

Inogen Inc
Form 10-Q
May 09, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2016

OR

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

For the Transition Period From _____ to _____

Commission file number: 001-36309

INOGEN, INC.

(Exact name of registrant as specified in its charter)

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

326 Bollay Drive	
Goleta, California	93117
(Address of principal executive offices)	(Zip Code)
(805) 562-0500	

Edgar Filing: Inogen Inc - Form 10-Q

(Registrant's telephone number, including area code)

None

(Former name, former address and former fiscal year, if changed since last report)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

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

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

As of April 29, 2016, the registrant had 19,915,360 shares of common stock, par value \$0.001, outstanding.

TABLE OF CONTENTS

	Page
	<u>Part I – Financial Information</u>
Item 1.	<u>Financial Statements (Unaudited)</u> 3
	<u>Balance Sheets as of March 31, 2016 and December 31, 2015</u> 3
	<u>Statements of Comprehensive Income for the Three Months Ended March 31, 2016 and March 31, 2015</u> 5
	<u>Statement of Stockholders’ Equity for the Three Months Ended March 31, 2016</u> 6
	<u>Statements of Cash Flows for the Three Months Ended March 31, 2016 and March 31, 2015</u> 7
	<u>Condensed Notes to the Financial Statements</u> 9
Item 2.	<u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u> 25
Item 3.	<u>Quantitative and Qualitative Disclosures about Market Risk</u> 43
Item 4.	<u>Controls and Procedures</u> 44
	<u>Part II – Other Information</u>
Item 1.	<u>Legal Proceedings</u> 45
Item 1A.	<u>Risk Factors</u> 46
Item 2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u> 71
Item 3.	<u>Defaults Upon Senior Securities</u> 72
Item 4.	<u>Mine Safety Disclosures</u> 72
Item 5.	<u>Other Information</u> 72
Item 6.	<u>Exhibits</u> 73
	<u>SIGNATURES</u> 74

INOGEN, INC.

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

Inogen, Inc.

Balance Sheets

(unaudited)

(amounts in thousands)

	March 31, 2016	December 31, 2015
Assets		
Current assets		
Cash and cash equivalents	\$72,400	\$66,106
Short-term investments	13,694	16,793
Accounts receivable, net	23,748	19,872
Inventories, net	10,275	8,648
Deferred cost of revenue	520	397
Income tax receivable	2,158	2,158
Prepaid expenses and other current assets	1,185	870
Total current assets	123,980	114,844
Property and equipment		
Rental equipment, net of allowances	54,876	54,677
Manufacturing equipment and tooling	4,818	4,680
Computer equipment and software	4,626	4,503
Furniture and equipment	802	732
Leasehold improvements	1,091	978
Land and building	126	125
Construction in process	847	578
Total property and equipment	67,186	66,273
Less accumulated depreciation	(37,542)	(35,593)
Property and equipment, net	29,644	30,680
Intangible assets, net	206	229
Deferred tax asset - noncurrent	14,474	15,464
Other assets	96	97
Total assets	\$168,400	\$161,314

See accompanying condensed notes to the financial statements.

Inogen, Inc.

Balance Sheets (continued)

(unaudited)

(amounts in thousands, except share and per share amounts)

	March 31, 2016	December 31, 2015
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable and accrued expenses	\$17,220	\$12,867
Accrued payroll	3,017	5,271
Current portion of long-term debt	238	315
Warranty reserve - current	1,351	1,226
Deferred revenue - current	2,212	2,323
Income tax payable	6	11
Total current liabilities	24,044	22,013
Long-term liabilities		
Warranty reserve - noncurrent	1,078	747
Deferred revenue - noncurrent	4,768	4,199
Other noncurrent liabilities	321	337
Total liabilities	30,211	27,296
Commitments and contingencies (Note 9)		
Stockholders' equity		
Common stock, \$0.001 par value per share; 200,000,000 authorized; 19,877,486 and 19,782,403 shares issued and outstanding as of March 31, 2016 and December 31, 2015, respectively	20	20
Additional paid-in capital	181,030	179,143
Accumulated deficit	(42,743)	(45,108)
Accumulated other comprehensive loss	(118)	(37)
Total stockholders' equity	138,189	134,018
Total liabilities and stockholders' equity	\$168,400	\$161,314

See accompanying condensed notes to the financial statements.

Inogen, Inc.

Statements of Comprehensive Income

(unaudited)

(amounts in thousands, except share and per share amounts)

	Three months ended March 31,	
	2016	2015
Revenue		
Sales revenue	\$32,811	\$23,049
Rental revenue	10,178	10,703
Total revenue	42,989	33,752
Cost of revenue		
Cost of sales revenue	16,507	12,589
Cost of rental revenue, including depreciation of \$2,947 and \$2,956, respectively	5,203	5,140
Total cost of revenue	21,710	17,729
Gross profit		
Gross profit-sales revenue	16,304	10,460
Gross profit-rental revenue	4,975	5,563
Total gross profit	21,279	16,023
Operating expense		
Research and development	1,168	863
Sales and marketing	8,965	6,924
General and administrative	7,869	5,718
Total operating expense	18,002	13,505
Income from operations	3,277	2,518
Other income (expense)		
Interest expense	(3)	(7)
Interest income	29	12
Other income (expense)	97	(105)
Total other income (expense), net	123	(100)
Income before provision for income taxes	3,400	2,418
Provision for income taxes	1,035	846
Net income	2,365	1,572
Other comprehensive loss, net of tax		
Unrealized loss on foreign currency hedging	(92)	—
Unrealized gain on available-for-sale investments	11	—
Total other comprehensive loss, net of tax	(81)	—
Comprehensive income	\$2,284	\$1,572
Basic net income per share attributable to common stockholders (Note 5)	\$0.12	\$0.08
Diluted net income per share attributable to common stockholders (Note 5)	\$0.11	\$0.08
Weighted-average number of shares used in calculating net income per share attributable to common stockholders:		

Edgar Filing: Inogen Inc - Form 10-Q

Basic common shares	19,827,669	19,167,585
Diluted common shares	20,783,943	20,562,040

See accompanying condensed notes to the financial statements.

Inogen, Inc.

Statement of Stockholders' Equity

(unaudited)

(amounts in thousands, except share amounts)

	Common stock Shares	Amount	Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Total stockholders' equity
Balance, December 31, 2015	19,782,403	\$ 20	\$ 179,143	\$ (45,108)	\$ (37)	\$ 134,018
Stock-based compensation	—	—	1,295	—	—	1,295
Employee stock purchases	17,724	—	500	—	—	500
Stock options exercised	77,359	—	92	—	—	92
Net income	—	—	—	2,365	—	2,365
Other comprehensive loss	—	—	—	—	(81)	(81)
Balance, March 31, 2016	19,877,486	\$ 20	\$ 181,030	\$ (42,743)	\$ (118)	\$ 138,189

See accompanying condensed notes to the financial statements.

Inogen, Inc.

Statements of Cash Flows

(unaudited)

(amounts in thousands)

	Three months ended March 31,	
	2016	2015
Cash flows from operating activities		
Net income	\$2,365	\$1,572
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	3,448	3,444
Loss on rental units and other fixed assets	306	205
Provision for sales returns	2,066	966
Provision for doubtful accounts	841	297
Provision for rental revenue adjustments	2,644	2,481
Provision for inventory obsolescence	23	32
Recovery on other inventory losses	(6)	(9)
Stock-based compensation expense	1,295	518
Deferred tax assets	990	—
Excess tax benefits from stock-based compensation arrangements	—	(1,818)
Changes in operating assets and liabilities:		
Accounts receivable	(9,486)	(6,203)
Inventories	(2,170)	(199)
Deferred costs of revenue	(123)	83
Income tax receivable	—	814
Prepaid expenses and other current assets	(315)	(162)
Accounts payable and accrued expenses	4,260	2,975
Accrued payroll	(2,254)	586
Warranty reserve	456	276
Deferred revenue	458	221
Income tax payable	(5)	—
Other noncurrent liabilities	(16)	(18)
Net cash provided by operating activities	4,777	6,061
Cash flows from investing activities		
Purchases of available-for-sale investments	(6,990)	—
Maturities of available-for-sale investments	10,100	—
Investment in intangible assets	—	(11)
Production and purchase of rental equipment	(1,455)	(3,477)
Purchases of property and equipment	(714)	(552)
Reimbursement of deposit	1	—
Net cash provided by (used in) investing activities	942	(4,040)

(continued on next page)

See accompanying condensed notes to the financial statements.

