 Medicare data and our estimate of the ratio of the Medicare market to the total market. We estimate that there are 2.5 to 3 million patients in the United States and more than 4.5 million patients worldwide use oxygen therapy, and more than 60% of oxygen therapy patients in the United States are covered by Medicare. The number of oxygen therapy patients in the United States is projected to grow by approximately 7% to 10% per year between 2013 and 2019, which we believe is the result of earlier diagnosis of chronic respiratory conditions, demographic trends and longer durations of long-term oxygen therapy.

Long-term oxygen therapy has been shown to be a cost-efficient and clinically effective means to treat hypoxemia, a condition in which patients have insufficient oxygen in the blood. Hypoxemic patients are unable to convert oxygen found in the air into the bloodstream in an efficient manner, causing organ damage and poor health. Chronic obstructive pulmonary disease, or COPD, is a leading cause of hypoxemia. Approximately 70% of our patient population has been diagnosed with COPD, which we believe is reflective of the long-term oxygen therapy market in general. Industry sources estimate that 24 million people in the United States suffer from COPD, of which one-half are undiagnosed.

According to our analysis of 2013 Medicare data, approximately two-thirds of U.S. oxygen users require ambulatory oxygen and the remaining one-third require only stationary or nocturnal oxygen. Clinical data has shown that ambulatory patients that use oxygen twenty-four hours a day, seven days a week, or 24/7, regardless of whether such patients rely on portable oxygen concentrators or the delivery model, have approximately two times the survival rate and spend at least 60% fewer days annually in the hospital than non-ambulatory 24/7 patients. The cost of one year of oxygen therapy is less than the cost of one day in the hospital. Of the ambulatory patients, we estimate that approximately 85% rely upon the delivery model, which has the following disadvantages:

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

Portable oxygen concentrators were developed in response to many of the limitations associated with traditional oxygen therapy. Portable oxygen concentrators are designed to offer a self-replenishing, unlimited supply of oxygen that is concentrated from the surrounding air and to operate without the need for oxygen tanks or regular oxygen deliveries, enhancing patient independence and mobility. Additionally, because portable oxygen concentrators do not require the physical infrastructure and service intensity of the delivery model, we believe portable oxygen concentrators can provide long-term oxygen therapy with a lower cost structure. Despite the ability of portable oxygen concentrators to address many of the shortcomings of traditional oxygen therapy, we estimate based on 2013 Medicare data that the amount spent by patients with portable oxygen concentrators represents approximately 5% to 7% of total oxygen therapy spend. We believe the following has hindered the market acceptance of portable oxygen concentrators:

- to obtain portable oxygen concentrators, patients are dependent on home medical equipment providers, which have made significant investments in the physical distribution infrastructure to support the delivery model and which we believe are therefore disincentivized to encourage adoption of portable oxygen concentrators;
- constrained manufacturing costs of conventional portable oxygen concentrators, driven by home medical equipment provider preference for products that have lower upfront equipment cost; and
- limitations of conventional portable oxygen concentrators, including bulkiness, poor reliability and lack of suitability beyond intermittent or travel use.

Our solution

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

- drive patient awareness of our portable oxygen concentrator through direct marketing, sidestepping the home medical equipment channel that other manufacturers rely upon across their homecare businesses, and that is incentivized to continue to service oxygen patients through the delivery model;

capture the manufacturer and home medical equipment provider margins, allowing us to focus on the total cost of the solution and to invest in the development of product features instead of being constrained by the price required to attract representation from a distribution channel. For example, we have invested in features that improve patient satisfaction, product durability, reliability and longevity, which increase the cost of our hardware, but reduce the total cost of our solution by reducing our maintenance and repair cost; and

· access and utilize direct patient feedback in our research and development efforts, allowing us to innovate based on this feedback and stay at the forefront of patient preference. For example, we have integrated a double battery into our product offering based on direct patient feedback.

We believe the combination of our direct-to-consumer strategy with our singular focus on designing and developing oxygen concentrator technology has created the best-in-class portfolio of portable oxygen concentrators. Our two current portable product offerings, the Inogen One G3 and Inogen One G2, at approximately 4.8 and 7.0 pounds, respectively, are amongst the most lightweight portable oxygen concentrators on the market. We believe our Inogen One solutions offer the following benefits:

- Single solution for home, ambulatory, travel (including on commercial aircraft) and nocturnal treatment. We believe our Inogen One solutions are the only portable oxygen concentrators marketed as a single solution, by which we mean a patient can use our Inogen One systems as their only supplemental oxygen source with no need to also use a stationary concentrator regularly. Our compressors are specifically designed to enable our patients to run our portable oxygen concentrators 24/7, whether powered by battery or plugged into an outlet at home or in a car while the battery is recharging.
- Reliability. We have made product performance a priority and have improved reliability with each generation. For example, we have introduced patented air-dryer and patent-pending user-replaceable sieve beds to our products, which have improved product performance and, as a result, patient satisfaction. Reliability is not only critical to patient satisfaction, but also cost management, as our minimal physical infrastructure makes product exchanges more costly to us than providers with greater local physical infrastructure.
- Effective for nocturnal use. Our Intelligent Delivery Technology enables our portable oxygen concentrators to provide consistent levels of oxygen during sleep despite decreased respiratory rates. As a result, patients can rely on the Inogen One G3 and Inogen One G2 portable oxygen concentrators overnight while sleeping.
- Unparalleled flow capacity. Our 4.8 pound Inogen One G3 has at least 50% more flow capacity than other sub-5 pound portable oxygen concentrators, and our 7.0 pound Inogen One G2 has at least 15% more flow capacity than other sub-10 pound portable oxygen concentrators.
- User friendly features. Our systems are designed with multiple user friendly features, including long battery life and low noise-levels in their respective weight categories.

Our Inogen One systems and Inogen At Home system

We market our current portable product offerings, the Inogen One G3 and the Inogen One G2, as single solutions for oxygen therapy. This means our solutions can operate on a 24/7 basis for at least 60 months without a stationary concentrator. We believe the technology in our Inogen One G3 and our Inogen One G2 is effective for nocturnal use. Our Inogen One G2 and the Inogen One G3 are sub-5 and sub-10 pound portable oxygen concentrators that can operate reliably and cost-effectively over the long period of time needed to service oxygen therapy patients without supplemental use of a stationary concentrator or a replacement portable oxygen concentrator. The following table summarizes our key product features:

	Key Product Specifications	
	Inogen One G3	Inogen One G2
Capacity (ml/min)	840	1,260
Weight (lbs)	4.8 (single battery) 5.8 (double battery)	7.0 (single battery) 8.4 (double battery)
Battery run-time	Up to 4.5 hours (single battery) Up to 9.0 hours (double battery)	Up to 5 hours (single battery) Up to 10 hours (double battery)
Maintenance prevention advantages	User replaceable oxygen filtration cartridges & battery	Air dryer & user replaceable battery
Technology effective for overnight use	Yes	Yes
Sound	42 dBA	38 dBA

We have focused our research and development efforts on creating solutions that we believe have overcome the reputation of portable oxygen concentrators as being limited in durability and reliability as well as unsuitable for nighttime or 24/7 use. We specifically designed our compressors for 24/7 use. We have worked to improve our reliability and reduce service costs by equipping our portable oxygen concentrators with features such as membrane air dryers and user replaceable filtration cartridges.

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

The Inogen One G3, our latest portable oxygen concentrator released to market in September 2012, is among the most lightweight products on the market with substantially higher oxygen production capabilities than the other sub-5 pound portable oxygen concentrators on the market. We believe the performance parameters around the Inogen One G3 and Inogen One G2 allow us to serve approximately 95% of the ambulatory oxygen patients and enable us to address a patient's particular clinical needs, as well as lifestyle and performance preferences.

The Inogen At Home stationary oxygen concentrator allows us to access the non-ambulatory patient market and serves as a backup to our Inogen One system for ambulatory patients. We currently provide a backup source of oxygen to our patients who are able to elect either a stationary concentrator or oxygen tank as their backup source.

We believe the Inogen At Home concentrator is the lightest five liter per minute continuous flow oxygen concentrator on the market today. At approximately 18 pounds, the Inogen At Home concentrator is lighter than current oxygen concentrators from leading manufacturers with equivalent flow capacity. Additionally, the Inogen At Home product has low power consumption with worldwide electrical compatibility, which should reduce the cost of electricity for oxygen therapy patients, as well as reduces manufacturing and distribution complexities. While the Inogen One product line is clinically validated for 24/7 use, the Inogen At Home represents a compelling solution for nocturnal-only oxygen therapy patients that do not yet require a portable solution, which are estimated to represent greater than 30% of total oxygen patients in the United States.

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

Sales and marketing

Our direct-to-consumer sales and marketing efforts are focused on generating awareness and demand for our Inogen One systems and Inogen At Home systems among patients, physicians and other clinicians, and third-party payors. As of December 31, 2014 we employed a marketing team of 6 people, an in-house sales team of 144 people, and a field-based sales force of 17 people, each based in the United States. Of the \$88.1 million of our 2014 revenue derived from the United States, approximately 45% represented direct-to-patient rentals, 33% represented cash pay sales to patients and 22% represented sales to third-party home medical equipment providers.

Patients who choose to use their Medicare or private insurance benefits rent our systems, while those who purchase our product outright are typically not eligible to use their insurance benefits due to their capped rental status, or chose to purchase because the patient prefers to own the equipment, or the patient has an upcoming trip where they have an immediate need for our product that cannot be processed in time. Our ability to rent to Medicare patients directly, bill Medicare and other third-party payors on their behalf, and service patients in their homes requires that we hold a valid Medicare supplier number, are accredited by an independent agency approved by Medicare, and comply with the differing licensure and process requirements in the 49 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 on a physician's order. The below chart describes our United States direct-to-consumer sales and rental process.

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

Concentration of Customers

We sell our products to home medical equipment providers in the United States and in foreign countries on a credit basis. No single customer represented more than 10% of our total revenue for 2014 and 2013. In 2012 one customer accounted for 12% of our total revenue.

We also rent products directly to patients, which results in a customer concentration relating to Medicare's service reimbursement programs. Medicare's service reimbursement programs (net of patient co-insurance obligations) accounted for 76%, 73% and 66% of rental revenue in 2014, 2013 and 2012, respectively, and based on total revenue were 27%, 29% and 27% for 2014, 2013 and 2012, respectively. Accounts receivable balances relating to Medicare's service reimbursement programs amounted to \$4,875 or 25% of total accounts receivable at December 31, 2014, \$2,560 or 25% of total accounts receivable at December 31, 2013 and \$3,043 or 33% of total accounts receivable at December 31, 2012.

