

Inogen Inc  
Form 10-K  
March 14, 2016

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, 2015

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 Stock Market LLC

(NASDAQ Global Select Market)

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically 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 <input type="checkbox"/>	Accelerated filer <input checked="" type="checkbox"/>
Non-accelerated filer <input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company <input type="checkbox"/>

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

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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 fiscal quarter, as reported on The NASDAQ Global Select Market, was approximately \$696.8 million.

As of February 29, 2016, the Registrant had 19,852,800 shares of common stock, par value \$0.001, outstanding.

### DOCUMENTS INCORPORATED BY REFERENCE

The information called for by Part III of this Annual Report on Form 10-K will be included to the extent stated herein in an amendment to this Form 10-K or incorporated by reference from the Registrant's definitive Proxy Statement relating to its 2016 Annual Meeting of Stockholders.

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INOGEN, INC.

PART I

Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or 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 expectations regarding government and third-party payor coverage and reimbursement;
- 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;
- our expectation to expand our sales and marketing channels, including through hiring additional sales representatives and securing contracts with healthcare payors and insurers;
- our internal control environment;
- the effects of seasonal trends on our results of operations;
- our expectations regarding the timing of the launch and specifications of our fourth-generation portable oxygen concentrator; 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.

Forward-looking statements represent our management's beliefs and assumptions only as of the date of this Annual Report on Form 10-K. 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.

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

data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

“Inogen,” “Inogen One,” “Inogen One G2,” “Inogen One G3,” “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 registered trademarks with the United States Patent and Trademark Office of Inogen, Inc. We own trademark registrations for the mark “Inogen” in Australia, Canada, South Korea, Mexico, and Europe (European Union registration). We own pending applications for “Inogen” in Japan and South Korea, and we own a pending application for “ ” in Japan. We own trademark registrations for the mark “Inogen One” in Australia, Canada, China, South Korea, Mexico, and Europe (European Union registration). We own trademark registrations for the mark “Satellite Conserver” in Canada and China. We own a trademark registration for the mark “Inogen At Home” in Europe (European Union 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 Annual Report on Form 10-K, “we,” “us” and “our” refer to Inogen, Inc.

## ITEM 1. BUSINESS

### General

We were incorporated in Delaware on November 27, 2001. We are a medical technology company that primarily develops, manufactures and markets innovative portable oxygen concentrators 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 G2® and Inogen One G3® have up to 5 and 4.5 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.

Portable oxygen concentrators represent the fastest-growing segment of the Medicare oxygen therapy market between 2012 and 2014 and the Company estimates based on 2014 Medicare data (which excludes private insurance and cash sales), that patients using portable oxygen concentrators represent approximately 6% to 8% of the total addressable oxygen market in the United States. Based on 2014 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 oxygen concentrators to more than 127,000 patients as of December 31, 2015.

We generated revenue of \$159.0 million, \$112.5 million and \$75.4 million in 2015, 2014 and 2013, respectively, while generating net income of \$11.6 million, \$6.8 million and \$25.4 million in 2015, 2014 and 2013, respectively.

#### Our market

We believe the current total addressable oxygen therapy market in the United States is approximately \$3 billion to \$4 billion, based on 2014 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 who 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 2015 and 2021, 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 2014 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 2014 Medicare data (which excludes private insurance and cash sales) that the amount spent by patients with portable oxygen concentrators represents approximately 6% to 8% of the total addressable oxygen market in the United States. 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 concentrators 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 among the lightest 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 a 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 higher flow capacity than other sub-5 pound portable oxygen concentrators, and our 7.0 pound Inogen One G2 has higher 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)	1,050	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 5.0 hours (single battery) Up to 10.0 hours (double battery)

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Maintenance prevention advantages	User replaceable oxygen filtration cartridges & battery	Air dryer & user replaceable battery
Technology effective for overnight use	Yes	Yes
Sound	39 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 and upgraded in December 2015, is among the lightest products on the market and has higher oxygen production capabilities than the other sub-5 pound portable oxygen concentrators on the market. 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 offer a backup source of oxygen to our patients who are able to elect either a stationary concentrator or oxygen tank as their backup source.