7

Inogen, Inc.

Statements of Cash Flows (continued)

(unaudited)

(amounts in thousands)

	Three months ended March 31,	
	2016	2015
Cash flows from financing activities		
Proceeds from stock options exercised	92	166
Proceeds from employee stock purchases	500	342
Repayment of debt from investment in intangible assets	(77)	(81)
Excess tax benefits from stock-based compensation arrangements	—	1,818
Net cash provided by financing activities	515	2,245
Effect of exchange rates on cash	60	—
Net increase in cash and cash equivalents	6,294	4,266
Cash and cash equivalents, beginning of period	66,106	56,836
Cash and cash equivalents, end of period	\$72,400	\$61,102
Supplemental disclosures of cash flow information		
Cash paid during the period for interest	\$4	\$8
Cash paid during the period for income taxes, net of refunds received	5	33

See accompanying condensed notes to the financial statements.

Inogen, Inc.

Condensed Notes to the Financial Statements

(unaudited)

(amounts in thousands, except share and per share amounts)

1. Business overview

Inogen, Inc. (Company or Inogen) was incorporated in Delaware on November 27, 2001. The Company is a medical technology company that primarily develops, manufactures and markets innovative portable oxygen concentrators used to deliver supplemental long-term oxygen therapy to patients suffering from chronic respiratory conditions. Traditionally, these patients have relied on stationary oxygen concentrator systems for use in the home and oxygen tanks or cylinders for mobile use, which the Company calls the delivery model. The tanks and cylinders must be delivered regularly and have a finite amount of oxygen, which requires patients to plan activities outside of their homes around delivery schedules and a finite oxygen supply. Additionally, patients must attach long, cumbersome tubing to their stationary concentrators simply to enable mobility within their homes. The Company's 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 4.8 or 7.0 pounds. The Company's Inogen One G3[®] and Inogen One G2[®] have up to 4.5 and 5 hours of battery life, respectively, with a single battery and can be plugged into an outlet when at home, in a car, or in a public place with outlets available. The Company's Inogen One systems reduce the patient's reliance on stationary concentrators and scheduled deliveries of tanks with a finite supply of oxygen, thereby improving patient quality of life and fostering mobility.

Portable oxygen concentrators represented the fastest-growing segment of the Medicare oxygen therapy market between 2012 and 2014. The Company estimates based on 2014 Medicare data that patients using portable oxygen concentrators represent approximately 6% to 8% of the total addressable oxygen market in the United States, although the Medicare data does not account for cash-pay sales into the market. Based on 2014 industry data, the Company believes it was 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. The Company believes it is the only manufacturer of portable oxygen concentrators that employs a direct-to-consumer strategy in the United States, meaning the Company markets its products to patients, processes their physician paperwork, provides clinical support as needed and bills Medicare or insurance on their behalf. To pursue a direct-to-consumer strategy, the Company's manufacturing competitors would need to meet national accreditation and state-by-state licensing requirements and secure Medicare billing privileges, as well as compete with the home medical equipment providers that many rely on across their entire homecare business.

Since adopting the Company's direct-to-consumer strategy in 2009 following its acquisition of Comfort Life Medical Supply, LLC, which had an active Medicare billing number but few other assets and limited business activities, the Company has directly sold or rented its Inogen oxygen concentrators to more than 145,000 patients as of March 31, 2016.

2. Basis of presentation and summary of significant accounting policies

The accompanying financial statements are unaudited. The balance sheet at December 31, 2015 has been derived from the audited financial statements of the Company. The accompanying financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America (U.S. GAAP) for interim financial information, and in management's opinion, includes all adjustments, consisting of only normal recurring adjustments, necessary for the fair statement of the Company's financial position, its results of operations, and cash flows for the interim periods presented. The results of operations for the three months ended March 31, 2016 are not necessarily indicative of the results to be expected for the full fiscal year or any other period.

The accompanying financial statements should be read in conjunction with the financial statements and notes thereto contained in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 14, 2016. There have been no significant changes in the Company's accounting policies from those disclosed in its Annual Report on Form 10-K filed with the SEC on March 14, 2016.

Inogen, Inc.

Condensed Notes to the Financial Statements (continued)

(unaudited)

(amounts in thousands, except share and per share amounts)

Use of estimates

The preparation of the Company's financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in these financial statements and accompanying condensed notes. Management bases these estimates and assumptions upon historical experience, existing and known circumstances, authoritative accounting pronouncements and other factors that management believes to be reasonable. Significant areas requiring the use of management estimates relate to revenue recognition, inventory and rental asset valuations and write-downs, accounts receivable allowances for bad debts, returns and adjustments, stock compensation expense, impairment assessments, depreciation and amortization, income tax provision and uncertain tax positions, fair value of financial instruments, and fair values of acquired intangibles. Actual results could differ materially from these estimates.

Recent accounting pronouncements

Income taxes: In November 2015, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2015-17, Balance Sheet Classification of Deferred Taxes, which simplifies the presentation of deferred income taxes. This ASU requires that deferred tax assets and liabilities be classified as noncurrent in a statement of financial position. The Company early adopted ASU 2015-17 effective December 31, 2015 on a prospective basis. Adoption of this ASU resulted in a reclassification of the Company's net current deferred tax asset to the net noncurrent deferred tax asset in the Company's balance sheets as of December 31, 2015. No prior periods were retrospectively adjusted.

Revenue Recognition: In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers, which supersedes nearly all existing revenue recognition guidance under U.S. GAAP. The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services. ASU 2014-09 defines a five step process to achieve this core principle and, in doing so, more judgment and estimates may be required within the revenue recognition process than are required under existing U.S. GAAP.

In August 2015, the FASB decided to delay the effective date of ASU 2014-09 by one year. The FASB also agreed to allow entities to choose to adopt the standard as of the original effective date. As such, the updated standard will be effective for the Company in the first quarter of 2018, with the option to adopt it in the first quarter of 2017. The Company is currently evaluating the impact of the Company's pending adoption of ASU 2014-09 on the Company's financial statements and has not yet determined the method by which the Company will adopt the standard.

Inventory: In July 2015, the FASB issued ASU No. 2015-11, Simplifying the Measurement of Inventory. The ASU requires entities to measure most inventory "at the lower of cost and net realizable value" thereby simplifying the current guidance under which an entity must measure inventory at the lower of cost or market. The ASU is effective prospectively for annual periods beginning after December 15, 2016, and interim periods within annual periods. Early application is permitted and should be applied prospectively. The adoption of ASU No. 2015-11 is not expected to have a material effect on the Company's financial statements.

Leases: On February 25, 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842). The new guidance will require organizations that lease assets—referred to as “lessees”—to recognize on the balance sheet the assets and liabilities for the rights and obligations created by those leases with lease terms of more than 12 months. This will increase the reported assets and liabilities – in some cases very significantly. ASU No. 2016-02 will take effect for public companies for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. Early adoption will be permitted for all entities. The Company is currently evaluating the effect of the new lease recognition guidance, and has not yet determined the impact on the Company’s results of operations and financial condition.