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

International

Approximately 22% of our sales were from outside the United States in 2014. We sell our products in 44 countries outside the United States through distributors or directly to large “house” accounts, which include gas companies and home oxygen providers. In this case, we sell to and bill the distributor or “house” accounts directly, leaving the patient billing, support, and clinical setup to the local provider. As of December 31, 2014, we had 5 people who focused on selling our products to distributors and “house” accounts worldwide. No single international customer represented more than 10% of our total revenue in 2014 or 2013.

International sales have been a rapidly growing portion of our business, and we estimate there are 2 million long-term oxygen therapy patients outside of the United States. We believe that the international market is attractive for the following reasons:

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

We will continue to focus on building out our international sales efforts.

Customer support and order fulfillment

Our procedures enable us to package and ship a system directly to the patient in the patient’s preferred configuration the same day the order is received in most cases. This enables us to minimize the amount of finished goods inventory we keep on hand. Our primary logistics partner is United Parcel Service, or UPS, and FedEx. UPS supports our domestic shipments and provides additional services that support our direct-to-consumer oxygen therapy program. The UPS pick up service is used to retrieve patient paperwork, products requiring repair and systems that are no longer needed by the patient. Additionally, UPS, when necessary and requested by us, will go into a patient’s home to remove a replacement product from the box, box the failed device and return it to us. In this manner, we are able to operate as a remote provider while maintaining the level of customer service of a local oxygen therapy provider. FedEx supports our international shipments.

We believe it is important to provide patients with the highest quality customer support to achieve satisfaction with our products and optimal outcomes. As of December 31, 2014, we had a dedicated client service team of 21 people who were trained on our products, a clinical support team of 17 people who were licensed nurses or respiratory therapists, and a dedicated billing services team of 52 people. We provide our patients with a dedicated 24/7 hotline that is only given to our patients and is not published publicly. Via the hotline, patients have direct access to our client services representatives, who can handle product-related questions. Additionally, clinical staff is on call 24/7 and available to patients whenever either the patient or the client services representative deems appropriate. 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 provide high-quality customer service to enhance patient comfort, satisfaction, compliance, and safety with our products. We believe our focus on providing the highest level of customer service has helped drive our sustained patient satisfaction rating of approximately 95%.

Third-party reimbursement

Medicare or private insurance rentals represented approximately 35% of our revenue in 2014. In cases where we rent our oxygen therapy solutions directly to patients, we bill third-party payors, such as Medicare or private insurance, for monthly rentals on behalf of our patients. We process and coordinate all physician paperwork necessary for reimbursement of our solutions. A common medical criterion for oxygen therapy reimbursement is insufficient blood oxygen saturation level. Our team in sales and sales administration 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. As of December 31, 2014, our direct to consumer inside sales administration groups consisted of 144 people.

We are authorized by Medicare to bill for oxygen therapy, and we believe that more than 60% of oxygen therapy patients have Medicare coverage. Our Inogen One systems are reimbursed under HCPCS codes E1390 and E1392. Our Inogen At Home system is reimbursed under HCPCS code E1390. E1390 covers stationary/nocturnal oxygen therapy systems, while E1392 provides additional reimbursement for portable oxygen concentrators for the treatment of ambulatory patients. Even though E1390 is a stationary oxygen code, we bill under both the E1390 and E1392 codes for our portable oxygen concentrators, assuming that the patient qualifies for portable oxygen, as well as stationary oxygen. Only in the event the patient solely qualifies for portable oxygen would we exclusively bill under the E1392 code, which is not typical. Currently, Medicare reimburses oxygen therapy as a monthly rental for up to 36 months. We retain equipment ownership at all times. After 36 months, payment is “capped,” meaning the monthly payment amounts are discontinued. After two additional years or another qualifying event, the patient is eligible for replacement equipment and a new capped rental period.

As of January 1, 2011, Medicare has phased in a program called competitive bidding. Competitive bidding impacts the amount Medicare pays suppliers for durable medical equipment, including portable oxygen concentrators. The program is defined geographically, with suppliers submitting bids to provide medical equipment for a specific product category within that geography. Once bids have been placed, an individual company’s bids across products within the category are aggregated and weighted by each product’s market share in the category. The weighted average price is then indexed against competitors. Medicare determines a “clearing price” out of these weighted average prices at which sufficient suppliers have indicated they will support patients in the category, and this threshold is typically designed to have theoretical supply two times greater than expected demand. Bids for each modality among the suppliers that made the cut are then arrayed to determine what Medicare will reimburse for each product category. The program has strict anti-collusion guidelines to ensure bidding is truly competitive. Competitive bidding contracts last up to three years once implemented, after which they are subject to re-bidding.

The competitive bidding program effectively reduces the number of oxygen suppliers that can participate in the Medicare program. We believe that more than 75% of existing oxygen suppliers were eliminated in round one of competitive bidding implemented January 1, 2011 in 9 U.S. Metropolitan Statistical Areas. Round two of competitive bidding was implemented July 1, 2013 in 91 U.S. Metropolitan Statistical Areas and we believe the impact on the number of oxygen suppliers will be similar when released. Combined with the round one of competitive bidding, we believe that approximately 59% of the market was covered by round one and two. The following table sets forth the current standard Medicare reimbursement rates and the weighted average of reimbursement rates applicable in Metropolitan Statistical Areas covered by rounds one and two of competitive bidding. The round one re-compete was completed in the same Metropolitan Statistical Areas as round one for the next three year period starting January 1, 2014 when the original contracts expire. Reimbursement rates under the Medicare competitive bidding program have been in the mid \$130s per month since mid-2013.

	Medicare standard allowable effective	Round one weighted average 1/1/11-12/31/13	Round two weighted average 7/1/13-6/30/16	Round one re-compete weighted average 1/1/14-12/31/16
E1390	\$ 180.92	\$ 116.16	\$ 93.07	\$ 95.74
E1392	51.63	41.89	42.72	38.08
Total	\$ 232.55	\$ 158.05	\$ 135.79	\$ 133.82
% of standard		68	% 58	% 58

In October 2014, the Centers for Medicare and Medicaid services released a ruling that sets forth methodologies to adjust the fee schedule amounts for items subject to competitive bidding in areas where competitive bidding is not implemented. The ruling applies rate reductions to all un-bid areas instead of doing an additional bidding process. The fee schedules in the un-bid areas will be adjusted based on regional averages of the single payment amounts for areas already under competitive bidding. The regional prices would be limited by a national ceiling (110% of the average of the regional prices) and a floor (90% of the average regional prices). The regions are defined as follows:

Region Name	States Covered
Far West	CA, NV, OR, WA
Great Lakes	IL, IN, MI, OH, WI
Mideast	DC, DE, MD, NJ, NY, PA
New England	CT, MA, NH, RI
Plains	IA, KS, MN, MO, NE
Rocky Mountain	CO, ID, UT
Southeast	AL, AR, FL, GA, KY, LA, NC, SC, TN, VA
Southwest	AZ, NM, OK, TX

The Centers for Medicare and Medicaid defines frontier states as states where more than 50% of the counties in the state have a population density of 6 people or less per square mile and rural states are defined as states where more than 50% of the population lives in rural areas per census data. Current frontier states include MT, ND, SD and WY; rural states include ME, MS, VT and WV; and non-contiguous United States areas include AK, HI, Guam and Puerto Rico. For frontier and rural states, and frontier and rural zip codes in non-frontier/rural states, the single payment amount will be the national ceiling (110% of the average of the regional prices) to account for higher servicing costs in these areas. For non-contiguous United States areas, single payment amounts will be the higher of the national ceiling, or the average of competitive bidding pricing from these areas, if the areas had been bid through competitive bidding.

While we are monitoring the implementation of this ruling, we believe that the net effect of the ruling would be an approximately 3-4% headwind to 2016 total revenue since this pricing will be applied partially from January 1, 2016 to June 30, 2016 and completely starting July 1, 2016.

The Centers for Medicare and Medicaid Services accepted bids through March 26, 2015 for competitive bidding round two re-compete, associated with approximately 50% of the market with contracts set to begin July 1, 2016 and continue through December 31, 2018. The Centers for Medicare and Medicaid Services updated the product categories and the competitive bidding areas. Respiratory equipment includes oxygen, oxygen equipment, continuous positive airway pressure devices, respiratory assist devices and related supplies and accessories. Nebulizers are now their own separate product category instead of being included in the respiratory equipment category. Round two re-compete is in the same geographic areas that were included in the original round two. However, as a result of the Office of Management and Budget's updates to the original 91 round two metropolitan statistical areas, there are now 90 metropolitan statistical areas for round two re-compete and 117 competitive bidding areas (CBAs). Any CBA that was previously located in multi-state metropolitan statistical areas was redefined so that no CBA is included in more than one state. The round two re-compete competitive bidding areas have nearly the same ZIP codes as the round two competitive bidding areas; the associated changes in the zip codes since competitive bidding was implemented are reflective in this round two re-compete.

On March 17, 2015 the House of Representatives approved the Medicare DMEPOS (Durable Medical Equipment, Prosthetics, Orthotics and Supplies) Competitive Bidding Improvement Act of 2015 which would require Medicare suppliers that bid under the DMEPOS competitive bidding program to obtain a \$50,000 to \$100,000 bid surety bond for each competitive bidding area (CBA). The bill is intended to prevent suppliers from submitting not-binding, “low-ball” bids that artificially drive down prices and jeopardize beneficiary access to equipment. If the supplier bids lower than the median composite bid rate and does not accept a contract for a CBA, the bid bond would be forfeited. The bill also would codify that competitive bidding contracts can only be awarded to suppliers that meet applicable state licensure requirements. On April 14, 2015, this bill was passed by the Senate and then signed by President Obama into law on April 16, 2015, thus we will incur additional expense to obtain the appropriate surety bonds in the CBAs where we win contracts. There are currently 9 CBAs under contract in round 1 re-compete and 117 CBAs under contract in round 2 re-compete. CBAs are defined by Medicare and are subject to change at each new bidding period. This cost is not expected to be material to our financial results.

As of December 31, 2014, we had contracts with 63 non-Medicare payors. These contracts enable us to become an in-network provider for these payors, which enables patients to use our systems at the same cost as other in-network solutions, including the delivery model. Based on our patient population, we believe non-Medicare payors represent at least 30% of all oxygen therapy patients. We believe that private payor reimbursement levels will generally be reset in accordance with Medicare reimbursement level determined by competitive bidding.