At approximately 18 pounds, we believe the Inogen At Home concentrator is the lightest five liter per minute continuous flow oxygen concentrator on the market today. Additionally, the Inogen At Home product has low power consumption with worldwide electrical compatibility, which should reduce the cost of electricity for oxygen therapy patients, as well as reduce manufacturing and distribution complexities. While the Inogen One product line is clinically validated for 24/7 use, the Inogen At Home 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

In the United States, we market and distribute our products directly to consumers, through a wide variety of direct-to-consumer marketing strategies including a physician referral model, as well as through distributors, resellers, private label partners, and home medical equipment providers. In addition, we sell through distributors, resellers, and home medical equipment providers in certain markets within Europe, the Asia-Pacific region, Latin America, the Middle East, and Africa.

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, 2015 we employed a marketing team of 7 people, an in-house sales team of 183 people, and a field-based sales force of 14 people, each based in the United States. Of the \$123.7 million of our 2015 revenue derived from the United States, approximately 37% represented direct-to-consumer rentals, 35% represented cash-pay sales to consumers and 28% represented sales to third-party home medical equipment providers, distributors, and resellers.

Patients who choose to use their Medicare or private insurance benefits rent our systems. Those who purchase our product outright are typically not eligible to use their insurance benefits due to their capped rental status, or choose 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 by their primary insurance carrier. 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 of a physician's order. The chart below describes our United States direct-to-consumer sales and rental process.

In addition to the direct-to-consumer marketing model, we are also 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 2015, 2014 or 2013.

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 74%, 76% and 73% of rental revenue in 2015, 2014 and 2013, respectively, and based on total revenue were 21%, 27% and 29% for 2015, 2014 and 2013, respectively. Accounts receivable balances relating to Medicare's service reimbursement programs (including held and unbilled receivables, net of reserves) amounted to \$7.4 million or 37% of total accounts receivable as of December 31, 2015 and \$6.1 million or 32% of total accounts receivable as of December 31, 2014.

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 2015. 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, 2015, we had 4 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 2015, 2014 or 2013.

International sales revenue grew to \$35.3 million in 2015 from \$24.4 million in 2014. 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. 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, package the failed device and return it to us. In this manner, we are able to operate as a remote provider while maintaining the level of customer service of a local oxygen therapy provider. FedEx primarily supports our international shipments and limited domestic 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, 2015, we had a dedicated client services team of 33 people who were trained on our products, a clinical support team of 27 people who were licensed nurses or respiratory therapists, and a dedicated billing services team of 66 people. We provide our patients with a dedicated 24/7 hotline. 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 94%.

#### Third-party reimbursement

Medicare or private insurance rentals represented approximately 29% of our revenue in 2015. 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, 2015, our direct-to-consumer inside sales administration groups consisted of 183 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 the Healthcare Procedure Coding System (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 revenue-generating rental period begins.

As of January 1, 2011, Medicare had phased in a program called competitive bidding. Competitive bidding impacts the amount Medicare reimburses suppliers for durable medical equipment rentals, 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 generate theoretical supply that is twice the 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 and geographic area. 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 a new round of bidding. Discounts off the standard Medicare allowable occur in competitive bidding Metropolitan Statistical Areas where contracts have been awarded as well as in cases where private payors pay less than this allowable. Competitive bidding rates are based on the zip code where the patient resides. Rental revenue includes payments for product, disposables, and customer service/support. As of January 1, 2016, competitive bidding has been nationalized. All areas previously not subject to bidding had rate reductions applied instead of doing another bidding process. The fee schedules in the un-bid areas are adjusted based on regional averages of the single payment amounts for areas already under competitive bidding. The regional prices are limited by a national ceiling (110% of the average of the regional prices) and a floor (90% of the average regional prices). Since January 1, 2016, the reimbursement rates for these un-bid areas (with dates of services from January 1, 2016 to June 30, 2016) are based on 50% of the un-adjusted (current) fee schedule amount and 50% of the adjusted (reduced) fee schedule amount which is based on the regional competitive bidding rates. Starting on July 1, 2016, reimbursement rates will be 100% of the adjusted fee schedule amount which will be based on regional competitive bidding rates, including any potential adjustments associated with competitive bidding round two re-compete.

