

Inogen Inc
Form S-1/A
January 28, 2014
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Registration No. 333-192605

As filed with the Securities and Exchange Commission on January 28, 2014.

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

**AMENDMENT NO. 3
TO
FORM S-1
REGISTRATION STATEMENT
Under
The Securities Act of 1933**

INOGEN, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

5960
(Primary Standard Industrial
Classification Code Number)
326 Bollay Drive

33-0989359
(I.R.S. Employer
Identification Number)

Goleta, California 93117

(805) 562-0500

(Address, including ZIP code, and telephone number, including area code, of registrant's principal executive offices)

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(805) 562-0500

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act, as amended, check the following box. "

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. "

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. "

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. "

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. (Check one):

Large accelerated filer " Accelerated filer " Non-accelerated filer Smaller reporting company "

(Do not check if a
smaller reporting company)

The registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment that specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to such Section 8(a), may determine.

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The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to completion, dated January 28, 2014

Prospectus

shares

Common stock

This is an initial public offering of common stock of Inogen, Inc. We are selling _____ shares of common stock, and the selling stockholders are selling _____ shares of common stock. We will not receive any proceeds from the sale of shares by the selling stockholders. The estimated initial public offering price is expected to be between \$ _____ and \$ _____ per share.

Prior to this offering, there has been no public market for our common stock. We intend to apply to list our common stock on the NASDAQ Global Market under the symbol `INGN`.

We are an emerging growth company under applicable Securities and Exchange Commission rules and will be subject to reduced public company reporting requirements.

	Per share	Total
Initial public offering price	\$ _____	\$ _____
Underwriting discounts and commissions(1)	\$ _____	\$ _____
Proceeds to Inogen, Inc., before expenses	\$ _____	\$ _____
Proceeds to selling stockholders	\$ _____	\$ _____

(1) See Underwriting for additional disclosure regarding underwriting discounts, commissions and estimated offering expenses. The selling stockholders have granted the underwriters a 30-day option to purchase up to an additional _____ shares of common stock.

Investing in our common stock involves a high degree of risk. See Risk factors beginning on page 14.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares to purchasers on or about _____, 2014.

J.P. Morgan

Leerink Partners

William Blair

, 2014

Stifel

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Neither we, the selling stockholders nor the underwriters have authorized anyone to provide any information other than that contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We, the selling stockholders and the underwriters are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus is accurate only as of the date on the front cover of this prospectus, regardless of the time of delivery of this prospectus or any sale of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

Until _____, 2014 (25 days after the commencement of this offering), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to

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deliver a prospectus. This is in addition to the dealers obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

For investors outside of the United States: Neither we, the selling stockholders nor the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. Persons outside of the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside of the United States.

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Prospectus summary

The items in the following summary are described in more detail later in this prospectus. This summary provides an overview of selected information and does not contain all of the information you should consider before buying our common stock. Therefore, you should read the entire prospectus carefully, especially the Risk factors section beginning on page 12 and our financial statements and the related notes appearing at the end of this prospectus, before deciding to invest in our common stock. In this prospectus, unless the context otherwise requires, references to we, us, our or Inogen refer to Inogen, Inc.

Overview

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 delivery model limits lifestyle flexibility by requiring patients to plan their activities around a finite oxygen supply outside the home and to be tethered to a stationary concentrator in the home. 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 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 Medicare data from 2012 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 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 private payors on their behalf.

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, which we believe are disincentivized to encourage adoption of portable oxygen concentrators due to their investments in the physical infrastructure and personnel required for the delivery model. 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 technology that eliminates most of the delivery model's infrastructure and service requirements, gives us a cost structure advantage over our competitors.

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Since adopting our direct-to-consumer strategy in 2009, 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 \$48.6 million in 2012. In 2012, approximately 60% of our total revenue came from our direct-to-consumer business and approximately 40% came from our business-to-business sales. Of our direct-to-consumer revenue of \$29.0 million in 2012, \$19.9 million came from our domestic rental business and \$9.1 million came from domestic sales of our systems. Of our business-to-business revenue of \$19.6 million in 2012, \$13.0 million came from international markets, and \$6.7 million came from domestic distributors. We have increased our proportion of both recurring revenue and international revenue in 2012 compared to 2011. In 2012, 26.8% of our revenue came from international markets (versus 25.9% in 2011) and 40.9% from oxygen rentals (versus 35.8% in 2011). Additionally, we have increased our gross margin from 48.0% in 2011 to 49.3% in 2012 by increasing rental mix, 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 \$0.6 million in 2012.

Our market

Overview of oxygen therapy market

We believe the current total addressable oxygen therapy market in the United States is approximately \$3 billion to \$4 billion, based on 2012 Medicare data and our estimate of the ratio of the Medicare market to the total market. We estimate that more than 2.5 million patients in the United States and more than 4.5 million patients worldwide use oxygen therapy, and more than 60% of oxygen therapy patients in the United States are covered by Medicare. The number of oxygen therapy patients in the United States is projected to grow by approximately 7% to 10% per year between 2013 and 2019, which we believe is the result of earlier diagnosis of chronic respiratory conditions, demographic trends and longer durations of long-term oxygen therapy.

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

According to our analysis of 2011 and 2012 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. Of the ambulatory patients, we estimate that approximately 85% rely upon the delivery model that 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;

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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, allowing patients to enhance their 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 2012 Medicare data that the amount spent by patients with portable oxygen concentrators represents approximately 5% to 6% of total oxygen therapy spend. We believe the following has hindered the market acceptance of portable oxygen concentrators:

to obtain portable oxygen concentrators, patients are dependent on home medical equipment providers, which have made significant investments in the physical distribution infrastructure to support the delivery model;

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 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 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 that improve patient satisfaction, product reliability, durability and longevity; and

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access and utilize direct patient feedback in our research and development efforts, allowing us to stay at the forefront of patient preference. Our two product offerings, the Inogen One G3 and Inogen One G2, at approximately 4.8 and 7.0 pounds, respectively, offer portability without compromising or constraining other patient-friendly features. We believe our Inogen One solutions offer the following benefits:

single solution for home, ambulatory, travel and nocturnal treatment, meaning our portable oxygen concentrators do not need to be used with another oxygen solution in the home;

patented air-dryer and patent-pending user-replaceable sieve beds, both of which are critical to patient satisfaction, product performance, and our cost management;

clinical validation for nocturnal use, demonstrating the efficacy of our Intelligent Delivery Technology in providing consistent levels of oxygen during sleep despite decreased patient respiratory rates;

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; and

our systems are designed with multiple user friendly features, including long battery life and low noise-levels in their respective weight categories.

Our strengths

We believe our products and business model position us well to compete not only against other oxygen device manufacturers, but also to increase our share of the overall oxygen therapy market. We believe we have the following advantages relative to both traditional oxygen therapy providers and other oxygen device manufacturers:

Attractive economic model. Our non-delivery model allows us to receive a premium monthly Medicare reimbursement for deployment of our devices to oxygen patients versus the delivery model. Standard Medicare reimbursement for ambulatory patients using the delivery model is \$208.21 per month versus \$229.87 per month for our portable oxygen concentrator model, representing a premium of \$21.66 per month. A similar premium was maintained in the round one recompetes (\$19.09 per month) and in the round two (\$23.30 per month) competitive bidding areas. In addition, we believe our portable oxygen concentrator technology and direct-to-consumer strategy allow us to provide our solutions through a more efficient cost structure. The delivery model requires ongoing gaseous or liquid oxygen container refills and regular home deliveries with accompanying costs, while our portable oxygen concentrator non-delivery model eliminates oxygen container refills and regular deliveries of oxygen containers and their associated costs. Following the first two rounds of competitive bidding and the round one recompetes, we retained access to approximately 90% of the U.S. long-term oxygen therapy market, with the majority of contracts through mid-2016, while many providers were priced out of this market.

Direct-to-consumer capabilities. We believe our direct-to-consumer strategy enables patient access and retention as well as innovation and investment in our product portfolio. Pursuing a direct-to-consumer strategy requires national accreditation, state-by-state licensing and

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Medicare billing privileges. Given that we are unaware of any manufacturing competitor that currently markets on a direct-to-consumer basis, we do not believe any of these manufacturers possesses the necessary qualification to do so. If any of our manufacturing competitors were to pursue a direct-to-consumer strategy, they would risk negative reaction from the home medical equipment providers that sell their other homecare products, which generally represent significantly larger portions of their businesses than oxygen therapy products.

Commitment to customer service. We are focused on providing our patients with the highest quality of customer service. We guide them through the reimbursement and physician paperwork process, perform clinical titration and offer 24/7 telephone support, which includes clinical support as required. We have a sustained patient satisfaction rating of approximately 95%, as measured by our customer satisfaction surveys.