Stock compensation: In March 2016, the FASB issued ASU No. 2016-09, Compensation – Stock Compensation, which simplifies the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The ASU is effective prospectively for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Early application is permitted for any entity in any interim or annual period. If early adoption is elected during an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. If early adoption is elected, all of the amendments must be adopted in the same period. The adoption of ASU No. 2016-09 and its impact to the financial statements is still being reviewed by the Company, and early adoption has not yet been determined.

Inogen, Inc.

Condensed Notes to the Financial Statements (continued)

(unaudited)

(amounts in thousands, except share and per share amounts)

Business segments

The Company operates in only one business segment – development, manufacturing, marketing, sales, and rental of respiratory products.

3. Fair value of financial instruments

The Company's financial instruments consist of cash and cash equivalents, short-term investments, accounts receivable, accounts payable and accrued expenses, debt and warrants. The carrying values of cash and cash equivalents, short-term investments, accounts receivable and accounts payable and accrued expenses approximate fair values based on the short-term nature of these financial instruments.

The fair value of the Company's debt approximates carrying value based on the Company's current incremental borrowing rate for similar types of borrowing arrangements. Imputed interest associated with the Company's non-interest bearing debt is insignificant and has been appropriately recognized in the respective periods.

Fair value accounting

Accounting Standards Codification (ASC) 820—Fair Value Measurements and Disclosures, creates a single definition of fair value, establishes a framework for measuring fair value in U.S. GAAP and expands disclosures about fair value measurements. ASC 820 emphasizes that fair value is a market-based measurement, not an entity-specific measurement, and states that a fair value measurement should be determined based on assumptions that market participants would use in pricing the asset or liability. Assets and liabilities adjusted to fair value in the balance sheet are categorized based upon the level of judgment associated with the inputs used to measure their fair value. Level inputs, as defined by ASC 820, are as follows:

Level input	Input definition
-------------	------------------

Level 1	Inputs are unadjusted, quoted prices for identical assets or liabilities in active markets at the measurement date.
---------	---

Level 2	Inputs, other than quoted prices included in Level 1 that are observable for the asset or liability through corroboration with market data at the measurement date.
---------	---

Level 3	Unobservable inputs that reflect management's best estimate of what market participants would use in pricing the asset or liability at the measurement date.
---------	--

The Company obtained the fair value of its available-for-sale investments, which are not in active markets, from a third-party professional pricing service using quoted market prices for identical or comparable instruments, rather than direct observations of quoted prices in active markets. The Company's professional pricing service gathers observable inputs for all of its fixed income securities from a variety of industry data providers (e.g., large custodial institutions) and other third-party sources. Once the observable inputs are gathered, all data points are considered and the fair value is determined. The Company validates the quoted market prices provided by its primary pricing service by comparing their assessment of the fair values against the fair values provided by its investment managers. The Company's investment managers use similar techniques to its professional pricing service to derive pricing as described above. As all significant inputs were observable, derived from observable information in the marketplace or supported by observable levels at which transactions are executed in the marketplace, the Company has classified its available-for-sale investments within Level 2 of the fair value hierarchy.

Edgar Filing: Inogen Inc - Form 10-Q

Inogen, Inc.

Condensed Notes to the Financial Statements (continued)

(unaudited)

(amounts in thousands, except share and per share amounts)

The following table summarizes fair value measurements by level for the assets measured at fair value on a recurring basis for cash, cash equivalents and short-term investments:

	As of March 31, 2016			Cash and cash equivalents	Short- term investments
	Gross		Fair		
	Adjusted cost	unrealized losses			
Cash	\$55,309	\$ —	\$55,309	\$ 55,309	\$ —
Level 1:					
Money market accounts	6,765	—	6,765	6,765	—
Level 2:					
Certificates of deposit	24,036	(16)	24,020	10,326	13,694
Total	\$86,110	\$ (16)	\$86,094	\$ 72,400	\$ 13,694

	As of December 31, 2015			Cash and cash equivalents	Short- term investments
	Gross		Fair		
	Adjusted cost	unrealized losses			
Cash	\$52,164	\$ —	\$52,164	\$ 52,164	\$ —
Level 1:					
Money market accounts	6,725	—	6,725	6,725	—
Level 2:					
Certificates of deposit	24,047	(37)	24,010	7,217	16,793
Total	\$82,936	\$ (37)	\$82,899	\$ 66,106	\$ 16,793

Derivative instruments and hedging activities

The Company transacts business in foreign currencies and has international sales and expenses denominated in foreign currencies, subjecting the Company to foreign currency risk. The Company may enter into foreign currency forward contracts, generally with maturities of twelve months or less, to reduce the volatility of cash flows primarily related to

forecasted revenue denominated in certain foreign currencies. These contracts allow the Company to sell Euros in exchange for U.S. dollars at specified contract rates. Forward contracts are used to hedge forecasted sales over specific months. Changes in the fair value of these forward contracts designed as cash flow hedges are recorded as a component of accumulated other comprehensive income (loss) within stockholders' equity, and are recognized in the Statements of Comprehensive Income during the period which approximates the time the corresponding sales occur. The Company may also enter into foreign exchange contracts that are not designated as hedging instruments for financial accounting purposes. These contracts are generally entered into to offset the gains and losses on certain asset and liability balances until the expected time of repayment. Accordingly, any gains or losses resulting from changes in the fair value of the non-designated contracts are reported in other income (expense), net in the Statements of Comprehensive Income. The gains and losses on these contracts generally offset the gains and losses associated with the underlying foreign currency-denominated balances, which are also reported in other income (expense), net.

The Company records the assets or liabilities associated with derivative instruments and hedging activities at fair value based on Level 2 inputs in other current assets or other current liabilities, respectively, in the balance sheet. The Company had a payable of \$197 and \$24 as of March 31, 2016 and December 31, 2015, respectively. The Level 2 inputs consist of forward contracts at the end of the reporting period. The accounting for gains and losses resulting from changes in fair value depends on the use of the derivative and whether it is designated and qualifies for hedge accounting.

Inogen, Inc.

Condensed Notes to the Financial Statements (continued)

(unaudited)

(amounts in thousands, except share and per share amounts)

The Company documents the hedging relationship and its risk management objective and strategy for undertaking the hedge, the hedging instrument, the hedged transaction, the nature of the risk being hedged, how the hedging instrument's effectiveness in offsetting the hedged risk will be assessed prospectively and retrospectively, and a description of the method used to measure ineffectiveness. The Company assesses hedge effectiveness and ineffectiveness at a minimum quarterly but may assess it monthly. For derivative instruments that are designed and qualify as part of a cash flow hedging relationship, the effective portion of the gain or loss on the derivative is reported in other comprehensive income (OCI) and reclassified into earnings in the same period or periods during which the hedged transaction affects earnings. Gains and losses on the derivative representing either hedge ineffectiveness or hedge components excluded from the assessment of effectiveness are recognized in current period earnings.

The Company will discontinue hedge accounting prospectively when it determines that the derivative is no longer effective in offsetting cash flows attributable to the hedge risk. The cash flow hedge is de-designated because a forecasted transaction is not probable of occurring, or management determines to remove the designation of the cash flow hedge. In all situations in which hedge accounting is discontinued and the derivative remains outstanding, the Company continues to carry the derivative at its fair value on the balance sheet and recognizes any subsequent changes in the fair value in earnings. When it is probable that a forecasted transaction will not occur, the Company will discontinue hedge accounting and recognize immediately in earnings gains and losses that were accumulated in OCI related to the hedging relationship.

