Inogen Inc
Form 10-K
April 01, 2014
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the Fiscal Year Ended December 31, 2013

OR

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

For the Transition Period From to

Commission file number: 001-36309

INOGEN, INC.

(Exact name of registrant as specified in its charter)

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

326 Bollay Drive

Goleta, California	**93117**
(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 x

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 x

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 x

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 x 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. x

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 x (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 x

As of June 30, 2013, the last business day of the registrant s most recently completed second fiscal quarter, the registrant s common stock was not listed on any exchange or over-the-counter market. The registrant s common stock began trading on the NASDAQ Global Select Market on February 14, 2014. The aggregate market value of Inogen, Inc. voting and non-voting common equity held by non-affiliates as of February 28, 2014, based on the closing sale price of $17.51 per share as reported on the NASDAQ Global Select Market on that date was $103,587,847 The registrant has provided this information as of February 28, 2014 because its common stock was not publicly traded as of the last business day of its most recently completed second fiscal quarter. Shares of the registrant s common stock held by each executive officer, director and holder of 5% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This calculation does not reflect a determination that certain persons are affiliates of the registrant for any other purpose.

As of February 28, 2014, the registrant had 18,147,544 shares of common stock, par value $0.001, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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INOGEN, INC.

PART I

Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements that are based on our management s beliefs and assumptions and on information currently available to our management. The forward-looking statements are contained principally in the sections entitled Business, Risk factors, and Management s discussion and analysis of financial condition and results of operations. Forward-looking statements include information concerning our possible or assumed future results of operations, business strategies, financing plans, competitive position, industry environment, potential growth opportunities, and the effects of competition. Forward-looking statements include statements that are not historical facts and can be identified by terms such as anticipates, believes, could, seeks, estimates, expects, intends, may, plans, potential, predicts, projects, should, will, would, or similar expressions and the negatives of those terms.

Forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements. We discuss these risks in greater detail in the section entitled 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.

ITEM 1. BUSINESS

General

We are a medical technology company that 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 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 2012 Medicare data that patients using portable oxygen concentrators represent

approximately 4% to 5% of the total addressable oxygen market in the United States. Based on 2012 industry data, 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

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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.

We believe our direct-to-consumer strategy has been critical to driving patient adoption of our technology. Other portable oxygen concentrator manufacturers access patients by selling through home medical equipment providers that we believe are disincentivized to encourage adoption of portable oxygen concentrators. In order to facilitate the regular delivery and pickup of oxygen tanks, home medical equipment providers have invested in geographically dispersed distribution infrastructure consisting of delivery vehicles, physical locations and delivery personnel within each area. Because portable oxygen concentrators eliminate the need for a physical distribution infrastructure, but have higher initial equipment costs than the delivery model, we believe converting to a portable oxygen concentrator model would require significant restructuring and capital investment for home medical equipment providers. Our direct-to-consumer marketing strategy allows us to sidestep the home medical equipment channel, appeal to patients directly and capture both the manufacturing and provider margin associated with long-term oxygen therapy. We believe our ability to capture this top-to-bottom margin, combined with our portable oxygen concentrators technology that eliminates the need for the service and infrastructure costs associated with the delivery model, gives us a cost structure advantage over our competitors.

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 40,000 patients, growing our revenue from $10.7 million in 2009 to $75.4 million in 2013. In 2013, 22% of our revenue came from our international markets and 41% of our revenue came from oxygen rentals. Our percentage of rental revenue increased from 35.8% in 2011, increasing our proportion of recurring revenue. Additionally, we have increased our gross margin from 49.3% in 2012 to 51.7% in 2013 primarily due to the change in sales mix toward direct-to-consumer from provider sales, improving system reliability, reducing material cost per system and lowering overhead cost per system. Our net loss was $2.6 million in 2009 transitioning to net income of $25.4 million in 2013. Adjusted net income excluding a one-time tax benefit was $3.6 million in 2013.

Our solution

Our Inogen One systems provide patients who require long-term oxygen therapy with a reliable, lightweight single solution product that 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.

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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 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 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

We market our current 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. To the extent our competitors portable oxygen solutions require supplemental use of a stationary oxygen concentrator, their solutions are less cost-effective and less convenient for patients. 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

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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 next-generation product, 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.

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 among patients, physicians and other clinicians, and third-party payors. In the United States as of December 31, 2013 we employed a marketing team of 5 people, an in-house sales team of 120 people, and a field-based sales force of 15 people. Of the $59 million of our 2013 revenue derived from the United States, approximately 52% represented direct-to-patient rentals, 30% represented cash pay sales to patients and 18% represented sales to third-party home medical equipment providers.

Our Medicare and private insurance patients rent our systems, while a portion of our patients choose to purchase our Inogen One products directly. Our ability to rent to patients directly, bill 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 unique 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. The below chart describes our United States direct-to-consumer sales process.

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In addition to the direct-to-consumer sales 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 capture a greater number of patients earlier in the course of their oxygen therapy.

We engage in a number of other initiatives to increase awareness, demand, and orders for Inogen One 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 2013. We sell our products in 43 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, 2013, we had four people who focused on selling our products to distributors and house accounts worldwide. In fiscal year 2012, an international distributor accounted for 12% of our revenue. However, no single customer represented more than 10% of our total revenue for 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.