Patient-friendly, single-solution, sub-5 and sub-10 pound portable oxygen concentrators. Our Inogen One G3 and Inogen One G2 portable oxygen concentrators are sub-5 and sub-10 pound portable oxygen concentrators that can operate reliably and cost-effectively to service long-term oxygen therapy patients on a 24/7 basis, similar to a stationary oxygen concentrator or replacement portable oxygen concentrators. The technology in our Inogen One portable oxygen concentrators has been clinically validated for nocturnal use, allowing patients to receive oxygen therapy around the clock from a single device.

Commitment to research and development and developing intellectual property portfolio. We have a broad patent portfolio covering the design and construction of our oxygen concentrators and system optimization. Additionally, we have made significant investments in research and development and have a robust product pipeline of next-generation oxygen concentrators.

Management team with proven track record and cost focus. Our management team has built our direct-to-consumer capabilities and launched our two current primary product offerings, Inogen One G2 and Inogen One G3. We continue to realize meaningful product manufacturing cost savings of approximately 36% from our Inogen One G1 to our Inogen One G3 as a result of management's improvements in design, sourcing and reliability, as well as higher production volumes.

Revenue growth, profitability and recurring revenue. We have grown our revenue from \$10.7 million in 2009 to \$48.6 million in 2012, representing a year-over-year growth rate of 58.8%. In 2012, our recurring rental revenue represented 40.9% of sales. Our net loss was \$2.6 million in 2009 transitioning to net income of \$0.6 million in 2012.

Our strategy

Our goal is to design, build and market oxygen solutions that redefine how oxygen therapy is delivered. To accomplish this goal, we will continue to invest in our product offerings and our commercial infrastructure to:

expand our sales and marketing channels, including more internal and physician-based salespeople, increased direct-to-consumer advertising and greater international distribution;

develop innovative products, including next-generation oxygen concentrators and other innovations that improve quality of life;

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secure contracts with private payors and Medicaid in order to become in-network with non-Medicare payors, which represent at least 30% of our home oxygen therapy patients, and we believe represent a younger and more active patient population; and

continue to focus on cost reduction through scalable manufacturing, reliability improvements, asset utilization and service cost reduction.

Risks associated with our business

Our ability to implement our business strategy is subject to numerous risks that you should be aware of before making an investment decision. These risks are described more fully in the section entitled "Risk factors" immediately following this prospectus summary. These risks include, among others:

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

The implementation of the competitive bidding process under Medicare could negatively affect our business and financial condition;

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

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

If we fail to expand and maintain an effective sales force or successfully develop our international distribution network, our business, financial condition and operating results may be adversely affected; and

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

Corporate history and information

We were incorporated in Delaware in November 2001. Our principal executive offices are located at 326 Bollay Drive, Goleta, California 93117. Our telephone number is (805) 562-0500. Our website address is www.inogen.com. Information contained on the website is not incorporated by reference into this prospectus, and should not be considered to be part of this prospectus.

We use Inogen, Inogen One, Inogen One G2, Inogen One G3, oxygen.anytime.anywhere and other marks as trademarks in the United States and other countries. This prospectus contains references to our trademarks and service marks and to those belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork and other visual displays, may appear without the ® or ™ symbols, but such references are not intended to indicate in any way that we will not assert, to

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the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other entities' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other entity.

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The offering

Common stock offered by us shares

Common stock offered by the selling stockholders shares (or shares if the underwriters exercise their option to purchase additional shares from the selling stockholders in full)

Common stock to be outstanding after this offering shares

Use of proceeds

We intend to use the net proceeds from this offering for investments in rental assets; sales and marketing activities; research and product development activities; for facilities improvements or expansions and the purchase of manufacturing and other equipment; and for working capital and other general corporate purposes. We may also use a portion of our net proceeds to acquire and invest in complementary products, technologies or businesses; however, we currently have no agreements or commitments to complete any such transaction. We will not receive any of the net proceeds from the sale of shares of common stock by the selling stockholders. See Use of proceeds.

Risk factors

You should read the Risk factors section of this prospectus for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.

Proposed NASDAQ Global Market symbol INGN

The number of shares of common stock to be outstanding following this offering is based on 14,519,525 shares of common stock outstanding as of September 30, 2013 and excludes:

2,079,338 shares of common stock issuable upon exercise of options outstanding, 1,466,789 of which were vested and then exercisable, at a weighted average exercise price of \$1.0876 per share;

276,334 shares of common stock issuable upon the exercise of options to purchase common stock granted after September 30, 2013, at a weighted average exercise price of \$8.37 per share;

1,074,415 shares of common stock reserved for future grants under our stock-based compensation plans as of the date of this prospectus, consisting of:

895,346 shares of common stock reserved for future grants under our 2014 Equity Incentive Plan, which will become effective immediately prior to the date of this prospectus, and any shares subject to stock options under our 2012 Equity Incentive Plan or our 2002 Amended Stock Incentive Plan that expire or otherwise terminate without having been exercised in

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full and any shares issued pursuant to awards granted under such plans that are forfeited to or repurchased by us, with the maximum number of shares to be added to the 2014 Equity Incentive Plan equal to 2,328,659 shares;

179,069 shares of common stock reserved for future issuance under of 2014 Employee Stock Purchase Plan, which will become effective immediately prior to the date of this prospectus; and

Any shares of common stock that become available subsequent to this offering under our 2014 Equity Incentive Plan and 2014 Employee Stock Purchase Plan pursuant to the provisions thereof that automatically increase the shares reserved for issuance under such plans each year, as more fully described in Executive compensation Employee benefit and stock plans; and

268,200 shares of common stock issuable upon the exercise of warrants outstanding as of September 30, 2013, at a weighted average exercise price of \$1.4216 per share, after conversion of the convertible preferred stock.
Unless otherwise indicated, this prospectus reflects and assumes the following:

the conversion of all outstanding shares of our convertible preferred stock into an aggregate of 14,218,319 shares of common stock upon the closing of this offering;

the cash exercise of warrants to purchase an aggregate of 24,588 shares of common stock at a weighted average exercise price of \$10.1635 per share, which we expect will occur prior to the closing of this offering as the warrants will otherwise expire at that time;

the filing of our amended and restated certificate of incorporation immediately upon the closing of this offering; and

no exercise by the underwriters of their over-allotment option.

On November 12, 2013, we effected a three-for-one reverse stock split of our outstanding common and preferred stock. This prospectus gives retroactive effect to the split for all periods presented.

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We have derived the following summary of statements of operations data for the years ended December 31, 2011 and 2012 from audited financial statements appearing elsewhere in this prospectus. We derived the following statements of operations data for the nine months ended September 30, 2012 and 2013 and the balance sheet data as of September 30, 2013 from unaudited interim financial statements included elsewhere in this prospectus. In the opinion of management, the unaudited financial statements reflect all adjustments, which include only normal recurring adjustments necessary for a fair statement of results of operations and financial position. Historical results are not necessarily indicative of the results that may be expected in the future and the results for the nine months ended September 30, 2013 are not necessarily indicative of the results that may be expected for the full year. The summary financial data set forth below should be read together with the financial statements and the related notes to those statements, as well as the sections of this prospectus captioned Management's discussion and analysis of financial condition and results of operations.

(amounts in thousands, except share and per share amounts)	Year ended December 31,		Nine months ended September 30,	
	2011	2012	2012	2013
	(as restated)		(unaudited)	
Statements of operations:				
Total revenue	\$ 30,634	\$ 48,576	\$ 34,735	\$ 55,681
Total cost of revenue	15,930	24,627	17,821	26,865
Gross profit	14,704	23,949	16,914	28,816
Operating expenses				
Research and development	1,789	2,262	1,731	1,817
Selling, general and administrative	14,637	20,858	14,558	23,088
Total operating expenses	16,426	23,120	16,289	24,905
Income (loss) from operations	(1,722)	829	625	3,911
Total other income (expense), net	(267)	(247)	(149)	(296)
Provision for income taxes	13	18	20	151
Net (loss) income	\$ (2,002)	\$ 564	\$ 456	\$ 3,464
Less deemed dividend on redeemable convertible preferred stock	\$ (3,027)	\$ (5,781)	\$ (4,119)	\$ (5,359)
Net loss attributable to common stockholders	\$ (5,029)	\$ (5,217)	\$ (3,663)	\$ (1,895)
Net loss per share attributable to common stockholders - basic and diluted(1)	\$ (20.15)	\$ (19.97)	\$ (14.02)	\$ (6.91)
Weighted average shares used in computing basic and diluted net loss per share(1)	249,519	261,268	261,216	274,357
Unaudited pro forma net income per share attributable to common stockholders(1):				
Basic:		\$ 0.04		\$ 0.24
Diluted:		\$ 0.04		\$ 0.22
Unaudited weighted average shares used in computing pro forma net income per share(1):				
Basic:		14,601,861		14,516,523
Diluted:		15,486,487		15,733,279

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Other financial data:				
EBITDA(2)	\$ 1,357	\$ 5,971	\$ 4,224	\$ 9,913
Adjusted EBITDA(2)	\$ 1,620	\$ 5,883	\$ 4,124	\$ 10,231

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- (1) See note 2 to each of our audited and unaudited financial statements included elsewhere in this prospectus for an explanation of the calculations of our basic and diluted net loss per share attributable to common stockholders and pro forma net loss per share attributable to common stockholders.
- (2) For a discussion of our use of EBITDA and Adjusted EBITDA and their calculations, please see Non GAAP financial measures below.