We cannot predict the extent to which reimbursement for our products will be affected by competitive bidding or by initiatives to reduce costs for private payors. The unavailability of third-party coverage or inadequacy of reimbursement for our current or future products would adversely affect our business, financial conditions, and results of operations.

Manufacturing

We have been developing and refining the manufacturing of our Inogen One systems over the past ten years. While nearly all of our manufacturing and assembly process was originally outsourced, assembly of the manifold, compressor, sieve bed and concentrator is now conducted in-house in order to improve quality control and reduce cost. Additionally, we use lean manufacturing practices to maximize our manufacturing efficiency. Bringing manufacturing and assembly largely in-house, combined with improvements in our manufacturing processes, has enabled us to reduce our cost of revenue per system by 40% from 2009 to 2014.

We rely on third party manufacturers to supply several components of our Inogen One systems and Inogen At Home systems. We typically enter into supply agreements for these components that specify quantity, quality requirements, and delivery terms, which, in certain cases, can be terminated by either party upon relatively short notice. We have elected to source certain key components from single sources of supply, including our batteries, bearings, carry bags, motors, pistons, valves, and molded plastic components. While alternative sources of supply are readily available for these components, we believe that maintaining a single-source of supply allows us to control production costs and inventory levels, and to manage component quality. In order to mitigate against the risks related to a single-source of supply, we qualify alternative suppliers and develop contingency plans for responding to disruptions. If any single-source supplier were no longer able to supply a component, we believe we would be able to promptly and cost-effectively switch to an alternative supplier without a significant disruption to our business and operations. We have adopted additional contingency plans to protect against an immediate disruption in supply of our battery and motor components, and any potential delay that may result from a switch to a new supplier. These contingency plans include our own inventory management, along with a requirement that each supplier maintain specified quantities of inventory in multiple locations, and our maintenance of back-up tooling that can easily be transferred to a new supplier. We believe that these contingency plans would limit any disruption to our business in the event of an immediate termination of either our battery or motor supply.

We currently manufacture in two leased buildings in Goleta, California and Richardson, Texas, that we have registered with the Federal Drug and Administration, or FDA, and for which we have obtained International Standards Organization, or ISO, 13485 certification. The Goleta, California facility is approximately 39,000 square feet. A subset is used for manufacturing activities in the Goleta facility. The Richardson, Texas manufacturing facility is approximately 24,000 square feet. Because we have two separate manufacturing facilities, in the event one facility is incapacitated, the other facility will enable us to continue manufacturing our products to meet our current level of demand. We believe we have sufficient capacity to meet anticipated demand.

Our entire organization is responsible for quality management. Our Quality Assurance department oversees this by tracking component, device and organization performance and by training team members outside the Quality Assurance department 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 Quality Assurance department also trains internal auditors to audit our adherence to the Quality Management system. Our Quality Management system has been certified to International Standards Organization, or ISO, 13485:2012 by Intertek, a Notified Body to ISO.

As a medical device manufacturer, our manufacturing facilities are subject to periodic inspection by the FDA and certain corresponding state agencies. We have been audited three times since April 2012 by the FDA and found to be in compliance with Good Manufacturing Practices guidelines. We have completed three surveillance audits and one certification audit by our notifying body over the same period and identified one minor non-conformance, which was addressed through implementation of new training software.

As of December 31, 2014, we had 93 employees in operations, manufacturing, quality assurance and repair.

Research and development

We are committed to ongoing research and development to stay at the forefront of patient preference in the oxygen concentrator field. As of December 31, 2014, our research and development staff included 19 engineers and scientists with expertise in air separation, compressors, pneumatics, electronics, embedded software, mechanical design, sensors and manufacturing technologies. Our current research and development efforts are focused primarily on increasing functionality, improving design for ease-of-use, and reducing production costs of our Inogen One systems and Inogen At Home systems, as well as development of our next-generation oxygen concentrators. Over the last 3 fiscal years, Inogen has invested over \$7.7 million to efficiently bring two new generations of portable oxygen concentrators and the first generation stationary oxygen concentrator to market (\$3.0, \$2.4 and \$2.3 million for the years ended 2014, 2013 and 2012), leveraging our 27 issued U.S. patents and one Canadian patent while also reducing the product manufacturing costs 40% from 2009 to 2014.

Utilizing lean product development methodologies, we have released four products over the last 10 years, including our Inogen One G1 in October 2004, our Inogen One G2 in March 2010, and our Inogen One G3 in September 2012 and our Inogen At Home system in October 2014. Our dedication to continuous improvement has also resulted in three mid-cycle product updates and numerous incremental improvements. Development projects utilize a combination of rapid prototyping and accelerated life testing methods to ensure products are taken from concept to commercialization in a fast and capital efficient manner. We leverage our direct patient expertise to rapidly gain insight from end users and to identify areas of innovation that we believe will lead to higher-quality products and lower total cost of ownership for its products.

Our product pipeline consists of our fourth generation, ultra-lightweight portable oxygen concentrator. Our fourth-generation portable oxygen concentrator will be smaller and lighter and less expensive to manufacture than our Inogen One G3 and we expect to commercialize this product in 2016. Additionally, we continue to focus our efforts on other design and functionality improvements that enhance patient quality of life.

Competition

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

Our significant manufacturing competitors are Invacare Corporation, Respironics (a subsidiary of Koninklijke Philips N.V.), AirSep Corporation and SeQual Technologies (subsidiaries of Chart Industries, Inc.), Inova Labs, Inc. and DeVilbiss Healthcare. Given the relatively low barriers to entry in the oxygen therapy device manufacturing market, we expect that the industry will become increasingly competitive in the future. Manufacturing companies compete for sales to providers primarily on the basis of product features, service and price. We believe that we compete favorably with respect to these factors, due to our manufacturing competitors' complete reliance on home medical equipment distribution, which compresses their margins and limits their ability to invest in product features that address consumer preferences. To pursue a direct-to-consumer 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 directly with the home medical equipment providers that many rely on across their entire homecare businesses. For our two largest medical device competitors, the entire oxygen business for each, including stationary and transfilling concentrators, represents less than 14% percent of each of their billion-dollar plus homecare businesses in 2013.

Lincare Inc., Apria Healthcare, Inc. Rotech Healthcare, Inc. and American HomePatient, Inc. have been among the market leaders in providing oxygen therapy for many years, while the remaining oxygen therapy market is serviced by

local providers. Because many oxygen therapy providers were either excluded from contracts in the Medicare competitive bidding process, or will have difficulty providing service at the prevailing Medicare reimbursement rates, we expect more industry consolidation. Oxygen 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. We believe that the investment made by oxygen therapy providers in the physical distribution required for oxygen delivery limits their ability to easily switch their business model and employ a solution directly competitive to Inogen.

Some of our competitors are large, well-capitalized companies with significantly greater resources than we have. As a consequence, 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 relations 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 or other incentives to gain a competitive advantage;
- greater history in conducting research and development, manufacturing, marketing and obtaining regulatory approval for oxygen device products; and
- greater financial and human resources for product development, sales and marketing, patent litigation and customer financing.

As a result, our competitors may be able to respond more quickly and effectively than we can to new or changing opportunities, technologies, standards or customer requirements. 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, 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, if any, margins and market share.

Government regulation

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

FDA's pre-market clearance and approval requirements

Unless an exemption applies, each medical device we seek to commercially distribute in the United States will require either a prior Section 510(k) of the Food, Drug and Cosmetic Act, or 501(k) clearance or a pre-market approval from the FDA. Medical devices are classified into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of control needed to ensure safety and effectiveness. Devices deemed to pose lower risks are placed in either Class I or II, which requires the manufacturer to submit to the FDA a premarket notification requesting permission to commercially distribute the device. This process is generally known as 510(k) clearance. Some low risk devices are exempted from this requirement. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously cleared 510(k) device, are placed in Class III, requiring premarket approval.

510(k) clearance pathway

When a 510(k) clearance is required, we must submit a premarket notification to the FDA demonstrating that our proposed device is substantially equivalent to a previously cleared and legally marketed 510(k) device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of a pre-market approval application. By regulation, the FDA is required to clear or deny a 510(k) premarket notification within 90 days of submission of the application. As a practical matter, clearance often takes significantly longer. The FDA may require further information, including clinical data, to make a determination regarding substantial

equivalence. If the FDA determines that the device, or its intended use, is not substantially equivalent to a previously-cleared device or use, the FDA will place the device, or the particular use, into Class III. We obtained 510(k) clearance for the original Inogen One system on May 13, 2004. We market the Inogen One G2 and G3 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.

Pre-market approval pathway

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

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

Clinical trials

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

Pervasive and ongoing regulation by the FDA

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

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

After a device receives 510(k) clearance or a pre-market approval, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, will require a new clearance or approval. The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with a manufacturer’s determination. We have modified various aspects of our Inogen One systems since receiving regulatory clearance, but we believe that new 510(k) clearances are not required for these modifications. If the FDA disagrees with our determination not to seek a new 510(k) clearance, the FDA may

retroactively require us to seek 510(k) clearance or pre-market approval. The FDA could also require us to cease marketing and distribution and/or recall the modified device until 510(k) clearance or pre-market approval is obtained. Also, in these circumstances, we may be subject to significant regulatory fines and penalties.

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

As a medical device manufacturer, our manufacturing facilities are subject to periodic inspection by the FDA and certain corresponding state agencies. We have been audited three times since April 2012 by the FDA and found to be in compliance with Good Manufacturing Practices guidelines. We have completed three surveillance audits and one certification audit by our notifying body over the same period and identified one minor non-conformance, which was addressed through implementation of new training software.

International sales of medical devices are subject to foreign government regulations, 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, 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

In April 2009, we became a Durable, Medical Equipment, Prosthetics, Orthotics, and Supplies accredited Medicare supplier by 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 through passage of an on-site inspection. Our current accreditation with Medicare is due to expire in May 2015. Several states require that durable medical equipment providers be licensed in order to sell products to patients in that state. Certain of these states require that durable medical equipment providers maintain an in-state location. Most of our state licenses are renewed on an annual or bi-annual basis. Although we believe we are in compliance with all applicable state regulations regarding licensure requirements, if we were found to be noncompliant, we could lose our licensure in that state, which could prohibit us from selling our current or future products to patients in that state. In addition, we are subject to certain state laws regarding professional licensure. We believe that our certified clinicians are in compliance with all such 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.