Accumulated other comprehensive loss

The components of accumulated other comprehensive income (loss), net of tax, were as follows:

	Unrealized gains (losses) on available-for- sale investments	Unrealized losses on cash flow hedges	Accumulated other comprehensive loss
Balance as of December 31, 2015	\$ (23)	\$ (14)	\$ (37)
Other comprehensive gain (loss), net of tax	11	(92)	(81)
Balance as of March 31, 2016	\$ (12)	\$ (106)	\$ (118)

Comprehensive income (loss) is the total net earnings and all other non-owner changes in equity. Except for net income and unrealized gains and losses on cash flow hedges and available-for-sale investments, the Company does not have any transactions or other economic events that qualify as comprehensive income (loss).

4. Balance sheet components

Cash, cash equivalents, and short-term investments

The Company considers all short-term highly liquid investments with a maturity of three months or less to be cash equivalents. Cash equivalents are recorded at cost plus accrued interest, which approximates fair value. Certificates of deposit are included in cash equivalents and short-term investments based on the maturity date of the security.

The Company considers investments with maturities greater than three months, but less than one year, to be short-term investments. Investments that have maturities of more than one year are classified as long-term investments. Investments are classified as available-for-sale and are reported at fair value with unrealized gains or losses, if any, reported, net of tax, in accumulated other comprehensive income (loss). All income generated and realized gains or losses from investments are recorded to other income (expense), net.

Inogen, Inc.

Condensed Notes to the Financial Statements (continued)

(unaudited)

(amounts in thousands, except share and per share amounts)

The Company reviews its investments to identify and evaluate investments that have an indication of possible impairment. Factors considered in determining whether a loss is temporary include the length of time and extent to which fair value has been less than the cost basis, the financial condition and near-term prospects of the investee, and the Company's intent and ability to hold the investment for a period of time sufficient to allow for any anticipated recovery in market value. Credit losses and other-than-temporary impairments are declines in fair value that are not expected to recover and are charged to other income (expense), net. During the three months ended March 31, 2016 and 2015, respectively, no losses were recognized for other-than-temporary impairments. Cash, cash equivalents and short-term investments consist of the following:

	March 31, 2016	December 31, 2015
Cash and cash equivalents		
Cash	\$55,309	\$ 52,164
Money market accounts	6,765	6,725
Certificates of deposit	10,326	7,217
Total cash and cash equivalents	\$72,400	\$ 66,106
Short-term investments		
Certificates of deposit	\$ 13,694	\$ 16,793
Total short-term investments	\$ 13,694	\$ 16,793

Accounts receivable and allowance for bad debts, returns, and adjustments

Accounts receivable are customer obligations due under normal sales and rental terms. The Company performs credit evaluations of the customers' financial condition and generally does not require collateral. The allowance for doubtful accounts is maintained at a level that, in management's opinion, is adequate to absorb potential losses related to accounts receivable and is based upon the Company's continuous evaluation of the collectability of outstanding balances. Management's evaluation takes into consideration such factors as past bad debt experience, economic conditions and information about specific receivables. The Company's evaluation also considers the age and composition of the outstanding amounts in determining their net realizable value.

The allowance for doubtful accounts is based on estimates, and ultimate losses may vary from current estimates. As adjustments to these estimates become necessary, they are reported in earnings in the periods in which they become known. This allowance is increased by bad debt provisions charged to bad debt expense, net of recoveries, in operating expense and is reduced by direct write-offs.

The Company generally does not allow returns from providers for reasons not covered under its standard warranty. Therefore, provision for sales returns applies primarily to direct-to-consumer sales. This reserve is calculated based on actual historical return rates under the Company's 30-day return program and is applied to the related sales revenue for

the last month of the quarter reported.

The Company also records an allowance for rental revenue adjustments, which is recorded as a reduction of rental revenue and net rental accounts receivable balances. These adjustments result from contractual adjustments, including untimely claims filings, or billings not paid due to another provider performing same or similar functions for the patient in the same period, all of which prevent billed revenue from becoming realizable. The reserve is based on historical revenue adjustments as a percentage of rental revenue billed and unbilled during the related period.

When recording the allowance for doubtful accounts, the bad debt expense account (general and administrative expense account) is charged; when recording allowance for sales returns, the sales returns account (contra sales revenue account) is charged; and when recording the allowance for rental reserve adjustments, the rental revenue adjustments account (contra rental revenue account) is charged.

As of March 31, 2016 and December 31, 2015, included in accounts receivable on the balance sheets were earned but unbilled receivables of \$5,067 and \$5,155, respectively. These balances reflect gross unbilled receivables prior to any allowances for adjustments and write-offs. The Company consistently applies its allowance estimation methodology from period-to-period. The Company's best estimate is made on an accrual basis and adjusted in future periods as required. Any adjustments to the prior period estimates are included in the current period. As additional information becomes known, the Company adjusts its assumptions accordingly to change its estimate of the allowance.

Inogen, Inc.

Condensed Notes to the Financial Statements (continued)

(unaudited)

(amounts in thousands, except share and per share amounts)

Gross accounts receivable balance concentrations by major category as of March 31, 2016 and December 31, 2015 were as follows:

	March 31, 2016	December 31, 2015
Gross accounts receivable		
Medicare	\$11,195	\$10,510
Medicaid/other government	683	683
Private insurance	4,970	4,852
Patient responsibility	3,928	3,603
Business-to-business & other receivables	10,495	6,369
Total gross accounts receivable	\$31,271	\$26,017

Net accounts receivable (gross accounts receivable net of allowances) balance concentrations by major category as of March 31, 2016 and December 31, 2015 were as follows:

	March 31, 2016	December 31, 2015
Net accounts receivable		
Medicare	\$7,432	\$7,441
Medicaid/other government	503	550
Private insurance	3,907	3,895
Patient responsibility	2,211	2,060
Business-to-business & other receivables	9,695	5,926
Total net accounts receivable	\$23,748	\$19,872

The following tables set forth the allowances for accounts receivable as of March 31, 2016 and December 31, 2015:

Edgar Filing: Inogen Inc - Form 10-Q

	March 31, 2016	December 31, 2015
Allowances - accounts receivable		
Doubtful accounts	\$2,021	\$ 1,664
Rental revenue adjustments	4,761	4,115
Sales returns	741	366
Total allowances - accounts receivable	\$7,523	\$ 6,145

Concentration of credit risk

Financial instruments that potentially subject the Company to concentration of credit risk consist principally of cash, cash equivalents, short-term investments and accounts receivable. At times, cash account balances may be in excess of the amounts insured by the Federal Deposit Insurance Corporation (FDIC). However, management believes the risk of loss to be minimal. The Company performs periodic evaluations of the relative credit standing of these institutions and has not experienced any losses on its cash and cash equivalents to date. The Company has entered into hedging relationships with a single counterparty to offset the forecasted Euro based revenues. The credit risk has been reduced due to a net settlement arrangement whereby the Company is allowed to net settle transactions with a single net amount payable by one party to the other.

Concentration of customers and vendors

The Company primarily sells its products to home medical equipment providers, distributors, and resellers in the United States and in foreign countries on a credit basis. The Company primarily sells its products to consumers on a prepayment basis. No single customer represented more than 10% of the Company's total revenue for the three months ended March 31, 2016 and March 31, 2015. No single customer represented more than 10% of the Company's total accounts receivable balance as of March 31, 2016 or as of December 31, 2015.

Inogen, Inc.

Condensed Notes to the Financial Statements (continued)

(unaudited)

(amounts in thousands, except share and per share amounts)

The Company also rents products directly to consumers for insurance reimbursement, which resulted in a customer concentration relating to Medicare's service reimbursement programs. Medicare's service reimbursement programs accounted for 82.2% and 82.1% of rental revenue for the three months ended March 31, 2016 and March 31, 2015, respectively, and based on total revenue were 19.5% and 26.0% for the three months ended March 31, 2016 and March 31, 2015, respectively. Accounts receivable balances relating to Medicare's service reimbursement programs (including held and unbilled, net of allowances) amounted to \$7,432 or 31.3% of total accounts receivable as of March 31, 2016 as compared to \$7,441, or 37.4% of total accounts receivable as of December 31, 2015.