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 Services (CMS) 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. We estimate that less than 10% of our patients will be eligible to receive the 110% of the regional prices for rural and frontier areas based on the geographic locations of our current patient population.

CMS has also re-bid for competitive bidding round two re-compete, associated with approximately 50% of the Medicare market with contracts set to begin July 1, 2016 and continue through December 31, 2018. CMS 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. Pricing is expected to be announced in winter 2016 according to CMS, and will impact both the zip codes covered under round two and also the rates for the un-bid areas effective July 1, 2016.

CMS has begun the bidding process for the round one 2017 contracts effective January 1, 2017 through December 31, 2018. Bids were due by December 16, 2015. In round one 2017, there are 9 metropolitan statistical areas and 13 CBAs to make sure each CBA does not cross state boundaries. We estimate approximately 9% of the Medicare market will be impacted by these contracts set to begin January 1, 2017 and continue through December 31, 2018.

The following table sets forth the current Medicare standard allowable 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 expired.

	Round two weighted- average 7/1/13- 6/30/16	Round one re-compete weighted- average 1/1/14- 12/31/16
E1390	\$ 93.07	\$ 95.74
E1392	42.72	38.08
Total	\$ 135.79	\$ 133.82

In addition to reducing the Medicare reimbursement rates in the Metropolitan Statistical Areas, the competitive bidding program has effectively reduced 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, which was implemented January 1, 2011 in 9 Metropolitan Statistical Areas. Round two of competitive bidding was implemented July 1, 2013 in 91 Metropolitan Statistical Areas and we believe the impact on the number of oxygen suppliers was similar to round one. We believe that 59% of the market was covered by round one and round two of competitive bidding.

Cumulatively in rounds one, two and round one re-compete, we were offered contracts for a substantial majority of the competitive bidding areas and products for which we submitted bids. However, there is no guarantee that we will garner additional market share as a result of these contracts. The contracts include products that may require us to subcontract certain services or products to third parties, which must be approved by CMS.

Following round one of competitive bidding, we were excluded from the Kansas City-MO-KS, Miami-Fort Lauderdale-Pompano-FL, and Orlando-Kissimmee-FL competitive bidding areas and Honolulu-Hawaii, where we have never maintained a license. After round one re-compete of competitive bidding, we gained access to Kansas City-MO-KS and were excluded from the following competitive bidding areas: Cleveland-Elyria-Mentor-OH, Cincinnati-Middletown-OH, Miami-Fort Lauderdale-Pompano-FL, Orlando-Kissimmee-FL, Pittsburg-PA, and Riverside-San Bernardino-Ontario-CA. After round two of competitive bidding, we were excluded from an additional 10 competitive bidding areas, including Akron-OH, Cape Coral-Fort Myers-FL, Deltona-Daytona Beach-Ormond

Beach-FL, Jacksonville-FL, Lakeland-Winter Haven-FL, North Port-Bradenton-Sarasota-FL, Ocala, Palm Bay-Melbourne-Titusville-FL, Tampa-St. Petersburg-Clearwater-FL and Toledo-OH. Collectively, we have incrementally lost access to approximately seven percent of the Medicare market as of July 1, 2013. As a result, on a going forward basis we will continue to have access to approximately 90% of the Medicare market based on our analysis of the 92 competitive bidding areas that we have won out of the 109 competitive bidding areas, representing 59% of the market, with the remaining 41% of the market not subject to competitive bidding rounds and instead in these areas the rates are applied as discussed above. The incremental loss of access to approximately seven percent of the Medicare market is not expected to have a material adverse impact on our rental business. Medicare revenue, including patient co-insurance and deductible obligations, represented 21.0% of our total revenue in 2015. We expect the decline in total revenue resulting from the loss of competitive bidding contracts in the areas that we were excluded from to be partially offset by the “grandfathering” of existing Medicare patients, direct sales to former Medicare patients with third-party insurance coverage, or Medicare patients paying out-of-pocket to purchase our products. Our revenue from Medicare in the 17 competitive bidding areas where we were not offered contracts was approximately \$0.5 million in 2015 and \$1.0 million in 2014.