(in thousands)	As of September 30, 2013		
	Actual	Pro forma(1)	adjusted(2)(3)
		(unaudited)	
Balance sheet data:			
Cash and cash equivalents	\$ 17,059	\$ 17,309	\$
Working capital	12,352	12,602	
Total assets	60,862	61,112	
Preferred stock warrant liability	201	173	
Total liabilities	26,667	26,639	
Redeemable convertible preferred stock	116,744		
Preferred Stock	247		
Common Stock	1	15	
Additional paid in capital		117,255	
Total stockholders (deficit) equity	(82,549)	34,473	

- (1) Gives effect to (i) the conversion of all outstanding shares of convertible preferred stock into an aggregate of 14,218,319 shares of common stock upon the closing of this offering, (ii) the cash exercise of warrants to purchase an aggregate of 24,588 shares of common stock, which we expect will occur prior to the closing of this offering as the warrants will otherwise expire at that time, and (iii) the reclassification of our preferred stock warrant liability to additional paid-in-capital upon the closing of this offering.
- (2) Gives further effect to our sale of _____ shares of common stock in this offering at an assumed initial public offering price of \$ _____ per share, the midpoint of the range reflected on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.
- (3) A \$1.00 increase (decrease) in the assumed initial public offering price of \$ _____ per share, the midpoint of the price range reflected on the cover page of this prospectus, would increase (decrease) each of pro forma as adjusted cash and cash equivalents, working capital, total assets and total stockholders' equity by approximately \$ _____ million, assuming that the number of shares offered by us, as set forth on the cover of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. A 1,000,000 share increase (decrease) in the number of shares offered by us would increase (decrease) each of pro forma as adjusted cash and cash equivalents, working capital, total assets and total stockholders' equity by approximately \$ _____ million after deducting estimated underwriting discounts and commissions and any estimated offering expenses payable by us.

Non-GAAP financial measures

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

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

Our use of EBITDA and Adjusted EBITDA have limitations as analytical tools, and you should not consider them in isolation or as a substitute for analysis of our results as reported under GAAP. Some of these limitations are:

EBITDA and Adjusted EBITDA do not reflect our cash expenditures for capital equipment or other contractual commitments;

Although depreciation and amortization are non-cash charges, the assets being depreciated and amortized may have to be replaced in the future, and EBITDA and Adjusted EBITDA do not reflect capital expenditure requirements for such replacements;

EBITDA and Adjusted EBITDA do not reflect changes in, or cash requirements for, our working capital needs;

EBITDA and Adjusted EBITDA do not reflect the interest expense or the cash requirements necessary to service interest or principal payments on our indebtedness; and

Other companies, including companies in our industry, may calculate EBITDA and Adjusted EBITDA measures differently, which reduces their usefulness as a comparative measure.

In evaluating EBITDA and Adjusted EBITDA, you should be aware that in the future we will incur expenses similar to the adjustments in this presentation. Our presentation of EBITDA and Adjusted EBITDA should not be construed as an inference that our future results will be unaffected by these expenses or any unusual or non-recurring items. When evaluating our performance, you should consider EBITDA and Adjusted EBITDA alongside other financial performance measures, including our net loss and other GAAP results.

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

EBITDA and adjusted EBITDA (in thousands)	2011	Year ended December 31, 2012	2012	Nine months ended September 30, 2013
Net income (loss)	\$ (2,002)	\$ 564	\$ 456	\$ 3,464
Non-GAAP adjustments:				
Interest income	(113)	(88)	(84)	(9)
Interest expense	261	493	381	312
Provision for income taxes	13	18	20	151
Depreciation and amortization	3,198	4,984	3,451	5,995
EBITDA	1,357	5,971	4,224	9,913
Change in fair value of preferred stock warrant liability	119	(148)	(148)	202
Stock-based compensation	144	60	48	116
Adjusted EBITDA	\$ 1,620	\$ 5,883	\$ 4,124	\$ 10,231

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Risk factors

Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information in this prospectus, including our financial statements and related notes, before deciding whether to purchase shares of our common stock. If any of the following risks are realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. In that event, the price of our common stock could decline and you could lose part or all of your investment.

Risks related to our business and strategy

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

As a provider of oxygen product rentals, we have historically depended heavily on Medicare reimbursement as a result of the higher proportion of elderly persons suffering from chronic respiratory conditions. Medicare Part B, or Supplementary Medical Insurance Benefits, provides coverage to eligible beneficiaries that includes items of durable medical equipment for use in the home, such as oxygen equipment and other respiratory devices. We believe that more than 60% of oxygen therapy patients in the United States have primary coverage under Medicare Part B. In 2011 and 2012, we derived approximately 26% and 27%, respectively, of our revenue from Medicare. There are increasing pressures on Medicare to control health care costs and to reduce or limit reimbursement rates for home medical products.

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

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

The Deficit Reduction Act of 2005 limited the total number of continuous rental months for which Medicare will pay for oxygen equipment to 36 months, after which time there is generally no additional reimbursement to the supplier (other than for periodic, in-home maintenance and servicing). The Deficit Reduction Act of 2005 also provided that title of the equipment would transfer to the beneficiary, which was later repealed by the Medicare Improvements for Patients and Providers Act of 2008. For purposes of the rental cap, the Deficit Reduction Act of 2005 provided for a new 36-month rental period that began January 1, 2006 for all oxygen equipment. After the 36th continuous month during which payment is made for the oxygen equipment, the supplier is generally required to continue to furnish the equipment during the period of medical need for the remainder of the useful lifetime of the equipment, provided there are no breaks in service due to medical necessity that exceed 60 days. The reasonable useful lifetime for portable oxygen equipment is 60 months. After 60 months, if the

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patient requests, the rental cycle starts over and a new 36-month capped rental period begins. There are no limits on the number of 60-month cycles over which a Medicare patient may receive benefits and an oxygen therapy provider may receive reimbursement, so long as such equipment continues to be medically necessary for the patient. We anticipate that the Deficit Reduction Act of 2005 oxygen payment rules will continue to negatively affect our net revenue on an ongoing basis, as each month additional customers reach the 36-month capped service period, resulting in potentially two or more years without rental income from these customers. We cannot state with certainty the number of patients in the capped rental period or the potential impact to revenue associated with patients in the capped rental period.

Medicare Improvements for Patients and Providers Act of 2008 retroactively delayed the implementation of competitive bidding for 18 months from previously established dates and decreased the 2009 fee schedule payment amounts by 9.5% for product categories included in competitive bidding. In addition to the 9.5% reduction under Medicare Improvements for Patients and Providers Act of 2008, the Centers for Medicare & Medicaid Services implemented a reduction to the monthly payment amount for stationary oxygen equipment by 2.3% in 2009 and 1.5% in 2010, which reduced the monthly payment rate to \$175.79 and \$173.17 in 2009 and 2010, respectively. The stationary oxygen payment rate for 2011 and 2012 was increased by 0.1%, 1.6%, and 0.7% in 2011, 2012, and 2013, respectively, thereby increasing the monthly payment rate to \$173.31, \$176.06, and \$177.36 in 2011, 2012, and 2013, respectively. The monthly payment rate for non-delivery ambulatory oxygen in the relevant period was flat at \$51.63.

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

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

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

The implementation of the competitive bidding process under Medicare could negatively affect our business and financial condition.

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

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The Centers for Medicare & Medicaid Services, the agency responsible for administering the Medicare program, conducts a competition for each competitive acquisition area under which providers submit bids to supply certain covered items of durable medical equipment. Successful bidders must meet certain program quality standards in order to be awarded a contract and only successful bidders can supply the covered items to Medicare beneficiaries in the acquisition area. There are, however, regulations in place that allow non-contracted providers to continue to provide products and services to their existing customers at the new competitive bidding payment amounts. The contracts are expected to be re-bid every three years. The Centers for Medicare & Medicaid Services is required to award contracts to multiple entities submitting bids in each area for an item or service, but has the authority to limit the number of contractors in a competitive acquisition area to the number it determines to be necessary to meet projected demand.