The Company currently purchases raw materials from a limited number of vendors, which resulted in a concentration of three major vendors. The three major vendors supply the Company with raw materials used to manufacture the Company's products. For the three months ended March 31, 2016, the Company's three major vendors accounted for 14.1%, 11.8%, and 7.1%, respectively, of total raw material purchases. For the three months ended March 31, 2015, the Company's three major vendors accounted for 22.7%, 18.0% and 5.8%, respectively, of total raw material purchases.

A portion of revenue is earned from sales outside the United States. Approximately 68.3% and 22.0% of the non-U.S. revenue for the three months ended March 31, 2016 and March 31, 2015, respectively, was invoiced in Euros. A breakdown of the Company's revenue from U.S. and non-U.S. sources for the three months ended March 31, 2016 and March 31, 2015 is as follows:

	Three months ended March 31,	
	2016	2015
U.S. revenue	\$33,024	\$25,354
Non-U.S. revenue	9,965	8,398
Total revenue	\$42,989	\$33,752

Inventories

Inventories are stated at the lower of cost or market. Cost is determined using a standard cost method, including material, labor and manufacturing overhead, whereby the standard costs are updated at least quarterly to reflect approximate actual costs using the first-in, first-out (FIFO) method and market represents the lower of replacement cost or estimated net realizable value. The Company records adjustments at least quarterly to inventory for potentially excess, obsolete, slow-moving or impaired items. Inventories consist of the following:

	March 31, 2016	December 31, 2015
Raw materials and work-in-progress	\$8,785	\$ 7,097
Finished goods	1,655	1,679
Less: reserves	(165)	(128)
Inventories	\$10,275	\$ 8,648

Property and equipment

Property and equipment are stated at cost. Depreciation and amortization are calculated using the straight-line method over the assets' estimated useful lives as follows:

Rental equipment	1.5-5 years
Manufacturing equipment and tooling	2-5 years
Computer equipment and software	2-3 years
Furniture and equipment	3-5 years
Leasehold improvements	Shorter of 3-10 years or remaining life of underlying lease

Expenditures for additions, improvements and replacements are capitalized and depreciated to a salvage value of \$0. Repair and maintenance costs are included in cost of revenue on the statements of comprehensive income. Repair and maintenance expense, which includes labor, parts and freight for rental equipment was \$687 and \$570 for the three months ended March 31, 2016 and March 31, 2015, respectively.

Inogen, Inc.

Condensed Notes to the Financial Statements (continued)

(unaudited)

(amounts in thousands, except share and per share amounts)

Included within property and equipment is construction in process, primarily related to the design and engineering of tooling, jigs and other machinery. In addition, this item also includes computer software or development costs that have been purchased, but have not completed the final configuration process for implementation into the Company's systems. These items have not been placed in service; therefore, no depreciation or amortization was recognized for these items in the respective periods.

Depreciation and amortization expense related to property and equipment and rental equipment are summarized below for the three months ended March 31, 2016 and March 31, 2015, respectively.

	Three months ended March 31,	
	2016	2015
Rental equipment	\$2,947	\$2,956
Other property and equipment	478	467
Total depreciation and amortization	\$3,425	\$3,423

Property and equipment and rental equipment with associated accumulated depreciation is summarized below for March 31, 2016 and December 31, 2015, respectively.

	March 31, 2016	December 31, 2015
Property and equipment		
Rental equipment, net of allowances of \$850 and \$850	\$54,876	\$54,677
Other property and equipment	12,310	11,596
Property and equipment	67,186	66,273
Accumulated depreciation		
Rental equipment	30,365	28,894
Other property and equipment	7,177	6,699
Accumulated depreciation	37,542	35,593
Net property and equipment		
Rental equipment	24,511	25,783
Other property and equipment	5,133	4,897
Property and equipment, net	\$29,644	\$30,680

Long-lived assets

The Company accounts for the impairment and disposition of long-lived assets in accordance with ASC 360-Property, Plant, and Equipment. In accordance with ASC 360, long-lived assets to be held are reviewed for events or changes in circumstances that indicate that their carrying value may not be recoverable. The Company periodically reviews the carrying value of long-lived assets to determine whether or not impairment to such value has occurred. No impairments were recorded during the three months ended March 31, 2016 and March 31, 2015.

Intangible assets

There were no impairments recorded related to the Company's intangible assets during the three months ended March 31, 2016 and March 31, 2015. Amortization expense for intangible assets for the three months ended March 31, 2016 and March 31, 2015 was \$23 and \$21, respectively.

Inogen, Inc.

Condensed Notes to the Financial Statements (continued)

(unaudited)

(amounts in thousands, except share and per share amounts)

The following tables represent the changes in net carrying values of the intangibles as of the respective dates:

	Average estimated useful lives	Gross carrying amount	Accumulated amortization	Net amount
March 31, 2016	(in years)			
Licenses	10	\$ 185	\$ 104	\$ 81
Patents and websites	5	873	787	86
Commercials	2	174	135	39
Total		\$ 1,232	\$ 1,026	\$ 206

	Average estimated useful lives	Gross carrying amount	Accumulated amortization	Net amount
December 31, 2015	(in years)			
Licenses	10	\$ 185	\$ 100	\$ 85
Patents and websites	5	873	779	94
Commercials	2	174	124	50
Total		\$ 1,232	\$ 1,003	\$ 229

Current liabilities

Accounts payable and accrued expenses as of March 31, 2016 and December 31, 2015 consisted of the following:

	March 31, 2016	December 31, 2015
Accounts payable	\$8,504	\$ 7,448
Accrued inventory (in-transit and unvouchered receipts) and trade payables	5,398	3,548
Accrued purchasing card liability	2,754	1,581
Accrued franchise and use taxes	49	45
Other accrued expenses	515	245
Accounts payable and accrued expenses	\$17,220	\$ 12,867

5. Earnings per share

Earnings per share (EPS) is computed in accordance with ASC 260—Earnings per Share, and is calculated using the weighted-average number of common shares outstanding during each period. Diluted EPS assumes the conversion, exercise or issuance of all potential common stock equivalents (which can include dilution of outstanding stock options and common stock warrants) unless the effect is to reduce a loss or increase the income per share. For purposes of this calculation, common stock subject to repurchase by the Company, options and warrants are considered to be common stock equivalents and are only included in the calculation of diluted earnings per share when their effect is dilutive.

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

Inogen, Inc.

Condensed Notes to the Financial Statements (continued)

(unaudited)

(amounts in thousands, except share and per share amounts)

The computation of EPS is as follows:

	Three months ended March 31,	
	2016	2015
Numerator—basic and diluted:		
Net income	\$2,365	\$1,572
Denominator:		
Weighted-average common shares - basic common stock	19,827,669	19,167,585
Weighted-average common shares - diluted common stock	20,783,943	20,562,040
Net income per share - basic common stock	\$0.12	\$0.08
Net income per share - diluted common stock	\$0.11	\$0.08
Denominator calculation from basic to diluted:		
Weighted-average common shares - basic common stock	19,827,669	19,167,585
Warrants	—	9,649
Stock options	956,274	1,384,806
Weighted-average common shares - diluted common stock	20,783,943	20,562,040
Shares excluded from diluted weighted-average shares:		
Stock options	773,033	110,000
Shares excluded from diluted weighted-average shares	773,033	110,000

The computations of diluted net income attributable to common stockholders exclude common stock options which were anti-dilutive for the three months ended March 31, 2016 and March 31, 2015, respectively.