Under the Medicare competitive bidding program, providers may “grandfather” existing patients on service up to the effective date of the competitive bidding round. This means providers may retain all existing patients and continue to receive reimbursement for

them so long as the new reimbursement rate is accepted and the applicable beneficiary chooses to continue to receive equipment from the provider. Providers must either keep or release all patients under this “grandfathering” arrangement in each competitive bidding area; specific individual selection of patients for retention or release is not allowed. Providers can continue to sell equipment in competitive bid areas where they were not awarded contracts to patients paying out-of-pocket or with third-party insurance coverage.

We have elected to “grandfather” and retain all patients in competitive bid areas where contracts were not awarded to us. In addition, we continue to accept patients in competitive bidding areas where we did not receive contracts through private insurance. We also pursue retail sales of our equipment to patients in those areas.

Medicare reimbursement for oxygen rental equipment is limited to a maximum of 36 months within a 60-month period and the equipment is always owned by the home oxygen provider. The provider that billed Medicare for the 36th month continues to be responsible for the patient’s oxygen therapy needs for months 37 through 60, and there is generally no additional reimbursement for oxygen generating portable equipment for these later months. CMS does not separately reimburse suppliers for oxygen tubing, cannulas and supplies that may be required for the patient. The provider is required to keep the equipment provided in working order and in some cases CMS will reimburse for repair costs. After the five year useful life is reached, the patient may request replacement equipment and, if he or she can be re-qualified for the Medicare benefit, a new maximum 36-month payment cycle out of the next 60 months of service would begin. The provider may not arbitrarily issue new equipment. We have analyzed the potential impact to revenue associated with patients in the capped rental period and have deferred \$0 associated with the capped rental period for 2015 and 2014, respectively.

Our obligations to service assigned Medicare patients over the contract rental period include supplying working equipment that meets the patient’s oxygen needs pursuant to their doctor’s prescription and certificate of medical necessity form and supplying all disposables required for the patient to operate the equipment, including cannulas, filters, replacement batteries, carts and carry bags, as needed. If the equipment malfunctions, we must repair or replace the equipment. We determine what equipment the patient receives, that meets the physician’s prescription, and we can deploy used assets in working order as long as the prescription requirements are met. We must also procure a recertification of the certificate of medical necessity from the patient’s doctor to confirm the patient’s need for oxygen therapy one year after first receiving oxygen therapy and one year after each new 36-month reimbursement period begins. These contracts are cancellable by the patient at any time and by the provider in certain circumstances when the patient can transition to another provider.

In addition to the adoption of the competitive bidding program, reimbursable fees for oxygen rental services in non-competitive bidding areas were eligible to receive mandatory annual Consumer Price Index for all Urban Consumers, or CPI-U, updates beginning in 2010. For 2014, the CPI-U was +1.8%, but the multi-factor productivity adjustment, “adjustment”, was -0.8%, so the net result was a 1.0% increase in fee schedule payments in 2014 for items and services not included in an area subject to competitive bidding. However, the stationary oxygen equipment codes payment amounts, as required by statute, must be adjusted on an annual basis, as necessary, to ensure budget neutrality of the new payment class for oxygen generating portable equipment. Thus, the increase in allowable payment amounts for stationary oxygen equipment codes increased 0.5% from 2013 to 2014. For 2015, the CPI-U was +2.1%, but the adjustment was -0.6%, so the net result was a 1.5% increase in fee schedule payments in 2015 for stationary oxygen equipment for items and services not included in an area subject to competitive bidding. This does not apply for 2016 as the standard allowables were set based on regional averages of the competitive bidding prices as described previously.

In addition, the President’s proposed federal budget for fiscal year 2017 includes multiple provisions that could impact the Company if they were enacted. The budget proposed eliminating the 36-month cap for oxygen equipment and reducing the monthly payment amount for oxygen and oxygen equipment by the necessary percentage to be budget

neutral. The Company's patient population may materially differ from the Medicare population, which could lead to either more or less revenue if this is enacted. In addition, this would likely also impact the number of patients interested in a cash purchase and could increase rental patients and decrease out-of-pocket purchases. The proposed budget also proposes to extend the authority to require prior authorization to all Medicare fee-for-service items and services, particularly those that are at the highest risk for improper payment. The proposed budget also contains multiple provisions related to the Medicare appeals process including establishing a refundable filing fee (non-refundable if denied), providing the Office of Medicare Hearings and Appeals and Department Appeals Board Authority to use Recovery Audit Contractor collections, and increase minimum amount in controversy for administrative law judge adjudication of claims to equal the amount required for judicial review. In addition, this proposal includes the ability to remand appeals to the redetermination level with the introduction of new evidence and the ability to sample and consolidate similar claims for administrative efficiency.