Federal anti-kickback and self-referral laws

The Federal Anti-Kickback Statute prohibits the knowing and willful offer, payment, solicitation or receipt of any form of remuneration in return for, or to induce the:

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

The Federal Anti-Kickback Statute applies to our arrangements with sales representatives, customers and health care providers, as well as certain coding and billing information that we may provide to purchasers of our Inogen One and Inogen At Home systems. Although we believe that we have structured such arrangements to be in compliance with the Anti-Kickback Statute and other applicable laws, regulatory authorities may determine otherwise. Noncompliance with the federal anti-kickback statute can result in exclusion from Medicare, Medicaid or other governmental 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 a provision commonly known as the “Stark Law,” which prohibits a physician from referring Medicare or Medicaid patients to an entity providing “designated health services,” including a company that furnishes durable medical equipment, in which the physician has an ownership or investment interest or with which the physician has entered into a compensation arrangement. Violation of the Stark Law could result in denial of payment, disgorgement of reimbursements received under a noncompliant arrangement, civil penalties, and exclusion from

Medicare, Medicaid or other governmental programs. Although we believe that we have structured our provider arrangements to comply with current Stark Law requirements, these arrangements may not expressly meet the requirements for applicable exceptions from the law.

Additionally, as some of these laws are still evolving, we lack definitive guidance as to the application of certain key aspects of these laws as they relate to our arrangements with providers with respect to patient training. We cannot predict the final form that these regulations will take or the effect that the final regulations will have on us. As a result, our provider arrangements may ultimately be found to be not in compliance with applicable federal law.

Federal False Claims Act

The Federal False Claims Act provides, in part, that the federal government may bring a lawsuit against any person whom it believes has knowingly presented, or caused to be presented, a false or fraudulent request for payment from the federal government, or who has made a false statement or used a false record to get a claim approved. In addition, amendments in 1986 to the Federal False Claims Act have made it easier for private parties to bring “qui tam” whistleblower lawsuits against companies. Although we believe that we are in compliance with the federal government’s laws and regulations, if we are found in violation of these laws, penalties include fines ranging from \$5,500 to \$11,000 for each false claim, plus three times the amount of damages that the federal government sustained because of the act. We believe that we are in compliance with the federal government’s laws and regulations concerning the filing of reimbursement claims.

Civil monetary penalties law

The Federal Civil Monetary Penalties Law prohibits the offering or transferring of remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary’s selection of a particular supplier of Medicare or Medicaid payable items or services. We sometimes offer customers various discounts and other financial incentives in connection with the sales of our products. While it is our intent to comply with all applicable laws, the government may find that our marketing activities violate the Civil Monetary Penalties Law. If we are found to be in noncompliance, we could be subject to civil monetary penalties of up to \$10,000 for each wrongful act, assessment of three times the amount claimed for each item or service and exclusion from the Federal healthcare programs. In addition, to the extent we are found to not be in compliance, we may be required to curtail or restructure our operations. Any penalties, damages, fines, exclusions, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results.

State fraud and abuse provisions

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

HIPAA

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

In 2009, Congress passed the American Recovery and Reinvestment Act of 2009, or ARRA, which included sweeping changes to HIPAA, including an expansion of HIPAA’s privacy and security standards. ARRA includes HITECH, which, among other things, made HIPAA’s privacy and security standards directly applicable to business associates of covered entities effective February 17, 2010. A business associate is a person or entity that performs certain functions or activities on behalf of a covered entity that involve the use or disclosure of protected health information in

connection with recognized health care operations activities. As a result, business associates are now subject to significant civil and criminal penalties for failure to comply with applicable standards. Moreover, HITECH creates a new requirement to report certain breaches of unsecured, individually identifiable health information and imposes penalties on entities that fail to do so. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney fees and costs associated with pursuing federal civil actions. The 2013 final HITECH omnibus rule modifies the breach reporting standard in a manner that will likely make more data security incidents qualify as reportable breaches.

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

International regulation

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

The primary regulatory body in Europe is the European Union, which has adopted numerous directives and has promulgated voluntary standards regulating the design, manufacture, clinical trials, labeling and adverse event reporting for medical devices. Devices that comply with the requirements of a relevant directive will be entitled to bear the CE conformity marking, indicating that the device conforms to the essential requirements of the applicable directives and, accordingly, can be commercially distributed throughout the member states of the European Union, and other countries that comply with or mirror these directives. The method of assessing conformity varies depending on the type and class of the product, but normally involves a combination of self-assessment by the manufacturer and a third-party assessment by a notified body, an independent and neutral institution appointed by a country to conduct the conformity assessment. This third-party assessment may consist of an audit of the manufacturer's quality system and specific testing of the manufacturer's device. Such an assessment may be required in order for a manufacturer to commercially distribute the product throughout these countries. ISO 9001 and ISO 13485 certifications are voluntary standards. Compliance establishes the presumption of conformity with the essential requirements for a CE Marking. We have the authorization to affix the CE Mark to our products and to commercialize our devices in the European Union. Our ISO 13485 certification was issued on April 21, 2005 and our EC-Certificate was issued on March 16, 2007.

Before we can sell our devices in Canada we must submit a license application and obtain clearance, implement and comply with ISO Standard 13485, and undergo an audit by a registrar accredited by Health Canada. On January 25, 2006, we received our Medical Device License in Canada. In Australia, we must appoint an agent sponsor who will interact on our behalf with the Therapeutics Goods Administration (TGA). We must also prepare a technical file and declaration of conformity to essential requirements under Australian law, provide evidence of CE Marking of the device and submit this information via our agent sponsor to the TGA in a Medical Device Application. On June 4, 2007, we received our Certificate for Inclusion of a Medical Device in Australia.

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, 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 work day, developed using our property or related to our business. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to copy aspects of our Inogen One systems or to obtain and use information that we regard as proprietary.

Patents

As of December 31, 2014, we had 27 issued U.S. patents, one issued Canadian patent and 5 additional pending U.S. patent applications relating to design and construction of our oxygen concentrators and our Intelligent Delivery Technology. We anticipate it will take several years for the most recent of these U.S. patent applications to result in issued patents, if successful.

Our patent portfolio contains three principal sets of patents and patent applications. The first set relates to the construction and design of specific Inogen products. For example, U.S. Patent Nos. 8,440,004; 8,366,815; 8,377,181; and 8,568,519 are directed to design elements of the Inogen One G2 portable oxygen concentrator. These patents expire in 2031 (without taking into account any patent term adjustments) and may serve to deter competitors from reverse engineering or copying our design elements. This set of patents and patent applications also contains a pending U.S. patent application that relates to the design of the Inogen One G3 portable oxygen concentrator.

The second set of patents and patent applications within our portfolio pertains to operating algorithms and design optimization techniques. U.S. Patent Nos. 7,841,343; 7,585,351; 7,857,894; 8,142,544; and 6,605,136 are directed toward optimization of the Pressure Swing Adsorption oxygen generating system and the oxygen conserving technology used across all of our products. These patents expire in 2027, 2026, 2027, 2026 and 2022 respectively (without taking into account any patent term adjustments). These algorithms and optimization techniques are developed to facilitate the design and manufacturing of our products. These patents may prevent competitors from achieving the same levels of optimization as found in our products.

The third set of patents and patent applications includes system component designs that may be incorporated into our products. For example, U.S. Patent No. 8,580,015, which expires in 2027 (without taking into account any patent term adjustments), is directed to product improvements that have been utilized in the Inogen One and Inogen One G2 products. Also within this class of patents are U.S. Patent Nos. 7,686,870 and 7,922,789 that are directed to designs that may be utilized in future Inogen products to improve performance over current product offerings. These patents expire in 2027 and 2023 respectively (without taking into account any patent term adjustments).

Trademarks

We have registered the trademarks Inogen; Inogen One; Inogen One G2; Inogen One G3; Oxygenation; Live Life in Moments, not Minutes; Never Run Out of Oxygen; Oxygen Therapy on Your Terms; Oxygen. Anytime. Anywhere; Reclaim Your Independence; Intelligent Delivery Technology; Inogen At Home; and the Inogen design with the United States Patent and Trademark Office. We have registered the trademark Inogen in Australia, Canada, China, South Korea, Mexico, and in Europe (European Community Registration). We have registered the trademark Inogen One in Australia, Canada, China, South Korea, Mexico, and in Europe (European Community Registration). We have registered the trademark Satellite Conserver in Canada, and China. We have registered the trademark Inogen At Home in Europe (European Community Registration).

Employees

As of December 31, 2014, we had 411 full and part-time employees, including 205 in sales, marketing, clinical and client services, 93 in operations, manufacturing, quality assurance and repair, 94 in general administration and 19 in research and development. None of our employees is represented by a collective bargaining agreement. We believe that our employee relations are good.

Corporate and available information

We were incorporated in Delaware in November 2001. Our principal executive offices are located at 326 Bollay Drive, Goleta, California 93117. Our telephone number is (805) 562-0500. Our website address is www.inogen.com. We make available on our website, free of charge, our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and any amendments to those reports, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission, or SEC. Our SEC reports can be accessed through the investor relations page of our website located at <http://investor.inogen.com/sec.cfm>. The SEC also maintains a website that contains our SEC filings. The address of the site is www.sec.gov. Additionally, a copy of this Annual Report on Form 10-K and other materials that we file with the SEC are available at the SEC's Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. Information on the operation of the Public Reference Room can be obtained by calling the SEC at 1-800-SEC-0330.

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. 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.

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.

Backlog

We have no material backlog of orders.

Geographic information

During the years ended 2014, 2013 and 2012, all of our long-lived assets were located within the United States. Approximately 22% of our 2014 revenue, 22% of our 2013 revenue, and 27% of our 2012 revenue came from international markets. Please see Note 2 to our audited financial statements included elsewhere in this Annual Report on Form 10-K for additional information related to our U.S. and non-U.S. revenue.

Seasonality

We believe our sales may be impacted by seasonal factors. For example, we typically experience higher sales in the second quarter, as a result of consumers traveling, vacationing during the summer months, and warmer weather.

ITEM 1A. RISK FACTORS

We operate in a rapidly changing environment that involves numerous uncertainties and risks. The following risks and uncertainties may have a material and adverse effect on our business, financial condition or results of operations. You should consider these risks and uncertainties carefully, together with all of the other information included or incorporated by reference in this report on Form 10-K. 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 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.

Risks related to our business and strategy

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

As a provider of oxygen product rentals, we have historically depended heavily on Medicare reimbursement as a result of the higher proportion of elderly persons suffering from chronic 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. We believe that more than 60% of oxygen therapy patients in the United States have primary coverage under Medicare Part B. For the years ended December 31, 2014 and 2013, we derived approximately 26.5% and 29.4%, respectively, of our total revenue from Medicare's program or beneficiaries (including patient co-insurance obligations). There are increasing pressures on Medicare to control healthcare costs and to reduce or limit reimbursement rates for home medical products.