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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. 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 both our domestic and international 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.

We believe it is crucial to provide patients with the highest quality customer support to achieve satisfaction with our products and optimal outcomes. As of December 31, 2013, we had a dedicated client service team of 24 people who were trained on our products, a clinical support team of 16 people who were licensed nurses or respiratory therapists, and a dedicated billing services team of 50 people. We provide our patients with a dedicated 24/7 hotline that is only given to our Inogen One 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 41% of our revenue in 2013. 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, 2013, our sales and sales administration consisted of 135 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. 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 five 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

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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 three years once implemented, after which they are subject to re-bidding or competitive bidding re-compete.

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.

	Medicare standard allowable effective 1/1/14	**Round one weighted average 1/1/11-12/11/13**	**Round two weighted average 7/1/13-6/30/16**	**Round one recompete weighted average 1/1/14-12/31/16**
E1390	$ 178.24	$ 116.16	$ 93.07	$ 95.74
E1392	51.63	41.89	42.72	38.08
Total	$ 229.87	$ 158.05	$ 135.79	$ 133.82
% of standard		69%	59%	58%

Medicare has not announced specific plans to implement competitive bidding nationwide, but by 2016 Medicare must implement competitive bidding or competitive bidding pricing for included items in non-competitive bidding areas. In February 2014, Medicare solicited public comment on the methodology it would use to comply with this statute.

As of December 31, 2013, we had contracts with 44 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 eight 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

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and reduce cost. Additionally, we use lean manufacturing practices to maximize our manufacturing efficiency. Bringing manufacturing and assembly largely in-house, combined with our consistent focus on driving efficient manufacturing processes, has enabled us to reduce our cost of revenue per system by 40% over the past four years.

We rely on third party manufacturers to supply several components of our Inogen One 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 maintains specified quantities of inventory in multiple locations, and our maintenance of back-up tooling that can easily be transferred to the 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, which we have registered with the FDA and for which have obtained ISO 13485 certification. The Goleta, California facility is approximately 39,000 square feet. The Richardson, Texas facility is approximately 31,000 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 twice since April 2012 by the FDA and found to be in compliance with Good Manufacturing Practices guidelines. We have completed two surveillance audits by our notifying body over the same period and identified one minor non-conformance, which is currently being addressed through implementation of new training software. Additionally, we have had two unannounced inspections by state inspectors from California and Texas within the past year and were determined to be in complete compliance with state health and safety requirements.

As of December 31, 2013, we had approximately 76 employees in operations, manufacturing and quality assurance.

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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, 2013, our research and development staff included 16 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, as well as development of our next-generation oxygen concentrators. Over the last 3 fiscal years, Inogen has invested over $6.5 million to efficiently bring two new generations of portable oxygen concentrators to market ($2.4, $2.3 and $1.8 million for the years ended 2013, 2012 and 2011), leveraging our 24 issued U.S. patents and one issued Canadian patent while also reducing the bill of product costs 36% from the original Inogen One G1.

Utilizing lean product development methodologies, we have released three generations of disruptive products over the last 10 years into the marketplace, including our Inogen One G1 in October 2004, our Inogen One G2 in March 2010, and our Inogen One G3 in September 2012. 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 lead to higher-quality products and lower total cost of ownership for its products.

Our product pipeline consists of both a stationary concentrator and a fourth generation, ultra-lightweight portable oxygen concentrators. The stationary concentrator, which we are calling Inogen At Home, will allow us to access non-ambulatory patients and will serve as a backup to our Inogen One 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 are not able to bill or be reimbursed for these backup sources and we supply them at our own cost, which is included in our cost of rental revenues. These backup sources are currently acquired from third parties; however, upon the launch of our Inogen At Home product, we will be manufacturing and supplying these stationary backup sources. The Inogen At Home 510(k) submission was received by the FDA s Devices and Radiological Health Document Control Center on August 8, 2013 and is currently in process. We expect to commercialize Inogen At Home in 2014. Our fourth-generation portable oxygen concentrators will be smaller and lighter than our Inogen One G3 and we expect to commercialize this product in the next several years. 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 our manufacturing competitors complete reliance on home medical equipment distribution 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, their entire oxygen business, including stationary and homefill, represents less than 13% percent of their billion-dollar plus homecare businesses.

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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 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 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 510(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

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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.

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.

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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.

We are subject to announced and unannounced inspections by the FDA, and these inspections may include the manufacturing facilities of our subcontractors. Inogen has been audited twice since April 2012 by the FDA and found to be in compliance with the Quality System Regulation. We cannot assure you that we can maintain a comparable level of regulatory compliance in the future at our facility.

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.

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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 Inogen One 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.

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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 of that person. 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 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 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

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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 environment in Europe is that of 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 with 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 13845 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 and obtain clearance of a license application, 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.

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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 who 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 that relate 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, 2013, we had 24 issued U.S. patents, one issued Canadian patent and six additional pending U.S. patent applications. We anticipate it will take several years for the most recent of these U.S. patent applications to result in issued patents, if at all.

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 to 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