Although the Centers for Medicare & Medicaid Services concluded the bidding process for the first round of Metropolitan Statistical Areas in September 2007, in July 2008, Congress enacted Medicare Improvements for Patients and Providers Act of 2008, which retroactively delayed the implementation of competitive bidding. Medicare Improvements for Patients and Providers Act of 2008 also reduced Medicare prices nationwide by 9.5% beginning in 2009 for the product categories, including oxygen, that were initially included in competitive bidding.

In 2009, the Centers for Medicare & Medicaid Services implemented a new bidding process in nine Metropolitan Statistical Areas, covering approximately 9% of the Medicare oxygen market. Reimbursement rates from the re-bidding process were publicly released by the Centers for Medicare & Medicaid Services on June 30, 2010. The Centers for Medicare & Medicaid Services announced average savings of approximately 35% off the current standard Medicare payment rates in effect for the product categories included in competitive bidding. As of January 1, 2011, these payment rates were in effect in the nine markets only. We were offered six three-year contracts to provide oxygen equipment in six of the nine markets, and we accepted and signed those contracts.

The Centers for Medicare & Medicaid Services implemented the second phase of competitive bidding in an additional 100 competitive bidding areas covering approximately 50% of the Medicare oxygen market, with three-year contracts effective July 1, 2013. The Centers for Medicare & Medicaid Services announced average savings of approximately 45% off the current standard Medicare payment rates in effect for the product categories included in competitive bidding. As of July 1, 2013, these payment rates were in effect in the 100 competitive bidding areas. We were offered 89 contracts to provide oxygen equipment in 89 of the 100 Competitive Bidding Areas, and we accepted and signed those contracts.

Round one re-competes are expected or planned to go into effect in January 2014; reimbursement rates from the re-bidding process were publicly released by the Centers for Medicare & Medicaid Services on October 1, 2013. The Centers for Medicare & Medicaid Services announced average savings of approximately 37% off the current standard Medicare payment rates in effect from the product categories included in competitive bidding. We were offered 3 contracts to provide respiratory equipment in 3 of the 9 competitive bidding areas, and we accepted and signed those contracts. We are required to be able to supply additional respiratory products such as sleep and aerosol therapy, which have lower margins than our existing products. This could have a negative impact on our financial conditions and results of operations.

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The Patient Protection and Affordable Care Act legislation requires the Centers for Medicare & Medicaid Services to expand competitive bidding further to additional geographic markets or to use competitive bid pricing information to adjust the payment amounts otherwise in effect for areas that are not competitive acquisition areas by January 1, 2016.

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

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

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

Our significant manufacturing competitors are Invacare Corporation, Respironics (a subsidiary of Koninklijke Philips N.V.), AirSep Corporation and SeQual Technologies (subsidiaries of Chart Industries, Inc.), Inova Labs, Inc. and DeVilbiss Healthcare. Given the relatively straightforward regulatory path in the oxygen therapy device manufacturing market, we expect that the industry will become increasingly competitive in the future. Manufacturing companies compete for sales to providers primarily on the basis of product features, service and price.

Lincare Inc., Apria Healthcare, Inc. Rotech Healthcare, Inc. and American HomePatient, Inc. are 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.

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

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greater financial and human resources for product development, sales and marketing, patent litigation and customer financing. As a result, our competitors may be able to respond more quickly and effectively than we can to new or changing opportunities, technologies, standard regulatory and reimbursement development and customer requirements. In light of these advantages that our competitors maintain, even if our technology and direct-to-consumer distribution strategy is more effective than the technology and distribution strategy of our competitors, current or potential customers might accept competitor products and services in lieu of purchasing our products. We anticipate that we will face increased competition in the future as existing companies and competitors develop new or improved products and distribution strategies and as new companies enter the market with new technologies and distribution strategies. We may not be able to compete effectively against these organizations. Our ability to compete successfully and to increase our market share is dependent upon our reputation for providing responsive, professional and high-quality products and services and achieving strong customer satisfaction. Increased competition in the future could adversely affect our revenue, revenue growth rate, margins and market share.

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

In the United States, the legislative landscape, particularly as it relates to healthcare regulation and reimbursement coverage, continues to evolve. In March 2010, the Patient Protection and Affordable Care Act was passed, which has the potential to substantially change health care financing by both governmental and private insurers, and significantly impact the U.S. medical device industry. As discussed above, the Patient Protection and Affordable Care Act, among other things, imposes a new excise tax, which began in 2013, on entities that manufacture, produce or import medical devices in an amount equal to 2.3% of the price for which such devices are sold in the United States, however oxygen products such as ours were exempt. In addition, as discussed above, the Patient Protection and Affordable Care Act also expands the round two of competitive bidding to a total of 91 competitive bidding areas, and by 2016, the process must be nationalized or prices in non-competitive bidding areas must be adjusted to match competitive bidding prices.

In addition, other legislative changes have been proposed and adopted in the United States since the Patient Protection and Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect on April 1, 2013. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012 which, among other things, further reduced Medicare payments to certain providers, including physicians, hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressures.

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

We may not be able to compete as effectively with our competitors, and ultimately satisfy the needs and preferences of our customers, unless we can continue to enhance existing products and develop new innovative products. Product development requires significant financial, technological, and other resources. While we expended \$1.8 million and \$2.3 million for research and development efforts in 2011 and 2012, respectively, we cannot assure you that this level of investment in research and development will be sufficient to maintain a competitive advantage in product innovation, which could cause our business to suffer. Product improvements and new product introductions also require significant planning, design, development, and testing at the technological, product, and manufacturing process levels and we may not be able to timely develop product improvements or new products. Our competitors' new products may beat our products to market, be more effective with more features, obtain better market acceptance, or render our products obsolete. Any new products that we develop may not receive market acceptance or otherwise generate any meaningful sales or profits for us relative to our expectations based on, among other things, existing and anticipated investments in manufacturing capacity and commitments to fund advertising, marketing, promotional programs, and research and development.

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

A significant portion of our revenue is derived from reimbursement by third-party payors. We accept assignment of insurance benefits from customers and, in a majority of cases, invoice and collect payments directly from Medicare, private payors and Medicaid, as well as from customers under co-payment provisions. In 2012, approximately 41% of our revenue was derived from Medicare, private payors and Medicaid, and the balance directly from individual customers and commercial entities.

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

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

A portion of our revenue is derived from private payors. Based on our patient population, we estimate at least 30% of potential customers have non-Medicare insurance coverage, and we believe these patients represent a younger and more active patient population that will be drawn to the quality-of-life benefits of our solution. Failing to maintain and obtain private payor contracts from private insurance companies and employers and secure in-network provider status could have a material adverse effect on our financial condition and operating results. In addition, private payors are under pressure to increase profitability and reduce costs. In response, certain private payors are limiting coverage or reducing reimbursement rates for the products we provide. We believe that private payor reimbursement levels will generally be reset in accordance with the Medicare payment amounts determined by competitive bidding. We cannot predict the extent to which reimbursement for our products will be affected by competitive bidding or by initiatives to reduce costs for private payors. Failure to obtain or maintain private payor contracts or the unavailability of third-party coverage or inadequacy of reimbursement for our products would adversely affect our business, financial conditions, and results of operations.

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

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

Our suppliers may encounter financial hardships as a result of unfavorable economic and market conditions unrelated to our demand for components, which could inhibit their ability to fulfill our orders and meet our requirements;

Suppliers may fail to comply with regulatory requirements, be subject to lengthy compliance, validation or qualification periods, or make errors in manufacturing components that could negatively affect the efficacy or safety of our products or cause delays in supplying of our products to our customers;

Newly identified suppliers may not qualify under the stringent regulatory standards to which our business is subject;

We or our suppliers may not be able to respond to unanticipated changes in customer orders, and if orders do not match forecasts, we or our suppliers may have excess or inadequate inventory of materials and components;

We may be subject to price fluctuations due to a lack of long-term supply arrangements for key components;

We may experience delays in delivery by our suppliers due to changes in demand from us or their other customers;

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We or our suppliers may lose access to critical services and components, resulting in an interruption in the manufacture, assembly and shipment of our systems;

Our suppliers may be subject to allegations by other parties of misappropriation of proprietary information in connection with their supply of products to us, which could inhibit their ability to fulfill our orders and meet our requirements;

Fluctuations in demand for products that our suppliers manufacture for others may affect their ability or willingness to deliver components to us in a timely manner;

Our suppliers may wish to discontinue supplying components or services to us; and

We may not be able to find new or alternative components or reconfigure our system and manufacturing processes in a timely manner if the necessary components become unavailable.