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

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

The Deficit Reduction Act of 2005 limited the total number of continuous rental months for which Medicare will pay for oxygen equipment to 36 months, after which time there is generally no additional reimbursement to the supplier (other than for periodic, in-home maintenance and servicing). The Deficit Reduction Act of 2005 also provided that title of the equipment would transfer to the beneficiary, which was later repealed by the Medicare Improvements for Patients and Providers Act of 2008. For purposes of the rental cap, the Deficit Reduction Act of 2005 provided for a new 36-month rental period that began January 1, 2006 for all oxygen equipment. After the 36th continuous month during which payment is made for the oxygen equipment, the supplier is generally required to continue to furnish the equipment during the period of medical need for the remainder of the useful lifetime of the equipment, provided there are no breaks in service due to medical necessity that exceed 60 days. The reasonable useful lifetime for portable oxygen equipment is 60 months. After 60 months, if the patient requests, the rental cycle starts over and a new 36-month capped rental period begins. There are no limits on the number of 60-month cycles over which a Medicare patient may receive benefits and an oxygen therapy provider may receive reimbursement, so long as such equipment continues to be medically necessary for the patient. We anticipate that the Deficit Reduction Act of 2005 oxygen payment rules will continue to negatively affect our net revenue on an ongoing basis, as each month additional customers reach the 36-month capped service period, resulting in potentially two or more years without rental income from these customers. We cannot state with certainty the number of patients in the capped rental period or the potential impact to revenue associated with patients in the capped rental period.

The Medicare Improvements for Patients and Providers Act of 2008 retroactively delayed the implementation of competitive bidding for 18 months from previously established dates and decreased the 2009 fee schedule payment amounts by 9.5% for product categories included in competitive bidding. In addition to the 9.5% reduction under Medicare Improvements for Patients and Providers Act of 2008, the Centers for Medicare & Medicaid Services implemented a reduction to the monthly payment amount for stationary oxygen equipment. The monthly payment rate for non-delivery ambulatory oxygen in the relevant period was flat at \$51.63. The table below summarizes the increases and decreases in the monthly payment amounts for stationary oxygen equipment.

(dollars in dollars)	2009	2010	2011	2012	2013	2014	2015
Stationary oxygen percentage rate changes	-2.30 %	-1.50 %	0.10 %	1.60 %	0.70 %	0.50 %	1.50 %
Stationary oxygen monthly payment amounts	\$175.79	\$173.17	\$173.31	\$176.06	\$177.36	\$178.24	\$180.92

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, includes, among other things, a deductible excise tax on any entity that manufactures or imports medical devices offered for sale in the United States, with limited exceptions including oxygen products such as ours, which began in 2013, new face-to-face physician encounter requirements for durable medical equipment and home health services, and a requirement that by 2016, the competitive bidding process must be nationalized or prices in non-competitive bidding areas must be adjusted to match competitive bidding prices.

These legislative provisions, as currently in effect and when fully implemented, have had and will continue to have a material and adverse effect on our business, financial condition and operating results.

Due to budgetary shortfalls, many states are considering, or have enacted, cuts to their Medicaid programs. These 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 implementation of the competitive bidding process under Medicare could negatively affect our business and financial condition.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 requires the Secretary of Health and Human Services 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.

In October 2014, the Centers for Medicare and Medicaid services released a ruling that sets forth methodologies to adjust the fee schedule amounts for items subject to competitive bidding in areas where competitive bidding is not implemented. The ruling applies rate reductions to all un-bid areas instead of doing an additional bidding process. The fee schedules in the un-bid areas will be adjusted based on regional averages of the single payment amounts for areas already under competitive bidding. The regional prices would be limited by a national ceiling (110% of the average of the regional prices) and a floor (90% of the average regional prices). The regions are defined as follows:

Region Name	States Covered
Far West	CA, NV, OR, WA
Great Lakes	IL, IN, MI, OH, WI
Mideast	DC, DE, MD, NJ, NY, PA
New England	CT, MA, NH, RI
Plains	IA, KS, MN, MO, NE
Rocky Mountain	CO, ID, UT
Southeast	AL, AR, FL, GA, KY, LA, NC, SC, TN, VA
Southwest	AZ, NM, OK, TX

The Centers for Medicare and Medicaid defines frontier states as states where more than 50% of the counties in the state have a population density of 6 people or less per square mile and rural states are defined as states where more than 50% of the population lives in rural areas per census data. Current frontier states include MT, ND, SD and WY; rural states include ME, MS, VT and WV; and non-contiguous United States areas include AK, HI, Guam and Puerto Rico. For frontier and rural states, and frontier and rural zip codes in non-frontier/rural states, the single payment amount will be the national ceiling (110% of the average of the regional prices) to account for higher servicing costs in these areas. For non-contiguous United States areas, single payment amounts will be the higher of the national ceiling, or the average of competitive bidding pricing from these areas, if the areas had been bid through competitive bidding.

While we are monitoring the implementation of this ruling, we believe that the net effect of the ruling would be an approximately 3-4% decrease in 2016 revenue since this pricing will be applied partially from January 1, 2016 to June 30, 2016 and completely starting July 1, 2016.

The Centers for Medicare and Medicaid Services accepted bids through March 26, 2015 for competitive bidding round two re-compete, associated with approximately 50% of the market with contracts set to begin July 1, 2016 and continue through December 31, 2018. The Centers for Medicare and Medicaid Services updated the product categories and the competitive bidding areas. Respiratory equipment includes oxygen, oxygen equipment, continuous positive airway pressure devices, respiratory assist devices and related supplies and accessories. Nebulizers are now their own separate product category instead of being included in the respiratory equipment category. Round two re-compete is in the same geographic areas that were included in the original round two. However, as a result of the Office of Management and Budget’s updates to the original 91 round two metropolitan statistical areas, there are now 90 metropolitan statistical areas for round two re-compete and 117 competitive bidding areas (CBAs). Any CBA that was previously located in multi-state metropolitan statistical areas was redefined so that no CBA is included in more than one state. The round two re-compete competitive bidding areas have nearly the same ZIP codes as the round two competitive bidding areas; the associated changes in the zip codes since competitive bidding was implemented are reflective in this round two re-compete.

On March 17, 2015 the House of Representatives approved the Medicare DMEPOS (Durable Medical Equipment, Prosthetics, Orthotics and Supplies) Competitive Bidding Improvement Act of 2015 which would require Medicare

suppliers that bid under DMEPOS competitive bidding program to obtain a \$50,000 to \$100,000 bid surety bond for each competitive bidding area (CBA). The bill is intended to prevent suppliers from submitting not-binding, “low-ball” bids that artificially drive down prices and jeopardize beneficiary access to equipment. If the supplier bids lower than the median composite bid rate and does not accept a contract for a CBA, the bid bond would be forfeited. The bill also would codify that competitive bidding contracts can only be awarded to suppliers that meet applicable state licensure requirements. On April 14, 2015, this bill was passed by the Senate and then signed by President Obama into law on April 16, 2015, thus we will incur additional expense to obtain the appropriate surety bonds in the CBAs where we win contracts. There are currently 9 CBAs under contract in round 1 re-compete and 117 CBAs under contract in round 2 re-compete. CBAs are defined by Medicare and are subject to change at each new bidding period. This cost is not expected to be material to our financial results.

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 payment 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 payment rates will continue to fluctuate and a large negative payment adjustment could adversely affect our business, financial conditions and results of operations.

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

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

Our significant manufacturing competitors are Invacare Corporation, Respironics (a subsidiary of Koninklijke Philips N.V.), AirSep Corporation and SeQual Technologies (subsidiaries of Chart Industries, Inc.), Inova Labs, Inc. and DeVilbiss Healthcare. 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. Manufacturing companies compete for sales to providers primarily on the basis of product features, service and price.

For many years, Lincare Inc., Apria Healthcare, Inc. Rotech Healthcare, Inc. and American HomePatient, Inc. have been among the market leaders in providing oxygen therapy, while the remaining oxygen therapy market is serviced by local providers. Because many oxygen therapy providers were either excluded from contracts in the Medicare competitive bidding process, or will have difficulty providing service at the prevailing Medicare reimbursement rates, we expect more industry consolidation. Oxygen 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. As a consequence, 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 relations 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 or other incentives to gain a competitive advantage;
- greater history in conducting research and development, manufacturing, marketing and obtaining regulatory approval for oxygen device products; and
- greater financial and human resources for product development, sales and marketing, patent litigation and customer financing.

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. 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, 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.

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 the potential to substantially change healthcare financing by both governmental and private insurers, and significantly impact the U.S. medical device

industry. In addition, as discussed above, the Patient Protection and Affordable Care Act also expands the round two of competitive bidding to a total of 117 competitive bidding areas, and by 2016, the process must be nationalized or prices in non-competitive bidding areas must be adjusted to match competitive bidding prices.

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 among other things, created 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 reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect on April 1, 2013, and will remain in effect through 2024 unless additional Congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012 which, among other things, further reduced Medicare payments to certain providers, including physicians, hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. We expect that additional state and federal healthcare reform 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.

If we are unable to continue to enhance our existing products and develop and market new 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 and develop new innovative products. Product development requires significant financial, technological and other resources. While we expended \$3.0 million, \$2.4 million and \$2.3 million for research and development efforts for the twelve months ended December 31, 2014, December 31, 2013 and December 31, 2012, respectively, we cannot assure you that this level of investment in research and development 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, and testing at the technological, product, and manufacturing process levels and we may not be able to timely develop product improvements or new products. Our competitors' new products may enter the market before our new products reach market, be more effective with more features, obtain better market acceptance, or render our products obsolete. Any new products that we develop 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.

We depend upon reimbursement from Medicare, private payors and Medicaid 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 suffer.

A significant portion of our 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 from customers under co-insurance provisions. For the twelve months ended December 31, 2014 and December 31, 2013, approximately 35.0% and 40.5% of our total revenue was derived from Medicare, private payors, Medicaid, and individual customers who directly receive reimbursement from third-party payors.

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 reimbursement process and collect payments for our products promptly. If we fail to manage the complex and lengthy reimbursement process, it would adversely affect our business, financial conditions and results of operations.

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

A portion of our revenue is derived from private payors. Based on our patient population, we estimate at least 30% of potential customers have non-Medicare insurance coverage, and we believe these patients represent a younger and more active patient population that will be drawn to the quality-of-life benefits of our solution. 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 operating results. 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 payment amounts determined by competitive bidding. We cannot predict the extent to which reimbursement for our products will be affected by competitive bidding or by initiatives to reduce costs for private payors. Failure to obtain or maintain private payor contracts or the unavailability of third-party coverage or inadequacy of reimbursement for our products would adversely affect our business, financial conditions and results of operations.