6. Long-term debt

JPMorgan Chase Bank debt

As of March 31, 2016 and December 31, 2015, the Company had no outstanding borrowings under its revolving line of credit.

Edgar Filing: Inogen Inc - Form 10-Q

The contractual obligations schedule below relates to the acquisition of patents which are reflected in intangible assets and were acquired in 2011.

	March 31, 2016	December 31, 2015
Contractual obligation, bearing imputed interest at prime plus two, quarterly payments of \$53 beginning May 2011 through October 2014 and quarterly payments of \$81 beginning January 2015 through October 2016	\$ 238	\$ 315
Less: current maturities	(238)	(315)
Long-term debt, net of current portion	\$ —	\$ —

As of March 31, 2016, the minimum aggregate payments due under non-cancelable debt are summarized as follows:

	March 31, 2016
Remaining 9 months of 2016	\$ 238
2017	—
Total	\$ 238

Inogen, Inc.

Condensed Notes to the Financial Statements (continued)

(unaudited)

(amounts in thousands, except share and per share amounts)

7. Income taxes

The Company accounts for income taxes in accordance with ASC 740—Income Taxes. Under ASC 740, income taxes are recognized for the amount of taxes payable or refundable for the current period and deferred tax liabilities and assets are recognized for the future tax consequences of transactions that have been recognized in the Company's financial statements or tax returns. A valuation allowance is provided when it is more likely than not that some portion, or all, of the deferred tax asset will not be realized.

The Company accounts for uncertainties in income tax in accordance with ASC 740-10—Accounting for Uncertainty in Income Taxes. ASC 740-10 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. This accounting standard also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition.

The Company recognizes interest and penalties on taxes, if any, within its income tax provision. No significant interest or penalties were recognized during the periods presented.

The Company operates in multiple states. The statute of limitations has expired for all tax years prior to 2012 for federal and 2011 to 2012 for various state tax purposes. However, the net operating loss generated on the Company's federal and state tax returns in prior years may be subject to adjustments by the federal and state tax authorities.

Income tax expense was \$1,035 and \$846, an effective tax rate 30.4% and 35.0% for the three months ended March 31, 2016 and March 31, 2015, respectively. Variations in the tax rate year-over-year were primarily due to changes in the valuation allowance related to California net operating losses.

8. Stockholders' equity

The Company has a 2012 Equity Incentive Plan (2012 Plan) under which the Company granted options to purchase shares of its common stock. As of March 31, 2016, options to purchase 583,015 shares of common stock remained outstanding under the 2012 Plan. The 2012 Plan was terminated in connection with the Company's initial public offering, and accordingly, no new options are available for issuance under this plan. The 2012 Plan continues to govern outstanding awards granted thereunder.

The Company has a 2002 Stock Incentive Plan (2002 Plan) as amended, under which the Company granted options to purchase shares of its common stock. As of March 31, 2016, options to purchase 216,151 shares of common stock

remained outstanding under the 2002 Plan. The 2002 Plan was terminated in March 2012 in connection with the adoption of the 2012 Plan, and, accordingly, no new options are available for issuance under this plan. The 2002 Plan continues to govern outstanding awards granted thereunder.

The Company's board of directors adopted and its stockholders approved a 2014 Equity Incentive Plan (2014 Plan) effective immediately prior to the effectiveness of its initial public offering. The 2014 Plan provides for the grant of incentive stock options, within the meaning of Section 422 of the Internal Revenue Code, to the Company's employees and any parent and subsidiary corporation's employees, and for the grant of nonstatutory stock options, restricted stock, restricted stock units, stock appreciation rights, performance units and performance shares to its employees, directors and consultants and its parent and subsidiary corporations' employees and consultants.

As of March 31, 2016, options to purchase 1,397,470 shares of the Company's common stock were outstanding, and 1,085,770 shares of common stock remained available for issuance. The shares available for issuance under the 2014 Plan will be increased by any shares returned to the 2002 Plan, 2012 Plan and the 2014 Plan as a result of expiration or termination of awards (provided that the maximum number of shares that may be added to the 2014 Plan pursuant to such previously granted awards under the 2002 Plan and 2012 Plan is 2,328,569 shares). The number of shares available for issuance under the 2014 Plan also is increased annually on the first day of each fiscal year equal to the least of:

- 895,346 shares;
- 4% of the outstanding shares of common stock as of the last day of the Company's immediately preceding fiscal year;
- or
- such other amount as the Company's board of directors may determine.

For 2016, an additional 791,296 shares were added to the 2014 Plan share reserve pursuant to the provision described above.

Inogen, Inc.

Condensed Notes to the Financial Statements (continued)

(unaudited)

(amounts in thousands, except share and per share amounts)

Options typically expire between seven and ten years from the date of grant and vest over one to four year terms. Options have been granted to employees, directors and consultants of the Company at the deemed fair market value, as determined by the board of directors, of the shares underlying the options at the date of grant.

The activity for stock options under the Company's stock plans is as follows:

	Options	Price per share	Weighted-average exercise price	Remaining weighted-average contractual terms (in years)	Per share average intrinsic value
Outstanding as of December 31, 2015	2,295,370	\$0.60-\$46.66	\$ 19.36	5.98	\$ 21.07
Granted	—	—	—		
Exercised	(77,359)	0.60-18.93	1.19		
Forfeited	(21,375)	16.62-24.52	24.01		
Expired	—	—	—		
Outstanding as of March 31, 2016	2,196,636	0.60-46.66	19.95	5.77	25.08
Vested and exercisable as of March 31, 2016	967,017	0.60-46.66	8.57	5.43	36.41
Vested and expected to vest as of March 31, 2016	2,094,190	\$0.60-\$46.66	\$ 19.72	5.75	\$ 25.30

The Company's board of directors adopted and its stockholders approved a 2014 Employee Stock Purchase Plan (ESPP) effective immediately prior to the effectiveness of its initial public offering. The ESPP provides for the grant to all eligible employees an option to purchase stock under the ESPP, within the meaning Section 423 of the Internal Revenue Code. The ESPP permits participants to purchase common stock through payroll deductions of up to 15% of their eligible compensation, which includes a participant's base straight time gross earnings, incentive compensation, bonuses, overtime and shift premium, but exclusive of payments for equity compensation and other similar compensation. A participant may purchase a maximum of 1,500 shares during a purchase period. Amounts deducted and accumulated by the participant are used to purchase shares of the Company's common stock at the end of each six-month period. The purchase price of the shares will be 85% of the lower of the fair market value of the Company's common stock on the first trading day of each offering period or on the exercise date. The offering periods are currently approximately six months in length beginning on the first business day on or after March 1 and September 1 of each year and ending on the first business day on or after September 1 and March 1 approximately six months later.

As of March 31, 2016, a total of 458,019 shares of common stock were available for sale pursuant to the ESPP. The number of shares available for sale under the ESPP is increased annually on the first day of each fiscal year equal to the least of:

- 179,069 shares;
- 1.5% of the outstanding shares of the Company's common stock on the last day of the Company's immediately preceding fiscal year; or
- such other amount as may be determined by the administrator.

For 2016, an additional 179,069 shares were added to the ESPP share reserve pursuant to the provision described above.

Stock-based compensation expense recognized for the three months ended March 31, 2016 and March 31, 2015 for the ESPP was \$91 and \$85, respectively, and is combined with the 2014 Plan compensation expense for a total compensation expense of \$1,295 and \$518 for the three months ended March 31, 2016 and March 31, 2015, respectively.