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

If any of these risks materialize, costs could significantly increase and our ability to meet demand for our products could be impacted. If we are unable to satisfy commercial demand for our Inogen One systems in a timely manner, our ability to generate revenue would be impaired, market acceptance of our products could be adversely affected, and customers may instead purchase or use alternative products. In addition, we could be forced to secure new or alternative components and subassemblies through a replacement supplier. Finding alternative sources for these components and subassemblies could be difficult in certain cases and may entail a significant amount of time and disruption. In some cases, we would need to change the components or subassemblies if we sourced them from an alternative supplier. This, in turn, could require a redesign of our Inogen One systems and, potentially, require additional FDA clearance or approval before we could use any redesigned product with new components or subassemblies, thereby causing further costs and delays that could adversely affect our business, financial condition and operating results.

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

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

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

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

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

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

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

Reimbursement rates are established by fee schedules mandated by Medicare, private payors and Medicaid are likely to remain constant or decrease due, in part, to federal and state government budgetary constraints. As a result, with respect to Medicare and Medicaid related revenue, we

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are not able to offset the effects of general inflation on our operating costs through increases in prices for our products. In particular, labor and related costs account for a significant portion of our operating costs and we compete with other health care providers to attract and retain qualified or skilled personnel and with various industries for administrative and service employees. This competitive environment could result in increased labor costs. As such, we must control our operating costs, particularly labor and related costs, and failing to do so could adversely affect our financial conditions and results of operations.

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

Our success depends upon the skills, experience and efforts of our senior executives and other key technical personnel, including certain members of our engineering staff, and our sales and marketing executives. Much of our corporate expertise is concentrated in relatively few employees, the loss of which for any reason could negatively affect our business. Competition for our highly skilled employees is intense and we cannot prevent the resignation of any employee. We do not maintain key man life insurance on any of our senior executives. None of our senior executive team is bound by written employment contracts to remain with us for a specified period. In addition, we have not entered into non-compete agreements with members of our senior management team. The loss of any member of our senior management team could harm our ability to implement our business strategy and respond to the market conditions in which we operate.

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

We have a limited operating history and have incurred significant net losses in each fiscal year until fiscal year 2012, when we achieved positive net income. As of September 30, 2013, we had an accumulated deficit of \$82.5 million. These net losses have resulted principally from costs incurred in our research and development programs and from our selling, general and administrative expenses. We expect to incur increases in expenses for research and development and significant expansion of our sales and marketing capabilities. Additionally, following this offering, we expect that our selling, general and administrative expenses will increase due to the additional operational and reporting costs associated with being a public company. Because of the numerous risks and uncertainties associated with our commercialization efforts and future product development, we are unable to predict if we will maintain or increase our net income.

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

Our quarterly revenue and results of operations have varied in the past and may continue to vary significantly from quarter-to-quarter. This variability may lead to volatility in our stock price as research analysts and investors respond to these quarterly fluctuations. These fluctuations are due to numerous factors, including: fluctuations in consumer demand for our products; seasonal cycles in consumer spending; our ability to design, manufacture and deliver products to our consumers in a timely and cost-effective manner; quality control problems in our manufacturing operations; our ability to timely obtain adequate quantities of the components used in our products; new product introductions and enhancements by us and our competitors; unanticipated increases in costs or expenses; and fluctuations in foreign currency exchange rates.

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For example, we typically experience higher sales in the second quarter, as a result of consumers traveling and vacationing during the summer months. The foregoing factors are difficult to forecast, and these, as well as other factors, could materially and adversely affect our quarterly and annual results of operations. In addition, a significant amount of our operating expenses are relatively fixed due to our manufacturing, research and development, and sales and general administrative efforts. Any failure to adjust spending quickly enough to compensate for a revenue shortfall could magnify the adverse impact of such revenue shortfall on our results of operations. Our results of operations may not meet the expectations of research analysts or investors, in which case the price of our common stock could decrease significantly.

The terms of our revolving credit and term loan agreement may restrict our current and future operations, and could affect our ability to respond to changes in our business and to manage our operations.

We are parties to an amended and restated revolving credit and term loan agreement with Comerica Bank as administrative agent, which we refer to as our revolving credit and term loan agreement. The agreement provides for a previously existing term loan in the amount of \$3.0 million, another previously existing term loan in the amount of \$8.0 million and a new term loan facility in the amount of \$12.0 million. As of September 30, 2013, we had term loan borrowings outstanding under the agreement of \$11.1 million, which included \$0.7 million and \$4.4 million under the pre-existing term loans, and \$6.0 million under the new term loan. The agreement also provides for a \$1.0 million revolving line of credit, none of which was outstanding as of September 30, 2013. The revolver expired on October 13, 2013 and we have no plans to renew or replace it. The agreement is secured by all or substantially all of our assets.

Pursuant to the agreement, we are subject to certain financial covenants relating to liquidity, debt service, and leverage ratios. The liquidity ratio is the ratio of (i) liquidity (cash plus eligible accounts receivable) to (ii) the current portion of all indebtedness owed to the lenders. The debt service coverage ratio is the ratio on a basis of (a) Adjusted EBITDA, less (i) cash capital expenditures (including rental equipment) and (ii) taxes paid or payable, to (b) the sum of cash principal payments plus interest expense paid or payable, all such items in clauses (a) and (b) measured on an annualized trailing six (6) months basis; provided that cash capital expenditures shall not be subtracted from clause (a) hereof so long as we maintain at least \$1.5 million in unrestricted cash during the entire relevant fiscal period. The senior leverage ratio is the ratio of (a) funded debt basis to (b) Adjusted EBITDA measured on an annualized trailing six (6) months basis.

The agreement contains events of default customary for transactions of this type, including nonpayment, misrepresentation, breach of covenants, material adverse effect and bankruptcy. As of September 30, 2013, we had no outstanding balance under the revolving line of credit and an outstanding balance of \$11.1 million under the term loan. In the event we fail to satisfy our covenants, or otherwise go into default, Comerica Bank has a number of remedies, including sale of our assets and acceleration of all outstanding indebtedness. Certain of these remedies would likely have a material adverse effect on our business. As of September 30, 2013, in order to be in compliance with the liquidity requirements, debt service ratios, and leverage ratios of existing debt obligations, we were required to maintain \$2.5 million in unaudited Adjusted EBITDA in the previous six months, and we had \$6.6 million in actual unaudited Adjusted EBITDA, and \$7.8 million of cash and qualified accounts receivable, and we had \$17.1 million of actual cash.

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

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

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

As of December 31, 2012, we had federal net operating loss carryforwards, or NOLs, of approximately \$62.0 million, which expire in various years beginning in 2022, if not utilized. In general, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an ownership change is subject to limitations on its ability to utilize its pre-change NOLs to offset future taxable income. In general, an ownership change occurs if there is a cumulative change in our ownership by 5% shareholders that exceeds 50 percentage points over a rolling three-year period. Our existing NOLs may be subject to limitations arising from previous ownership changes, and if we undergo one or more ownership changes in connection with this offering or future transactions in our stock, our ability to utilize NOLs could be further limited by Section 382 of the Code. As a result of these limitations, we may not be able to utilize a material portion of the NOLs reflected on our balance sheet and for this reason, we have fully reserved against the value of our NOLs on our balance sheet.

Risks related to the regulatory environment

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

The federal government and all states in which we currently operate regulate various aspects of our business. In particular, our sales and customer service centers are subject to federal laws that regulate interstate motor-carrier transportation. Our operations also are subject to state laws governing, among other things, distribution of medical equipment and certain types of home health activities, and we are required to obtain and maintain licenses in each state to act as a durable medical equipment supplier. Certain of our employees are subject to state laws and regulations governing the professional practices of respiratory therapy.

As a health care provider participating in governmental healthcare programs, we are subject to laws directed at preventing fraud and abuse, which subject our marketing, billing, documentation and other practices to government scrutiny. To ensure compliance with Medicare, Medicaid and other regulations, government agencies or their contractors often conduct routine audits and request customer records and other documents to support our claims submitted for payment of services rendered. Government agencies or their contractors also periodically open investigations and obtain information from health care providers. Violations of federal and state

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regulations can result in severe criminal, civil and administrative penalties and sanctions, including debarment, suspension or exclusion from Medicare, Medicaid and other government reimbursement programs, any of which would have a material adverse effect on our business.