We obtain some of the components, subassemblies and completed products included in our Inogen One systems and our Inogen At Home from a single source or a limited group of manufacturers or suppliers, and the partial or complete loss of one of these manufacturers or suppliers could cause significant production delays, an inability to meet customer demand and a substantial loss in revenue.

We utilize single source suppliers for some of the components and subassemblies we use in our Inogen One systems and our Inogen At Home system. We have qualified alternate sources of supply sufficient to support future needs and we have taken other mitigating steps to reduce the impact of a change in supplier; however, there may be delays in switching to these alternative suppliers if our primary source is terminated without notice. Our dependence on single source suppliers of components may expose us to several risks, including, among other things:

- Our suppliers may encounter financial hardships as a result of unfavorable economic and market conditions unrelated to our demand for components, which could inhibit their ability to fulfill our orders and meet our requirements;
- Suppliers may fail to comply with regulatory requirements, be subject to lengthy compliance, validation or qualification periods, or make errors in manufacturing components that could negatively affect the efficacy or safety of our products or cause delays in supplying of our products to our customers;
- Newly identified suppliers may not qualify under the stringent regulatory standards to which our business is subject;
- 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;
- We may experience delays in delivery by our suppliers due to changes in demand from us or their other customers;
- We or our suppliers may lose access to critical services 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;
- Our suppliers may wish to discontinue supplying components or services to us; and
- We may not be able to find new or alternative components or reconfigure our system and manufacturing processes in a timely manner if the necessary components become unavailable.

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

used in our products. If any of these risks materialize, costs could significantly increase and our ability to meet demand for our products could be impacted. If we are unable to satisfy commercial demand for our Inogen One systems and Inogen At Home systems in a timely manner, our ability to generate revenue would be impaired, market acceptance of our products could be adversely affected, and customers may instead purchase or use alternative products. In addition, we could be forced to secure new or alternative components and subassemblies through a replacement supplier. Finding alternative sources for these components and subassemblies could be difficult in certain cases and may entail a significant amount of time and disruption. In some cases, we would need to change the components or subassemblies if we sourced them from an alternative supplier. This, in turn,

could require a redesign of our Inogen One systems and Inogen At Home systems and, potentially, require additional FDA clearance or approval before we could use any redesigned product with new components or subassemblies, thereby causing further costs and delays that could adversely affect our business, financial condition and operating results.

We do not have long-term supply contracts with many of our third-party suppliers.

We purchase components and subassemblies from third-party suppliers, including some of our single source suppliers, through purchase orders and do not have long-term supply contracts with many of these third-party suppliers. Many of our third-party suppliers, therefore, are not obligated to perform services or supply products to us for any specific period, in any specific quantity or at any specific price, except as may be provided in a particular purchase order. We do not maintain large volumes of inventory from most of these suppliers. If we inaccurately forecast demand for components or subassemblies, our ability to manufacture and commercialize our Inogen One systems and Inogen At Home systems could be delayed and our competitive position and reputation could be harmed. In addition, if we fail to effectively manage our relationships with these suppliers, we may be required to change suppliers which would be time consuming and disruptive and could adversely affect our business, financial condition and operating results.

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

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 operating results.

As manufacturers of medical devices, we may be subject to substantial warranty or product liability claims or other litigation in the ordinary course of business that may require us to make significant expenditures to defend these claims or pay damage awards. For example, our Inogen One systems contain lithium ion batteries, which, under certain circumstances, can be a fire hazard. We, as well as our key suppliers, maintain product liability insurance, but this insurance is limited in amount and subject to significant deductibles. There is no guarantee that insurance will be available or adequate to protect against all claims. Our insurance policies are subject to annual renewal and we may not be able to obtain liability 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 operating results may be adversely affected.

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

Reimbursement rates are established by fee schedules mandated by Medicare, private payors and Medicaid, and are likely to remain constant or decrease due, in part, to federal and state government budgetary constraints. As a result, with respect to Medicare and Medicaid related revenue, we are not able to offset the effects of general inflation on our operating costs through increases in prices for our products. In particular, labor and related costs account for a significant portion of our operating costs and we compete with other healthcare providers to attract and retain qualified or skilled personnel and with various industries for administrative and service employees. This competitive environment could result in increased labor costs. As such, we must control our operating costs, particularly labor and related costs and failing to do so could adversely affect our financial conditions 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 staff and our sales and marketing executives. 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 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 senior management team. The loss of any member of our senior management team could harm our ability to implement our business strategy and respond to the market conditions in which we operate.

We rely on information technology, and if we are unable to protect against service interruptions, data corruption, cyber-based attacks or network security breaches, our operations could be disrupted and our business could be negatively affected.

We rely on information technology networks and systems to process, transmit and store electronic and financial information; to coordinate our business; and to communicate within our company and with customers, suppliers, partners and other third-parties. These information technology systems may be susceptible to damage, disruptions or shutdowns, hardware or software failures, power outages, computer viruses, cyber-attacks, telecommunication failures, user errors or catastrophic events. If our information technology systems suffer severe damage, disruption or shutdown, and our business continuity plans do not effectively resolve the issues in a timely manner, our operations could be disrupted and our business could be negatively affected. In addition, cyber-attacks could lead to potential unauthorized access and disclosure of confidential information (including patient-identifiable health information), and data loss and corruption. There is no assurance that we will not experience these service interruptions or cyber-attacks in the future.

We incurred losses from inception until fiscal year 2012, and we have only recently achieved profitability.

We have a limited operating history and incurred significant net losses in each fiscal year until fiscal year 2012, when we achieved positive net income. As of December 31, 2014, we had an accumulated deficit of \$56.7 million. These net losses have resulted principally from costs incurred from our selling, general and administrative expenses and to a lesser extent in our research and development programs. We expect to incur significant expansion of our sales and marketing expenses and increases in expenses for research and development to a lesser extent. Additionally, since completing our initial public offering, we expect that our general and administrative expenses will increase due to the additional operational and reporting costs associated with being a public company. Because of the numerous risks and uncertainties associated with our commercialization efforts and future product development, we are unable to predict if we will maintain or increase our net income.

Our financial results 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; 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; and fluctuations in foreign currency exchange rates. For example, we typically experience higher sales in the second quarter, as a result of consumers traveling and vacationing during the summer months. 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. In addition, a significant amount of our operating expenses are relatively fixed due to our manufacturing, research and development and sales and general administrative efforts. Any failure to adjust spending quickly enough to compensate for a revenue shortfall could magnify the adverse impact of such revenue shortfall on our results of operations. Our results of operations may not meet the expectations of research analysts or investors, in which case the price of our common stock could decrease significantly.

If the market opportunities for our products are smaller than we believe they are, our revenues maybe 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 number of oxygen therapy patients, (iii) the number of patients requiring ambulatory and stationary oxygen, (iv) the number of patients who rely on the delivery model, and (v) the share of portable oxygen concentrators 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 oxygen therapy, or the type of 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 terms of our revolving credit agreement may restrict our current and future operations, and could affect our ability to respond to changes in our business and to manage our operations.

On November 7, 2014, we entered into a revolving credit agreement with JPMorgan Chase Bank, N.A., which we refer to as our revolving credit agreement. The agreement provides for a revolving credit facility in an aggregate principal amount of \$15.0 million with a sublimit of \$1.0 million for the issuance of letters of credit on our behalf. The agreement is secured by all or substantially all of our assets.

Pursuant to the revolving credit agreement, we are subject to certain financial covenants relating to our net worth and EBITDA. Tangible net worth under the revolving credit agreement is calculated by subtracting the sum of intangible assets and total liabilities from total assets. EBITDA is defined in the revolving credit agreement as our net income plus interest expense, plus depreciation expense, plus amortization expense, plus income tax expense, plus non-cash expense, plus extraordinary losses, minus non-cash income, and minus extraordinary gains, as computed during certain test periods provided in the revolving credit agreement. We are required to maintain at all times a tangible net worth of \$90 million and EBITDA (i) of \$10.0 million for any period of four consecutive quarters commencing with the four-quarter test period ending September 30, 2014 through the four-quarter test period ending March 31, 2016 and (ii) of \$12.5 million for any four-quarter test period commencing with the four-quarter test period ending June 30, 2016 and continuing thereafter.

The agreement contains events of default customary for transactions of this type, including nonpayment, misrepresentation, breach of covenants, and bankruptcy. In the event we fail to satisfy our covenants, or otherwise go into default, JPMorgan Chase Bank, N.A. has a number of remedies, including sale of our assets and acceleration of all outstanding indebtedness. Certain of these remedies would likely have a material adverse effect on our business. As of December 31, 2014, in order to be in compliance with the EBITDA and tangible net worth requirements, we were required to maintain \$10 million in EBITDA for the preceding test period, and we had \$24 million in EBITDA for that period, and we were required to maintain a tangible net worth of \$90.0 million and we had a tangible net worth of \$117.8 million.

An adverse outcome of a sales and use tax audit could have a material adverse effect on our results of operations and financial condition.

The California State Board of Equalization conducted a sales and use tax audit of our operations in California in 2008. As a result of the audit, the California State Board of Equalization confirmed that our sales are not subject to California sales and use tax. We believe that our sales in other states should not be subject to sales and use tax. There can be no assurance, however, that other states may agree with our position and we may be subject to an audit that may not be resolved in our favor. Such an audit could be expensive and time-consuming and result in substantial management distraction. If the matter were to be resolved in a manner adverse to us, it could have a material adverse effect on our results of operations and financial position.

Our ability to use net operating losses to offset future taxable income may be subject to certain limitations.

As of December 31, 2014, we had federal and state net operating loss carryforwards, or NOLs, of approximately \$59.3 and \$46.4 million, which expire in various years beginning in 2023 and 2015, respectively, if not utilized. Our existing NOLs are subject to limitations arising from an ownership change in the current period subject to the provisions of

Section 382 of the Internal Revenue Code of 1986, as amended, or the Code. If we undergo one or more future ownership changes our ability to utilize NOLs could be further limited. In general, under Section 382 of the Code, a corporation that undergoes an “ownership change” is subject to limitations on its ability to utilize its pre-change NOLs to offset future taxable income. In general, an “ownership change” occurs if there is a cumulative change in ownership by “5% shareholders” that exceeds 50 percentage points over a rolling three-year period. Even after factoring in the limitations of the current period ownership change, the Company was able to determine that, based upon future projections of income, it is more likely than not that all of its federal NOLs will be utilized before they expire. However, the Company determined that some of its California NOLs will expire unused and therefore has a valuation allowance of \$2.9 million relating to these NOLs. In the current period, the Company released (or reversed) \$1.2 million of the California NOLs valuation allowance due to expiration of California NOL’s and changes in estimates of future projections of income, resulting in a determination that it is more likely than not that all but \$32.8 million (\$2.9 million tax effect) of the California NOLs will be utilized.