As of December 31, 2015, we had 79 contracts with Medicaid and private payors. These contracts qualify us as an in-network provider for these payors. As a result, patients can rent or purchase our systems at the same patient obligation as other in-network oxygen providers. Based on our patient population, we believe at least 30% of all oxygen therapy patients are covered by private payors. Private payors typically provide reimbursement at 60% up to and above 100% of Medicare allowables for in-network plans,

and private payor plans can have 36-month capped rental periods similar to Medicare although they typically do not. We anticipate that private payor reimbursement levels will generally be reset in accordance with Medicare payment amounts established through competitive bidding.

We cannot predict the full extent to which reimbursement for our products will be affected by competitive bidding, the proposed budget for 2017, or by initiatives to reduce costs for private payors. We believe that we are well positioned to respond to the changing reimbursement environment because our product offerings are innovative, patient-focused and cost-effective. We have historically been able to reduce our costs through scalable manufacturing, better sourcing, continuous innovation, and reliability improvements, as well as innovations that reduce our product service costs by minimizing exchanges, such as user replaceable batteries and oxygen filtration cartridges. As a result of bringing manufacturing and assembly largely in-house and our commitment to driving efficient manufacturing processes, we have reduced our overall system cost by 45% from 2009 to 2015. We intend to continue to seek ways to reduce our cost of revenue through manufacturing and design improvements.

#### Manufacturing and raw materials

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.

Our manufacturing operations require a wide variety of raw materials, including electronic and mechanical components, batteries, materials, bearings, carry bags, motors, pistons, valves, and molded plastic components and other supplies. 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, motors, 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 certain suppliers maintain specified quantities of inventory in multiple locations, as well as requiring certain manufacturers to maintain redundant manufacturing sites. 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 Food and Drug 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, and a subset is used for manufacturing activities. The Richardson, Texas manufacturing facility is approximately 37,000 square feet. 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 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 inspected four times since April 2012 by the FDA and found to be in compliance with Good Manufacturing Practices guidelines. Most recently, our California facility was inspected by the FDA in March 2016. 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. 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.

As of December 31, 2015, we had 129 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, 2015, our research and development staff included 23 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 developing our next-generation oxygen concentrators. Over the last 3 fiscal years, Inogen has invested over \$9.6 million in research and development to efficiently bring an upgrade to one of our portable oxygen concentrators and to introduce our first generation stationary oxygen concentrator to market (\$4.2, \$3.0 and \$2.4 million for the years ended 2015, 2014 and 2013, respectively), leveraging our twenty-eight issued U.S. patents and one Canadian patent while also reducing the product manufacturing costs 45% from 2009 to 2015.

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 five mid-cycle product updates and numerous incremental improvements. Development projects utilize a combination of rapid prototyping and accelerated life testing methods to ensure products are taken from concept to commercialization in a fast and capital efficient manner. We leverage our direct patient expertise to rapidly gain insight from end users and to identify areas of innovation that we believe will lead to higher-quality products and lower total cost of ownership for our products.

Our product pipeline consists of our fourth-generation, ultra-lightweight portable oxygen concentrator. Our fourth-generation portable oxygen concentrator will be smaller, lighter and less expensive to manufacture than our Inogen One G3 and we expect to commercialize this product in the second quarter of 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. (a subsidiary of ResMed), DeVilbiss Healthcare (a subsidiary of Drive Medical), and O2 Concepts. 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 15% percent of their billion-dollar plus homecare businesses in 2014.

Lincare, Inc. (a subsidiary of the Linde Group), Apria Healthcare, Inc., Rotech Healthcare, Inc. and American HomePatient, Inc. (now a subsidiary of Lincare, 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 relationships with healthcare professionals, customers and third-party payors;
- established distribution networks;
- additional lines of products, and the ability to offer rebates or bundle products to offer higher discounts 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, 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