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

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

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

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

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

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

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

design, development and manufacturing;

testing, labeling, content and language of instructions for use and storage;

clinical trials;

product safety;

marketing, sales and distribution;

pre-market clearance and approval;

record keeping procedures;

advertising and promotion;

recalls and field safety corrective actions;

post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury;

post-market approval studies; and

product import and export.

Before we can market or sell a medical device in the United States, we must obtain either clearance from the FDA under Section 510(k) of the Federal Food, Drug, and Cosmetic Act, or the FDCA, or approval of a pre-market approval, application from the FDA, unless an exemption from pre-market review applies. In the 510(k) clearance process, the FDA must determine that a proposed device is substantially equivalent to a device legally on the market, known as a predicate device, with respect to intended use, technology and safety and effectiveness, in order to clear the proposed device for marketing. Clinical data is sometimes required to support substantial equivalence. The pre-market approval pathway requires an applicant to demonstrate the safety and effectiveness of the device based, in part, on extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data. The pre-market approval process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices. Products that are approved through a pre-market approval application generally need FDA approval before they can be modified. Similarly, some modifications made to products cleared through a 510(k) may require a new 510(k). Both the 510(k) and pre-market approval processes can be expensive and lengthy and require the payment of

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significant fees, unless an exemption applies. The FDA's 510(k) clearance process usually takes from three to 12 months, but may take longer. The process of obtaining a pre-market approval is much more costly and uncertain than the 510(k) clearance process and generally takes from one to three years, or longer, from the time the application is submitted to the FDA until an approval is obtained. The process of obtaining regulatory clearances or approvals to market a medical device can be costly and time consuming, and we may not be able to obtain these clearances or approvals on a timely basis, if at all.

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In the United States, our currently commercialized products are marketed pursuant to pre-market clearance under Section 510(k) of the FDCA. If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, our product introductions or modifications could be delayed or canceled, which could cause our sales to decline. In addition, the FDA may determine that future products will require the more costly, lengthy and uncertain pre-market approval process. Although we do not currently market any devices under a pre-market approval, the FDA may demand that we obtain a pre-market approval prior to marketing certain of our future products. In addition, if the FDA disagrees with our determination that a product we currently market is subject to an exemption from pre-market review, the FDA may require us to submit a 510(k) or pre-market approval application in order to continue marketing the product. Further, even with respect to those future products where a pre-market approval is not required, we cannot assure you that we will be able to obtain the 510(k) clearances with respect to those products.

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

we may not be able to demonstrate to the FDA's satisfaction that our products are safe and effective for their intended users;

the data from our pre-clinical studies and clinical trials may be insufficient to support clearance or approval, where required; and

the manufacturing process or facilities we use may not meet applicable requirements.

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

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

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

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

Furthermore, the FDA's ongoing review of the 510(k) program may make it more difficult for us to make modifications to our previously cleared products, either by imposing more strict requirements on when a manufacturer must submit a new 510(k) for a modification to a previously cleared product, or by applying more onerous review criteria to such submissions. Specifically, pursuant to the Food and Drug Administration Safety and Innovation Act, which was signed into law in July 2012, the FDA is obligated to prepare a report for Congress on the FDA's approach for determining when a new 510(k) will be required for modifications or changes to a previously cleared device. After submitting this report, the FDA is expected to issue revised guidance to assist device manufacturers in making this determination. Until then, manufacturers may continue to adhere to the FDA's 1997 guidance on this topic when making a determination as to whether or not a new 510(k) is required for a change or modification to a device, but the practical impact of the FDA's continuing scrutiny of these issues remains unclear.

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

The regulations to which we are subject are complex and have become more stringent over time. Regulatory changes could result in restrictions on our ability to continue or expand our operations, higher than anticipated costs or lower than anticipated sales. Even after we have obtained the proper regulatory clearance or approval to market a product, we have ongoing responsibilities under FDA regulations. The FDA and state authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state agencies, which may include any of the following sanctions:

warning letters, fines, injunctions, consent decrees and civil penalties;

recalls, termination of distribution, or seizure of our products;

operating restrictions or partial suspension or total shutdown of production;

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delays in the introduction of products into the market;

refusal to grant our requests for future 510(k) clearances or approvals of new products, new intended uses, or modifications to existing products;

withdrawals or suspensions of current 510(k) clearances or approvals, resulting in prohibitions on sales of our products; and

criminal prosecution.

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

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

Medical devices, such as our Inogen One systems, can experience performance problems in the field that require review and possible corrective action by us or the product manufacturer. We cannot provide assurance that component failures, manufacturing errors, design defects and/or labeling inadequacies, which could result in an unsafe condition or injury to the operator or the patient will not occur. The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. Manufacturers may also, under their own initiative, recall a product if any material deficiency in a device is found or withdraw a product to improve device performance or for other reasons. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Similar regulatory agencies in other countries have similar authority to recall devices because of material deficiencies or defects in design or manufacture that could endanger health. Any recall would divert management attention and financial resources, could cause the price of our stock to decline and expose us to product liability or other claims and harm our reputation with customers. A recall involving our Inogen One systems could be particularly harmful to our business, financial and operating results.

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

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

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

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

untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;

customer notifications or repair, replacement, refunds, recall, detention or seizure of our products;

operating restrictions or partial suspension or total shutdown of production;

refusing or delaying our requests for 510(k) clearance or pre-market approval of new products or modified products;

withdrawing 510(k) clearances or pre-market approvals that have already been granted;

refusal to grant export approval for our products; or

criminal prosecution.

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

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

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

Approximately 27% of our revenue was from sales outside of the United States in 2012. We sell our products in 41 countries outside of the United States through distributors or directly to large house accounts. In order to market our products in the European Union or other foreign jurisdictions, we must obtain and maintain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies from country to country and can involve additional testing. The time required to obtain approval abroad may be longer than the time required to obtain FDA clearance. The foreign regulatory approval process includes many of the risks associated with obtaining FDA clearance and we may not obtain foreign regulatory approvals on a timely basis, if at all. FDA clearance does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries. However, the failure to obtain clearance or approval in one jurisdiction may have a negative impact on our ability to obtain clearance or approval elsewhere. If we do not obtain or maintain necessary approvals to commercialize our products in markets outside the United States, it would negatively affect our overall market penetration.

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

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

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

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

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result, both covered entities and business associates are now subject to significant civil and criminal penalties for failure to comply with Privacy Standards and Security Standards.

HIPAA and the HITECH Act also include standards for common health care electronic transactions and code sets, such as claims information, plan eligibility, payment information and the use of electronic signatures, and privacy and electronic security of individually identifiable health information. Covered entities, such as health care providers, are required to conform to such transaction set standards pursuant to HIPAA.

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

If we do not comply with existing or new laws and regulations related to patient health information, we could be subject to criminal or civil sanctions. New health information standards, whether implemented pursuant to HIPAA, the HITECH Act, congressional action or otherwise, could have a significant effect on the manner in which we handle health care related data and communicate with payors, and the cost of complying with these standards could be significant.

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

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

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

The HIPAA transaction standards are complex, and subject to differences in interpretation by third-party payors. For instance, some third-party payors may interpret the standards to require

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

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

The federal anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering, or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid, or other federal financed healthcare programs. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, the exceptions and safe harbors are drawn narrowly, and any remuneration to or from a prescriber or purchaser of healthcare products or services may be subject to scrutiny if they do not qualify for an exception or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability.

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

The Patient Protection and Affordable Care Act also imposes new reporting and disclosure requirements on device and drug manufacturers for any transfer of value made or distributed to prescribers and other healthcare providers. Device and drug manufacturers will also be required to report and disclose any investment interests held by physicians and their immediate

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family members during the preceding calendar year. Failure to submit required information may result in civil monetary penalties of up to an aggregate of \$150,000 per year (and up to an aggregate of \$1 million per year for knowing failures), for all payments, transfers of value or ownership or investment interests not reported in an annual submission. As of August 1, 2013, manufacturers are required to collect data, and they will be required to submit their first data reports to the Centers for Medicare & Medicaid Services by March 31, 2014 and by the 90th day of each calendar year thereafter.

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

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

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restricting of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could harm our ability to operate our business and our financial results. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state fraud laws may prove costly.

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

We sell our products in 41 countries outside the United States through distributors or directly to large household accounts. In some foreign countries, particularly in the European Union, the pricing of medical devices is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to supply data that compares the cost-effectiveness of our Inogen One systems to other available oxygen therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, it may not be profitable to sell our products in certain foreign countries, which would negatively affect the long-term growth of our business.