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 or be required to make significant changes to our operations that could adversely affect our business, financial condition and operating results.

The federal government and all states in which we currently operate regulate various aspects of our business. In particular, our sales and customer service centers are subject to federal laws that regulate interstate motor-carrier transportation. Our operations also 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 each state to act as a durable medical equipment supplier. Certain of our employees are subject to state laws and regulations governing the professional practices 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 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 obtain information from healthcare providers. Violations of federal and state regulations can result in severe criminal, civil and administrative 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 burdensome and complex billing and record-keeping requirements in order to substantiate our claims for payment under federal, state and commercial healthcare reimbursement programs, and our failure to comply with existing requirements, or changes in those requirements or interpretations thereof, could adversely affect our business, financial condition and operating results.

We are subject to burdensome and 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. For example, we have also experienced a significant increase in pre-payment reviews of our claims by the Durable Medical Equipment Medicare Administrative Contractors, which has caused substantial delays in the collection of our Medicare accounts receivable as well as related amounts due under supplemental insurance plans.

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

We have been informed by these auditors that healthcare providers and suppliers of certain durable medical equipment product categories are expected to experience further increased scrutiny from these audit programs. When a

government auditor ascribes a high billing error rate to one or more of our locations, it generally results in protracted pre-payment claims review, payment delays, refunds and other payments to the government and/or our need to request more documentation from providers than has historically been required. It may also result in additional audit activity in other company locations in that state 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 operating results, but such impact could be material.

We are subject to significant regulation by numerous government agencies, including the U.S. Food and Drug Administration, or FDA. We cannot market or commercially distribute our products without obtaining and maintaining necessary regulatory clearances or approvals.

Our Inogen concentrators 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 procedures;
- advertising and promotion;
- recalls and field safety corrective actions;
- post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury;
- post-market approval studies; and
- product import and export.

Before we can market or sell a medical device in the United States, we must obtain either clearance from the FDA under Section 510(k) of the Federal Food, Drug, and Cosmetic Act, or the FDCA, or approval of a pre-market approval application from the FDA, unless an exemption from pre-market review applies. In the 510(k) clearance process, the FDA must determine that a proposed device is “substantially equivalent” to a device legally on the market, known as a “predicate” device, with respect to intended use, technology and safety and effectiveness, in order to clear the proposed device for marketing. Clinical data is sometimes required to support substantial equivalence. The pre-market approval pathway requires an applicant to demonstrate the safety and effectiveness of the device based, in part, on extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data. The pre-market approval process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices. Products that are approved through a pre-market approval application generally need FDA approval before they can be modified. Similarly, some modifications made to products cleared through a 510(k) may require a new 510(k). Both the 510(k) and pre-market approval processes can be expensive and lengthy and require the payment of significant fees, unless an exemption applies. The FDA’s 510(k) clearance process usually takes from three to twelve months, but may take longer. The process of obtaining a pre-market approval is much more costly and uncertain than the 510(k) clearance process and generally takes from one to three years, or longer, from the time the application is submitted to the FDA until an approval is obtained. The process of obtaining regulatory clearances or approvals to market a medical device can be costly and time consuming, and we may not be able to obtain these clearances or approvals on a timely basis, if at all.

In the United States, our currently commercialized products are marketed pursuant to pre-market clearance under Section 510(k) of the FDCA. 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 could cause our sales to decline. 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 under a pre-market approval, the FDA may demand that we obtain a pre-market approval prior to marketing certain of our 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) or pre-market approval application in order to continue marketing the product. Further, even with respect to

those future products where a pre-market approval is not required, we cannot assure you that we will be able to obtain the 510(k) clearances with respect to those products.

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

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

In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently approved or cleared products on a timely basis. For example, in response to industry and healthcare provider concerns regarding the predictability, consistency and rigor of the 510(k) regulatory pathway, the FDA initiated an evaluation of the program, and in January 2011, announced several proposed actions intended to reform the review process governing the clearance of medical devices. The FDA intends these reform actions to improve the efficiency and transparency of the clearance process, as well as bolster patient safety. Some of these proposals, if enacted, could impose additional regulatory requirements upon us which could delay our ability to obtain new 510(k) clearances, increase the costs of compliance or restrict our ability to maintain our current clearances. In addition, as part of the Food and Drug Administration Safety and Innovation Act, Congress reauthorized the Medical Device User Fee Amendments with various FDA performance goal commitments and enacted several "Medical Device Regulatory Improvements" and miscellaneous reforms which are further intended to clarify and improve medical device regulation both pre- and post-market.

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 efficacy of our products and dissuade our customers from using our products.

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

Our Inogen One systems and Inogen At Home system have received pre-market clearance under Section 510(k) of the FDCA. The modifications made to our Inogen One G2 and Inogen One G3 systems represent non-significant modifications to the original Inogen One system, have the same indications for use, and are covered under our initial Inogen One 510(k) clearance. Any modifications to a 510(k)-cleared device that could significantly affect its safety or effectiveness, or would constitute a major change in its intended use, manufacture, design, components, or technology requires the submission and clearance of a new 510(k) pre-market notification or, possibly, pre-market approval. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer's decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. We have modified some of our 510(k) cleared products, and have determined based on our review of the applicable FDA guidance that in certain instances new 510(k) clearances or pre-market approval are not required. If the FDA disagrees with our determination and requires us to submit new 510(k) notifications or pre-market approval for modifications to our previously cleared products for which we have concluded that new clearances or approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties.

Furthermore, the FDA's ongoing review of the 510(k) program may make it more difficult for us to make modifications to our previously cleared products, either by imposing more strict requirements on when a manufacturer

must submit a new 510(k) for a modification to a previously cleared product, or by applying more onerous review criteria to such submissions. Specifically, pursuant to the Food and Drug Administration Safety and Innovation Act, which was signed into law in July 2012, the FDA was obligated to prepare a report for Congress on the FDA's approach for determining when a new 510(k) will be required for modifications or changes to a previously cleared device. The FDA issued this report in 2014 and indicated that manufacturers should continue to adhere to the FDA's 1997 Guidance on this topic when making a determination as to whether or not a new 510(k) is required for a change or modification to a device. However, the practical impact of the FDA's continuing scrutiny of these issues remains unclear.

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

The regulations to which we are subject are complex and have become more stringent over time. Regulatory changes could result in restrictions on our ability to continue or expand our operations, higher than anticipated costs or lower than anticipated sales. Even after we have obtained the proper 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:

- warning letters, fines, injunctions, consent decrees and civil penalties;
- recalls, termination of distribution, or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- delays in the introduction of products into the market;
- refusal to grant our requests for future 510(k) clearances or approvals of new products, new intended uses, or modifications to 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 impact on us.

Medical devices, such as our Inogen concentrators, can experience performance problems in the field that require review and possible corrective action by us or the product manufacturer. We cannot provide assurance that component failures, manufacturing errors, design defects and/or labeling inadequacies, which could result in an unsafe condition or injury to the operator or the patient will not occur. 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 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. 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. 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. 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 and operating results.

In addition, under the FDA's medical device reporting regulations, we are required to report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. Repeated product malfunctions may result in a voluntary or involuntary product recall. Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new approvals or clearances for the device before we may market or distribute the corrected device. Seeking such approvals or clearances may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties, or civil or criminal fines. We

may also be required to bear other costs or take other actions that may have a negative impact on our sales as well as face significant adverse publicity or regulatory consequences, which could harm our business, including our ability to market our products in the future.

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

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

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

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

Any of these sanctions could adversely affect our business, financial conditions and operating results.

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.

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

Approximately 22% and 22% of our revenue was from sales outside of the United States for the twelve months ended December 31, 2014 and December 31, 2013, respectively. As of December 31, 2014, we sold our products in 44 countries outside of the United States through distributors or directly to large "house" accounts. In order to market our products in the European Union or other foreign jurisdictions, we must obtain and maintain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies from country to country and can involve additional testing. The time required to obtain approval abroad may be longer than the time required to obtain FDA clearance. The foreign regulatory approval process includes many of the risks associated with obtaining FDA clearance and we may not obtain foreign regulatory approvals on a timely basis, if at all. FDA clearance does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries. However, the failure to obtain clearance or approval in one jurisdiction may have a negative impact on our ability to obtain clearance or approval elsewhere. If we do not obtain or maintain necessary approvals to commercialize our products in markets outside the United States, it would negatively affect our overall market penetration.

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

Our promotional materials and training methods must comply with the FDA and other applicable laws and regulations, including the prohibition of the promotion of a medical device for a use that has not been cleared or approved by the FDA. Use of a device outside its cleared or approved indications is known as “off-label” use. 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 impact on our reputation and financial results.

Failure to comply with the Federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, the Health Information Technology for Economic and Clinical Health Act, or HITECH Act, and implementing regulations (including the final omnibus rule published on January 25, 2013) affecting the transmission, security and privacy of health information could result in significant penalties.

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

HIPAA and the HITECH Act also include standards for common healthcare electronic transactions and code sets, such as claims information, plan eligibility, payment information and the use of electronic signatures, and privacy and electronic security of individually identifiable health information. Covered entities, such as healthcare providers, are required to conform to such transaction set standards pursuant to 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. 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 do not comply with existing or new laws and regulations related to patient health information, we could be subject to criminal or civil sanctions. New health information standards, whether implemented pursuant to HIPAA, the HITECH Act, congressional action or otherwise, could have a significant effect on the manner in which we handle healthcare related data and communicate with payors, and the cost of complying with these standards could be significant.

The 2013 final HITECH omnibus rule modifies the breach reporting standard in a manner that will likely make more data security incidents qualify as reportable breaches. Any liability from a failure to comply with the requirements of HIPAA or the HITECH Act could adversely affect our 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. These new provisions, as modified, will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us, as well as our clients and strategic partners. In addition, we are unable to predict what changes to the HIPAA Privacy Standards and Security Standards might be made in the future or how those changes could affect our business. Any new legislation or regulation in the area of privacy and security of personal information, including personal health information, could also adversely affect our business operations.

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

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

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

If we fail to comply with state and federal fraud and abuse laws, including anti-kickback, false claims and anti-inducement laws, we could face substantial penalties and our business, 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 or in return for purchasing, leasing, ordering, or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid, or other federal financed healthcare programs. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities 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 they do 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.