Employee stock-based compensation expense recognized for the three months ended March 31, 2016 and March 31, 2015 was calculated based on awards ultimately expected to vest and has been reduced for estimated forfeitures at a rate of 7.5% and 7.6%, respectively, based on the Company's historical option cancellations. ASC 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

Inogen, Inc.

Condensed Notes to the Financial Statements (continued)

(unaudited)

(amounts in thousands, except share and per share amounts)

For the three months ended March 31, 2016 and March 31, 2015, stock-based compensation expense recognized under ASC 718, included in cost of revenues, sales and marketing expense, general and administrative expense, and research and development expense, totaled \$1,295 and \$518, respectively. The unrecognized compensation expense related to non-vested share based compensation granted under the Plans as of March 31, 2016 and March 31, 2015 was \$10,704 and \$4,528, respectively.

9. Commitments and contingencies

Leases

The Company leases its offices and certain equipment under operating leases that expire through January 2022. As of March 31, 2016, the minimum aggregate payments due under non-cancelable leases are summarized as follows:

	March 31, 2016
Remaining 9 months of 2016	\$887
2017	1,167
2018	1,154
2019	1,152
2020	752
Thereafter	269
	\$5,381

Rent expense of \$264 and \$220 for the three months ended March 31, 2016 and March 31, 2015, respectively, was included in the accompanying statements of comprehensive income.

Purchase obligations

The Company had \$23,006 of outstanding purchase orders with its outside vendors and suppliers as of March 31, 2016. In addition, the Company entered into agreements for other services. Future commitments under these purchase orders and other agreements do not extend beyond twelve months.

Warranty obligation

Edgar Filing: Inogen Inc - Form 10-Q

The following table identifies the changes in the Company's aggregate product warranty liabilities for the three and twelve month periods ended March 31, 2016 and December 31, 2015, respectively:

	March 31, 2016	December 31, 2015
Product warranty liability at beginning of period	\$1,973	\$ 1,115
Accruals for warranties issued	525	1,871
Adjustments related to preexisting warranties (including changes in estimates)	300	510
Settlements made (in cash or in kind)	(369)	(1,523)
Product warranty liability at end of period	\$2,429	\$ 1,973

Legislation and HIPAA

The healthcare industry is subject to numerous laws and regulations of federal, state and local governments. These laws and regulations include, but are not necessarily limited to, matters such as licensure, accreditation, government healthcare program participation requirements, reimbursement for patient services, and Medicare and Medicaid fraud and abuse. Government activity has continued with respect to investigations and allegations concerning possible violations of fraud and abuse statutes and regulations by healthcare providers. Violations of these laws and regulations could result in expulsion from government healthcare programs together with the imposition of significant fines and penalties, as well as significant repayments for patient services previously billed.

Inogen, Inc.

Condensed Notes to the Financial Statements (continued)

(unaudited)

(amounts in thousands, except share and per share amounts)

The Company believes that it is in compliance in all material respects with applicable fraud and abuse regulations and other applicable government laws and regulations. Compliance with such laws and regulations can be subject to future government review and interpretation as well as regulatory actions unknown or unasserted at this time. The Company believes that it complies in all material respects with the provisions of those regulations that are applicable to the Company's business.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) assures health insurance portability, reduces healthcare fraud and abuse, guarantees security and privacy of health information, and enforces standards for health information. The Health Information Technology for Economic and Clinical Health Act (HITECH Act) imposes notification requirements of certain security breaches relating to protected health information. The Company may be subject to significant fines and penalties if found not to be compliant with the provisions outlined in the regulations.

Legal proceedings

Inova Labs lawsuit

On November 4, 2011, the Company filed a lawsuit in the United States District Court for the Central District of California against Inova Labs Inc., or Defendant, for infringement of two of the Company's patents. The case, Inogen Inc. v. Inova Labs Inc., Case No. 8:11-cv-01692-JGB-AN, or the Inova Labs Lawsuit, involves U.S. Patent Nos. 7,841,343, entitled "Systems and Methods For Delivering Therapeutic Gas to Patients", or the '343 patent, and 6,605,136 entitled "Pressure Swing Adsorption Process Operation And Optimization", or the '136 patent. The Company alleged in the Inova Labs Lawsuit that certain of Defendant's oxygen concentrators infringe various claims of the '343 and '136 patents. The Inova Labs Lawsuit seeks damages, injunctive relief, costs and attorneys' fees.

The Defendant has answered the complaint, denying infringement and asserting various sets of defenses including non-infringement, invalidity and unenforceability, patent misuse, unclean hands, laches and estoppel. The Defendant also filed counterclaims against the Company alleging patent invalidity, non-infringement and inequitable conduct. The Company denied the allegations in the Defendant's counterclaims and filed a motion to dismiss Defendant's inequitable conduct counterclaim.

The Defendant filed requests with the U.S. Patent and Trademark Office seeking an inter partes reexamination of the '343 and '136 patents. The Defendant also filed a motion to stay the Inova Labs Lawsuit pending outcome of the reexamination. On March 20, 2012, the Court granted the Defendant's motion to stay the Inova Labs Lawsuit pending outcome of the reexamination and also granted the Company's motion to dismiss the Defendant's inequitable conduct counterclaim. On December 7, 2015, the U.S. Patent and Trademark Office issued an inter partes Reexamination Certificate for the '343 patent. Reexamination proceedings for the '136 patent have not concluded.

On February 4, 2016, ResMed announced the completion of the acquisition of Inova Labs Inc.

Securities class action lawsuit

On March 13 and March 19, 2015, plaintiffs Brad Christi and Roger D. Holford each filed, respectively, a lawsuit against Inogen, Raymond Huggenberger, Inogen's President and Chief Executive Officer, and Alison Bauerlein, Inogen's Executive Vice President and Chief Financial Officer, in the United States District Court for the Central District of California on behalf of a purported class of purchasers of the Company's securities between November 12, 2014 and March 11, 2015. The complaints alleged that Inogen, Mr. Huggenberger and Ms. Bauerlein violated Section 10(b) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and Rule 10b-5 promulgated thereunder, and that Mr. Huggenberger and Ms. Bauerlein violated Section 20(a) of the Exchange Act. Specifically, the complaints alleged that during the purported class period the Company's financial statements and disclosures concerning internal controls over financial reporting were materially false and misleading. The complaints sought compensatory damages in an unspecified amount, costs and expenses, including attorneys' fees and expert fees, prejudgment and post-judgment interest and such other relief as the court deemed proper. On May 7, 2015, plaintiff Roger D. Holford filed a notice of voluntary dismissal without prejudice pursuant to Federal Rule of Civil Procedure Rule 41(a)(1)(A) in the second filed action. On June 29, 2015, plaintiff Brad Christi filed a notice of voluntary dismissal without prejudice pursuant to Federal Rule of Civil Procedure Rule 41(a)(1)(A) in the first filed action. The case was closed by the Court as of June 29, 2015.

Inogen, Inc.

Condensed Notes to the Financial Statements (continued)

(unaudited)

(amounts in thousands, except share and per share amounts)

Separation Design Group litigation

On October 23, 2015, Separation Design Group IP Holdings, LLC (SDGIP) filed a lawsuit against the Company in the United States District Court for the Central District of California. On December 7, 2015, SDGIP filed a First Amended Complaint in the SDGIP Lawsuit.

SDGIP alleges that the Company willfully infringes U.S. Patent Nos. 8,894,751 and 9,199,055, both of which are titled "Ultra Rapid Cycle Portable Oxygen Concentrator." SDGIP also alleges misappropriation of trade secrets and breach of contract stemming from a meeting in September 2010. The Company never received any communication from SDGIP related to patent infringement, misuse of trade secrets, or breach of the mutual non-disclosure agreement prior to SDGIP filing the lawsuit. SDGIP seeks to recover an unspecified amount of damages (including compensatory and treble damages), costs and expenses (including attorneys' fees), pre-judgment and post-judgment interest, and other relief that the Court deems proper. SDGIP also seeks a permanent injunction against the Company.