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

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

Risks related to our intellectual property

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

Our commercial success depends, in part, on obtaining and maintaining patent and other intellectual property protection for the technologies used in our products. The patent positions of medical device companies, including ours, can be highly uncertain and involve complex and evolving legal and factual questions. Furthermore, we might in the future opt to license intellectual property from other parties. If we, or the other parties from whom we would license intellectual property, fail to obtain and maintain adequate patent or other intellectual property protection for intellectual property used in our products, or if any protection is reduced or eliminated, others could use the intellectual property used in our products, resulting in harm to our competitive business position. In addition, patent and other intellectual property protection may not:

- prevent our competitors from duplicating our products;
- prevent our competitors from gaining access to our proprietary information and technology; or
- permit us to gain or maintain a competitive advantage.

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

As of January 1, 2014, we had six pending U.S. patent applications, 24 issued U.S. patents and one issued Canadian patent relating to the design and construction of our oxygen concentrators and our intelligent delivery technology. We cannot specify which of these patents individually or as a group will permit us to gain or maintain a competitive advantage. U.S. patents and patent applications may be subject to interference proceedings, and U.S. patents may be subject to re-examination *inter partes* review, post-grant review, and derivation proceedings in the U.S. Patent and Trademark Office. Foreign patents may be subject to opposition or comparable proceedings in the corresponding foreign patent offices. Any of these proceedings could result in loss of the patent or denial of the patent application, or loss or reduction in the scope of one or more of the claims of the patent or patent application. Changes in either patent laws or in interpretations of patent laws may also diminish the value of our intellectual property or narrow the scope of our

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protection. Interference, re-examination and opposition proceedings may be costly and time consuming, and we, or the other parties from whom we might potentially license intellectual property, may be unsuccessful in defending against such proceedings. Thus, any patents that we own or might license may provide limited or no protection against competitors. In addition, our pending patent applications and those we may file in the future may have claims narrowed during prosecution or may not result in patents being issued. Even if any of our pending or future applications are issued, they may not provide us with adequate protection or any competitive advantages. Our patents and patent applications cover particular aspects of our products. Other parties may develop and obtain patent protection for more effective technologies, designs or methods for oxygen therapy. If these developments were to occur, it would likely have an adverse effect on our sales. Our ability to develop additional patentable technology is also uncertain.

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

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

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

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

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

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

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

cease selling or using any of our products that incorporate the asserted intellectual property, which would adversely affect our revenue;

pay damages for past use of the asserted intellectual property, which may be substantial;

obtain a license from the holder of the asserted intellectual property, which license may not be available on reasonable terms, if at all, and which could reduce profitability; and

redesign or rename, in the case of trademark claims, our products to avoid infringing the intellectual property rights of third parties, which may not be possible and could be costly and time-consuming if it is possible to do so.

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

We rely on a combination of trade secrets, copyrights, trademarks, confidentiality agreements and other contractual provisions and technical security measures to protect certain aspects of our technology, especially where we do not believe that patent protection is appropriate or

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

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

Many of our employees were previously employed at other medical device companies focused on the development of oxygen therapy products, including our competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in defending against these claims, litigation could result in substantial costs, damage to our reputation and be a distraction to management.

Risks related to being a public company

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

As a public company, and increasingly after we are no longer an emerging growth company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act and rules subsequently implemented by the SEC and the NASDAQ Global Market impose numerous requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Also, the Securities Exchange Act of 1934, as amended, or the Exchange Act, requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. Our management and other personnel will need to devote a substantial amount of time to compliance with these laws and regulations. These requirements

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have increased and will continue to increase our legal, accounting, and financial compliance costs and have made and will continue to make some activities more time consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to incur substantial costs to maintain the same or similar coverage. These rules and regulations could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or our board committees or as executive officers.

Overall, we estimate that our incremental costs resulting from operating as a public company, including compliance with these rules and regulations, may be between \$1.5 million and \$3.0 million per year. However, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

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

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

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

Effective internal control over financial reporting is necessary for us to provide reliable financial reports in a timely manner. In connection with the audits of our financial statements for the

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years ended December 31, 2011 and 2012, we concluded that there were material weaknesses in our internal control over financial reporting. A material weakness is a significant deficiency, or a combination of significant deficiencies, in internal control over financial reporting such that it is reasonably possible that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. The material weaknesses that we identified related to (1) a lack of sufficient staff to deal with the various rules and regulations with respect to financial reporting, (2) accounting for revenue recognition as it relates to properly recording deferred revenue, estimated earned but unbilled revenue and billing adjustments and (3) accounting for warranty revenue and cost recognition with regard to lifetime warranties.

In an attempt to remediate our staff resource weakness, we have taken steps to hire additional finance and accounting personnel to augment our accounting staff and to provide more resources for complex GAAP accounting matters. In an attempt to remediate our revenue recognition weakness, we intend to review our revenue recognition policies and procedures, enhance training of our personnel with respect to such policies and procedures and devote additional resources to our revenue recognition, including adding additional accounting staff with technical experience in revenue recognition arrangements. However, we cannot assure you that these efforts will remediate our material weaknesses in a timely manner, or at all, or prevent restatements of our financial statements in the future. If we are unable to successfully remediate our material weaknesses, or identify any future significant deficiencies or material weaknesses, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports, and the market price of our stock may decline as a result.

Our management and independent registered public accounting firm did not perform an evaluation of our internal control over financial reporting during any period in accordance with the provisions of the Sarbanes-Oxley Act. Had we and our independent registered public accounting firm performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act, additional control deficiencies amounting to material weaknesses may have been identified. We cannot be certain as to when we will be able to implement the requirements of Section 404 of the Sarbanes-Oxley Act. If we fail to implement the requirements of Section 404 in a timely manner, we might be subject to sanctions or investigation by regulatory agencies such as the SEC. In addition, failure to comply with Section 404 or the report by us of a material weakness may cause investors to lose confidence in our financial statements, and the trading price of our common stock may decline. If we fail to remedy any material weakness, our financial statements may be inaccurate, our access to the capital markets may be restricted and the trading price of our ordinary shares may suffer.

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

We are an emerging growth company, as defined in the Jumpstart Our Business Startups, or JOBS, Act enacted in April 2012, and may remain an emerging growth company for up to five years following the completion of this offering, although, if we have more than \$1.0 billion in annual revenue, if the market value of our common stock that is held by non-affiliates exceeds \$700 million as of June 30 of any year, or we issue more than \$1.0 billion of non-convertible debt over a three-year period before the end of that five-year period, we would cease to be an emerging growth company as of the following December 31. For as long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain

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disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced Management's discussion and analysis of financial condition and results of operations disclosure;

not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;

not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;

reduced disclosure obligations regarding executive compensation; and

exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We have taken advantage of reduced reporting burdens in this prospectus. In particular, in this prospectus, we have provided only two years of audited financial statements and have not included all of the executive compensation related information that would be required if we were not an emerging growth company. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards, delaying the adoption of these accounting standards until they would apply to private companies. We have elected to avail ourselves of this exemption and, as a result, our financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be reduced or more volatile.

Risks related to our common stock and this offering

We expect that our stock price will fluctuate significantly, and you may not be able to resell your shares at or above the initial public offering price.

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

actual or anticipated quarterly variation in our results of operations or the results of our competitors;

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announcements by us or our competitors of new commercial products, significant contracts, commercial relationships or capital commitments;

issuance of new or changed securities analysts' reports or recommendations for our stock;

developments or disputes concerning our intellectual property or other proprietary rights;

commencement of, or our involvement in, litigation;

market conditions in the oxygen therapy market;

reimbursement or legislative changes in the oxygen therapy market;

failure to complete significant sales;

manufacturing disruptions that could occur if we were unable to successfully expand our production in our current or an alternative facility;

any future sales of our common stock or other securities;

any major change to the composition of our board of directors or management; and

general economic conditions and slow or negative growth of our markets.

The stock market in general, and market prices for the securities of technology-based companies like ours in particular, have from time to time experienced volatility that often has been unrelated to the operating performance of the underlying companies. A certain degree of stock price volatility can be attributed to being a newly public company. These broad market and industry fluctuations may adversely affect the market price of our common stock, regardless of our operating performance. In several recent situations where the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders were to bring a lawsuit against us, the defense and disposition of the lawsuit could be costly and divert the time and attention of our management and harm our operating results.

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

The trading market for our common stock will rely in part on the research and reports that equity research analysts publish about us and our business. We do not currently have and may never obtain research coverage by equity research analysts. Equity research analysts may elect not to provide research coverage of our common stock after the completion of this offering, and such lack of research coverage may adversely affect the market price of our common stock. In the event we obtain equity research analyst coverage, we will not have any control of the analysts or the content and opinions included in their reports. The price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

Purchasers in this offering will experience immediate and substantial dilution in the book value of their investment.