Federal false claims laws prohibit 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 majority of states also have statutes or regulations similar to the federal anti-kickback law 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. These false claims statutes allow 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 statutes) 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 these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines and imprisonment. In addition, the recently enacted Patient Protection and Affordable Care Act, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this 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 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 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 Patient Protection and Affordable Care Act also imposes new reporting and disclosure requirements on device and drug manufacturers for any "transfer of value" made or distributed to prescribers and other healthcare providers. Device and drug manufacturers will also be required to report and disclose any investment interests held by physicians and their immediate family members during the preceding calendar year. Failure to submit required information may result in civil monetary penalties of up to an aggregate of \$150,000 per year (and up to an aggregate of \$1 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests not reported in an annual submission. As of August 1, 2013, manufacturers are required to collect data, and were required to submit their first data reports to the Centers for Medicare & Medicaid Services by March 31, 2014 and by the 90th day of each

calendar year thereafter.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians. Certain states, mandate implementation of compliance programs and/or the tracking and reporting of gifts, compensation and other remuneration to physicians. 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 prohibits the offering or giving of remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of items or services reimbursable by a Federal or state governmental healthcare program. We sometimes offer customers various discounts and other financial incentives in connection with the sales of our products. While it is our intent to comply with all applicable laws, the government may find that our marketing activities violate the Civil Monetary Penalties Law. If we are found to be in noncompliance, we could be subject to civil money penalties of up to \$10,000 for each wrongful act, assessment of three times the amount claimed for each item or service and exclusion from the federal or state healthcare programs.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restricting of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could harm our ability to operate our business and our financial results. 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.

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

As of December 31, 2014 we sold our products in 44 countries outside the United States through 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 Inogen One systems and our Inogen At Home to other available oxygen 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 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, 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.

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 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 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; or
- permit us to gain or maintain a competitive advantage.

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

As of December 31, 2014, we had five pending U.S. patent applications, 27 issued U.S. patents and one issued Canadian patent relating to the design and construction of our oxygen concentrators and our intelligent delivery technology. We cannot specify which of these patents individually or as a group will permit us to gain or maintain a competitive advantage. U.S. patents and patent applications may be subject to interference proceedings, and U.S. patents may be subject to re-examination, inter partes review, post-grant review, and derivation proceedings in the U.S. Patent and Trademark Office. Foreign patents may be subject to opposition or

comparable proceedings in the corresponding foreign patent offices. 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, re-examination, inter partes review, and opposition 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 adequate protection or any competitive advantages. Our patents and patent applications are directed to particular aspects of our products. Other parties may develop and obtain patent protection for more effective technologies, designs or methods for oxygen therapy. If these developments were to occur, it would likely have an adverse effect on our sales. Our ability to develop additional patentable technology is also uncertain.

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

Our products could infringe 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 patent infringement and intellectual property rights. Our competitors hold a significant number of patents relating to oxygen therapy devices and products. From time to time, we have commenced litigation to enforce our intellectual property rights. For example, we have pursued litigation against Inova Labs Inc. for infringement of two of our patents seeking damages, injunctive relief, costs, and attorneys' fees. An adverse decision in this action or in any other legal action could limit our ability to assert our intellectual property rights, limit the value of our technology or otherwise negatively impact our business, financial condition and results of operations.

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

We cannot provide assurance that our products or methods do not infringe 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.

Determining whether a product infringes a patent involves complex legal and factual issues, and the outcome of a patent litigation action is 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 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 vary by jurisdiction and some companies opt not to publish their patent applications, 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. 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 oxygen products and as 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 products or patents in litigation or other proceedings, including patent re-examinations, or inter partes reviews. As a result, we may become involved in unwanted litigation that could be costly, result in diversion of management's attention, require us to pay damages 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 and intellectual property rights of others. In the event that we become subject to a patent infringement or other intellectual property lawsuit and if the other party's patents or other intellectual property were upheld as valid and enforceable and we were found to infringe the other party's patents 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 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. 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 have registered the trademarks Inogen; Inogen One; Inogen One G2; Oxygenation; Live Life in Moments, not Minutes; Never Run Out of Oxygen; Oxygen Therapy on Your Terms; Oxygen. Anytime. Anywhere; Reclaim Your Independence; Intelligent Delivery Technology; and the Inogen design with the United States Patent and Trademark Office. We have applied with the United States Patent and Trademark Office to register the trademark Inogen at Home. We have registered the trademark Inogen in Australia, Canada, China, South Korea, Mexico, and in Europe (European Community registration). We have registered the trademark Inogen One in Australia, Canada, China, South Korea, Mexico, and in Europe (European Community registration). We have registered the trademark Satellite Conserver in Canada, and China. We have registered the trademark Inogen At Home in Europe (European Community Registration).

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

Many of our employees were previously employed at other medical device companies focused on the development of oxygen therapy products, including our competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we 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 such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. 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 new compliance initiatives and corporate governance practices.

On February 20, 2014 we completed our initial public offering. As a public company, and increasingly after we are no longer an “emerging growth company,” we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act and rules 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, 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 \$1.5 million and \$3.0 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. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. Additionally, we are involved in a securities class action lawsuit as discussed in “Item 3 – Legal Proceedings.”

The Sarbanes-Oxley Act requires, among other things, that we assess 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), will require 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. As an “emerging growth company” we expect to avail ourselves of the exemption from the requirement that our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting under Section 404(b). However, we may no longer avail ourselves of this exemption when we are no longer an “emerging growth company.” When our independent registered public accounting firm is required to undertake an assessment of our internal control over financial reporting, the cost of our compliance with Section 404(b) will correspondingly increase. Our compliance with applicable provisions of Section 404 will require that we incur substantial accounting expense and expend significant management time on compliance-related issues as we implement additional corporate governance practices and comply with reporting requirements.

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

We have identified a material weakness in our internal control over financial reporting. If we do not remediate the material weakness in our internal control over financial reporting, we may not be able to accurately report our financial results or file our periodic reports in a timely manner, which may cause investors to lose confidence in our reported financial information and may lead to a decline in the market price of our stock.

Effective internal control over financial reporting is necessary for us to provide reliable financial reports in a timely manner. In connection with the audit of our financial statements for the year ended December 31, 2014, we concluded that there was a material weakness with respect to internal control over the review of sales order documentation supporting our direct-to-customer sales and rentals prior to revenue recognition. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. We identified a material weakness with respect to internal control over the review of sales documentation related to our direct-to-customer sales and rentals prior to revenue recognition. The primary factors contributing to this material weakness were the improper use of technology to simulate medical documentation and absence of sufficient monitoring controls over illegitimate delivery of medical documentation.

We are in the process of implementing a remediation plan to supplement control over financial reporting to address this material weakness. Steps we are taking to remediate the material weakness in our internal control over financial reporting of revenue include: implementation of a combination of new and revised control procedures in our order review process and compliance program, supplemented document retention policies on sales documentation, additional quarterly screening through data analytics to confirm compliance with our policies, and improved processes and controls in our customer relationship management software system.

If one or more material weaknesses persist or if we fail to establish and maintain effective internal controls over financial reporting, our ability to timely and accurately report our financial results could be adversely affected. Although remediation efforts are still in progress, management is taking steps to remediate the material weakness in our internal control over financial reporting of revenue, including the implementation of new control procedures in our order review process and compliance audit program, thereby strengthening our control environment. However, we cannot assure you that these efforts will remediate our material weakness in a timely manner, or at all, or that our registered public accounting firm will be able to attest that such internal controls are effective when they are required to do so.

Although we believe these controls, once properly designed and implemented, will be effective, our management, internal audit department and independent registered public accounting firm did not perform an evaluation of our internal control over financial reporting during any period in accordance with the provisions of the Sarbanes-Oxley Act. Had management, the internal audit department and our independent registered public accounting firm performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act, additional control deficiencies amounting to material weaknesses may have been identified. As long as we qualify as an “emerging growth company” as defined by the Jumpstart our Business Startups Act of 2012, we will not be required to obtain an auditor’s attestation report on our internal controls in future annual reports on Form 10-K as otherwise required by Section 404(b) of the Sarbanes-Oxley Act. Our qualification as an emerging growth company may last for up to five years following our February 2014 IPO.

If our efforts to remediate this material weakness are not successful or if other deficiencies occur, our ability to accurately and timely report our financial position, results of operations, cash flows or key operating metrics could be impaired, which could result in late filings of our annual and quarterly reports under the Exchange Act, restatements of our financial statements or other corrective disclosures. Additional impacts could include a decline in our stock price, suspension of trading or delisting of our common stock by NASDAQ Global Select Market, or other material adverse effects on our business, reputation, results of operations, financial condition or liquidity. Furthermore, if we continue to have this existing material weakness or other material weaknesses or significant deficiencies in the future, it could create a perception that our financial results do not fairly state our financial condition or results of operations. Any of the foregoing could have an adverse effect on the value of our stock.

We are an “emerging growth company” and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an “emerging growth company,” as defined in the 2012 Jumpstart Our Business Startups (JOBS) Act, and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced financial disclosure obligations, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and any golden parachute payments not previously approved. We may take advantage of these provisions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company upon the earliest to occur of: the last day of the fiscal year in which we have more than \$1.0 billion

in annual revenue; the date we qualify as a large accelerated filer, with at least \$700 million of equity securities held by non-affiliates; the issuance, in any three-year period, by us of more than \$1.0 billion in non-convertible debt securities; and the last day of the fiscal year ending after the fifth anniversary of our initial public offering. We may choose to take advantage of some but not all of these reduced reporting burdens. If we take advantage of any of these reduced reporting burdens in future filings, the information that we provide our security holders may be different than you might get from other public companies in which you hold equity interests. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards, delaying the adoption of these accounting standards until they would apply to private companies. We have elected to avail ourselves of this exemption and, as a result, our financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be reduced or more volatile.

Risks related to our common stock

We expect that our stock price will fluctuate significantly, and you may have difficulty selling your shares.

Prior to our initial public offering, there was no public market for shares of our common stock. We cannot predict the extent to which investor interest in our company will lead to the development of an active trading market on the NASDAQ Global Select Market or otherwise or how liquid that market might become. If an active trading market does not develop, you may have difficulty selling any of our shares of common stock that you buy. In addition, the trading price of our common stock may be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include:

- actual or anticipated quarterly variation in our results of operations or the results of our competitors;
- announcements of secondary offerings;
- announcements by us or our competitors of new commercial products, significant contracts, commercial relationships or capital commitments;
- issuance of new or changed securities analysts' reports or recommendations for our stock