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The initial public offering price of our common stock is substantially higher than the net tangible book value per share of our common stock immediately prior to this offering. Therefore, if you

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purchase our common stock in this offering, you will incur an immediate dilution of \$ _____ in pro forma as adjusted net tangible book value per share as of September 30, 2013 from the price you paid, based on an assumed initial public offering price of \$ _____ per share, the midpoint of the range set forth on the cover page of this prospectus. In addition, new investors who purchase shares in this offering will contribute approximately _____ % of the total amount of equity capital raised by us through the date of this offering, but will only own approximately _____ % of the outstanding share capital and approximately _____ % of the voting rights. In addition, we have issued options and warrants to acquire common stock at prices below the initial public offering price. To the extent outstanding options and warrants are ultimately exercised, there will be further dilution to investors who purchase shares in this offering. In addition, if we issue additional equity securities, investors purchasing shares in this offering will experience additional dilution.

Future sales of shares of our common stock by existing stockholders could cause our stock price to decline.

Based on shares outstanding as of September 30, 2013, upon completion of this offering, we will have outstanding a total of _____ shares of common stock. Of these shares, only the _____ shares of common stock sold in this offering by us and the selling stockholders, or shares if the underwriters exercise their option to purchase additional shares in full, will be freely tradable, without restriction, in the public market immediately after the offering. Each of our directors and officers, and certain of our stockholders, have entered into lock-up agreements with the underwriters that restrict their ability to sell or transfer their shares. The lock-up agreements pertaining to this offering will expire 180 days from the date of this prospectus. Our underwriters, however, may, in their sole discretion, permit our officers, directors and other current stockholders who are subject to the contractual lock-up to sell shares prior to the expiration of the lock-up agreements. After the lock-up agreements expire, based on shares outstanding as of September 30, 2013, up to an additional _____ shares of common stock will be eligible for sale in the public market, _____ of which are held by our directors and executive officers and will be subject to volume limitations under Rule 144 under the Securities Act and various vesting agreements. In addition, _____ shares of our common stock that are subject to outstanding options as of September 30, 2013 will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements, the lock-up agreements and Rules 144 and 701 under the Securities Act. We cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale will have on the market price of our common stock. Future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of outstanding options, or the perception that such sales may occur, however, could adversely affect the market price of our common stock and also could adversely affect our future ability to raise capital through the sale of our common stock or other equity-related securities of ours at times and prices we believe appropriate.

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

Following the completion of this offering, our executive officers, directors and stockholders who owned more than 5% of our outstanding common stock before this offering and their respective affiliates will beneficially own or control approximately _____ % of the outstanding shares of our common stock, assuming no exercise of the underwriters' option to purchase additional shares.

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

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

Provisions in our certificate of incorporation and bylaws, as amended and restated upon the closing of this offering, may have the effect of delaying or preventing a change of control or changes in our management. Our amended and restated certificate of incorporation and amended and restated bylaws to become effective upon completion of this offering include provisions that:

authorize our board of directors to issue, without further action by the stockholders, up to 10,000,000 shares of undesignated preferred stock;

require that any action to be taken by our stockholders be effected at a duly called annual or special meeting and not by written consent;

specify that special meetings of our stockholders can be called only by our board of directors, the Chairman of the board of directors, or the Chief Executive Officer;

establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;

establish that our board of directors is divided into three classes, Class I, Class II and Class III, with each class serving staggered three year terms;

provide that our directors may be removed only for cause;

provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;

specify that no stockholder is permitted to cumulate votes at any election of directors; and

require a super-majority of votes to amend certain of the above-mentioned provisions.

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

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We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

We will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. We intend to use approximately \$15 million of the net proceeds from this offering for investments in rental assets; approximately \$5 million of the net proceeds for sales and marketing activities, including expansion of our sales force to support the ongoing commercialization of our products; approximately \$3 million of the net proceeds for research and product development activities; approximately \$11 million of the net proceeds for facilities improvements or expansions and the purchase of manufacturing and other equipment; and the remainder of the net proceeds for working capital and other general corporate purposes. We may also use a portion of our net proceeds to acquire and invest in complementary products, technologies or businesses; however, we currently have no agreements or commitments to complete any such transaction. We have not allocated these net proceeds for any specific purposes. We might not be able to yield a significant return, if any, on any investment of these net proceeds. You will not have the opportunity to influence our management's decisions on how to use the net proceeds from this offering, and our failure to apply these funds effectively could have a material adverse effect on our business and cause the price of our common stock to decline.

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

We have paid no cash dividends on any of our classes of capital stock to date, have contractual restrictions against paying cash dividends and currently intend to retain our future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

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Special note regarding forward-looking statements

This prospectus contains forward-looking statements that are based on management's beliefs and assumptions and on information currently available to management. Some of the statements under Prospectus summary, Risk factors, Management's discussion and analysis of financial condition and results of operations and Business and elsewhere in this prospectus contain forward-looking statements. In some cases, you can identify forward-looking statements by the following words: may, will, could, would, should, expect, intend, plan, anticipate, be predicted, project, potential, continue, ongoing or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words.

These statements involve risks, uncertainties and other factors that may cause actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this prospectus, we caution you that these statements are based on a combination of facts and factors currently known by us and our projections of the future, about which we cannot be certain.

In addition, you should refer to the Risk factors section of this prospectus for a discussion of other important factors that may cause actual results to differ materially from those expressed or implied by the forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this prospectus will prove to be accurate. Furthermore, if the forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. The Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act of 1933 do not protect any forward-looking statements that we make in connection with this offering.

This prospectus contains market data and industry forecasts that were obtained from industry publications. These data involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. We have not independently verified any third-party information. While we believe the market position, market opportunity and market size information included in this prospectus is generally reliable, such information is inherently imprecise.

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Use of proceeds

We estimate that the net proceeds to us from the sale of the shares of common stock in this offering will be approximately \$, based upon an assumed initial price to the public of \$ per share, the mid-point of the range reflected on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses. We will not receive any proceeds from the sale of common stock by the selling stockholders. Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share would increase (decrease) the net proceeds to us from this offering by approximately \$, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. We may also increase or decrease the number of shares we are offering. Each increase (decrease) of 1,000,000 shares in the number of shares offered by us would increase (decrease) the net proceeds to us from this offering by approximately \$, assuming that the assumed initial public offering price remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The principal purposes of this offering are to create a public market for our common stock, obtain additional capital, facilitate our future access to the public equity markets, increase awareness of our company among potential customers and improve our competitive position. We intend to use approximately \$15 million of the net proceeds from this offering for investments in rental assets; approximately \$5 million of the net proceeds for sales and marketing activities, including expansion of our sales force to support the ongoing commercialization of our products; approximately \$3 million of the net proceeds for research and product development activities; approximately \$11 million of the net proceeds for facilities improvements or expansions and the purchase of manufacturing and other equipment; and the remainder of the net proceeds for working capital and other general corporate purposes. We may also use a portion of our net proceeds to acquire and invest in complementary products, technologies or businesses; however, we currently have no agreements or commitments to complete any such transaction. The amount and timing of these expenditures will vary depending on a number of factors, including competitive and technological developments and the rate of growth, if any, of our business. Accordingly, we will have broad discretion in using these proceeds.

Pending their use, we plan to invest our net proceeds from this offering in short-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government. Our management will have broad discretion in the application of the net proceeds from this offering to us, and investors will be relying on the judgment of our management regarding the application of the proceeds.

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Dividend policy

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

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Capitalization

The following table summarizes our capitalization as of September 30, 2013:

on an actual basis;

on a pro forma basis, to reflect (i) the conversion of all outstanding shares of convertible preferred stock into an aggregate of 14,218,319 shares of common stock upon the closing of this offering, (ii) the cash exercise of warrants to purchase an aggregate of 24,588 shares of common stock, which we expect will occur prior to this offering as the warrants will otherwise expire at that time, (iii) the reclassification of our preferred stock warrant liability to additional-paid-in-capital upon the closing of this offering and (iv) the filing of our amended and restated certificate of incorporation; and

on a pro forma as adjusted basis, to further reflect the sale and issuance by us of _____ shares of common stock in this offering at an assumed initial public offering price of \$ _____ per share, the midpoint of the range reflected on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses.

You should read the information in this table together with the financial statements and related notes to those statements, as well as the sections of this prospectus captioned Selected financial data and Management s discussion and analysis of financial condition and results of operations.

	As of September 30, 2013	
	Actual	Pro forma as adjusted(1)
		(in thousands, except per share and share amounts)