The Company has and continues to vigorously contest SDGIP's claims. The Company has answered SDGIP's First Amended Complaint, denying SDGIP's allegations of patent infringement, trade secret misappropriation, and breach of contract and asserting several affirmative defenses.

Labor law dispute

On April 13, 2016, Ryan Casper and Shane Hofer (Plaintiffs) filed a lawsuit against the Company on behalf of themselves and all other similarly situated employees in the Superior Court for Santa Barbara County, California. The complaint alleges failure to pay overtime wages, failure to allow and pay for meal periods, and other alleged violations of California wage and hour law. The Plaintiffs and class members are seeking compensatory damages in the amount of all wages, interest, and penalties allegedly due, as well as liquidated damages, attorney's fees and other relief. The parties successfully mediated the claims and reached a settlement in April 2016. While the Company disputes the claims, it agreed to the settlement with no admission of liability to avoid the risks and costs associated with litigating the claims. As of March 31, 2016, the Company has accrued approximately \$980 for the settlement costs.

Other legal proceedings

The Company is party to various legal proceedings arising in the normal course of business. The Company carries insurance, subject to specified deductibles under the policies, to protect against losses from certain types of legal claims. At this time, the Company does not anticipate that any of these other proceedings will have a material adverse effect on the Company's business. Regardless of the outcome, litigation can have an adverse impact on the Company because of defense and settlement costs, diversion of management resources, and other factors.

10. Foreign currency exchange contracts and hedging

As of March 31, 2016, the Company's total non-designated and designated derivative contracts had notional amounts totaling approximately \$879 and \$4,408, respectively. These contracts were comprised of offsetting contracts with the same counterparty, each expires within one to nine months, and the designated contracts had an unrealized loss of approximately \$92, net of tax, during the three months ended March 31, 2016.

The nonperformance risk of the Company and the counterparty did not have a material impact on the fair value of the derivatives. During the three months ended March 31, 2016, the ineffective portion relating to these hedges was immaterial and the hedges remained effective through their respective settlement dates. As of March 31, 2016, the Company had twenty designated hedges.

11. Subsequent events

On April 13, 2016, Ryan Casper and Shane Hofer (Plaintiffs) filed a lawsuit against the Company on behalf of themselves and all other similarly situated employees in the Superior Court for Santa Barbara County, California. The complaint alleges failure to pay overtime wages, failure to allow and pay for meal periods, and other alleged violations of California wage and hour law. The Plaintiffs and class members are seeking compensatory damages in the amount of all wages, interest, and penalties allegedly due, as well as liquidated damages, attorney's fees and other relief. The parties successfully mediated the claims and reached a settlement in April 2016. While the Company disputes the claims, it agreed to the settlement with no admission of liability to avoid the risks and costs associated with litigating the claims. As of March 31, 2016, the Company has accrued approximately \$980 for the settlement costs.

Item 2: Management's Discussion and Analysis of Financial Condition and Results of Operations

Forward-Looking Statements

The following discussion and analysis should be read together with our financial statements and the condensed notes to those statements included elsewhere in this Quarterly Report on Form 10-Q. This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, that are based on our management's beliefs and assumptions and on information currently available to our management. The forward-looking statements are contained principally in the section entitled "Risk Factors" and this Management's Discussion and Analysis of Financial Condition and Results of Operations. Forward-looking statements include, but are not limited to, statements concerning the following:

- information concerning our possible or assumed future cash flow, revenue, sources of revenue and results of operations, operating and other expenses;
- our assessment of the impact from competitive bidding and the Centers for Medicare and Medicaid Services rules;
- our expectations regarding government and third-party payor coverage and reimbursement;
- our ability to develop new products, including our fourth-generation portable oxygen concentrator, improve our existing products and increase the value of our products;
- market share expectations, unit sales, business strategies, financing plans, expansion of our business, competitive position, industry environment, potential growth opportunities;
- our expectations regarding the market size, market growth and the growth potential for our business;
- our ability to sustain and manage growth, including our ability to develop new products and enter new markets;
- our expectations regarding the average selling price and manufacturing costs of our products;
- our expectation to expand our sales and marketing channels, including through hiring additional sales representatives and securing contracts with healthcare payors and insurers;
- our internal control environment;
- the effects of seasonal trends on our results of operations;
- our expectations regarding the timing of the launch and specifications of our fourth-generation portable oxygen concentrator; and
- the effects of competition.

Forward-looking statements include statements that are not historical facts and can be identified by terms such as "anticipates," "believes," "could," "seeks," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "would," or similar expressions and the negatives of those terms.

Forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements. We discuss these risks in greater detail in Part II, Item 1A, "Risk Factors," elsewhere in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

Except as required by law, we assume no obligation to update these forward-looking statements, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future. You should read this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results may be materially different from what we expect.

This Quarterly Report on Form 10-Q also contains estimates, projections and other information concerning our industry, our business, and the markets for certain diseases, including data regarding the estimated size of those

markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

“Inogen,” “Inogen One,” “Inogen One G2,” “Inogen One G3,” “G4,” “Oxygenation,” “Live Life in Moments, not Minutes,” “N Run Out of Oxygen,” “Oxygen Therapy on Your Terms,” “Oxygen.Anytime.Anywhere,” “Reclaim Your Independence,” “Intelligent Delivery Technology,” “Inogen At Home,” and the Inogen design are pending applications and/or registered trademarks with the United States Patent and Trademark Office of Inogen, Inc. We own trademark registrations for the mark “Inogen” in Australia, Canada, South Korea, Mexico, and Europe (European Union registration). We own pending applications for “Inogen” in Japan and South Korea, and we own a pending application for “ ” in Japan. We own trademark registrations for the mark “Inogen One” in Australia, Canada, China, South Korea, Mexico, and Europe (European Union registration). We own trademark registrations for the mark “Satellite Conserver” in Canada and China. We own a trademark registration for the mark “Inogen At Home” in Europe (European Union Registration). Other service marks, trademarks, and trade names referred to in this Quarterly Report on Form 10-Q are the property of their respective owners.

In this Quarterly Report on Form 10-Q, “we,” “us” and “our” refer to Inogen, Inc.

The following discussion of our financial condition and results of operations should be read together with our financial statements and the accompanying condensed notes to those statements included elsewhere in this document. Also, forward-looking statements represent our management’s beliefs and assumptions only as of the date of this Quarterly Report on Form 10-Q.

Critical accounting policies and significant estimates

Our discussion and analysis of our financial condition and results of operations is based upon our financial statements which have been prepared in accordance with generally accepted accounting principles in the United States, or U.S. GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities and related disclosure of contingent assets and liabilities, revenue and expenses at the date of the financial statements. Generally, we base our estimates on historical experience and on various other assumptions in accordance with U.S. GAAP that we believe to be reasonable under the circumstances. Actual results may differ from these estimates and such differences could be material to the financial position and results of operations.

There have been no material changes in our critical accounting policies and estimates in the preparation of our financial statements during the three months ended March 31, 2016 compared to those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2015, as filed with the SEC on March 14, 2016.

Overview

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

In May 2004, we received 510(k) clearance from the U.S. Food and Drug Administration, or the FDA, for our Inogen One G1. From our launch of the Inogen One G1 in 2004, through 2008, we derived our revenue almost exclusively from sales to healthcare providers and distributors. In December 2008, we acquired Comfort Life Medical Supply, LLC in order to secure access to the Medicare rental market and began accepting Medicare reimbursement for our oxygen solutions in certain states. At the time of the acquisition, Comfort Life Medical Supply, LLC had an active Medicare billing number but few other assets and limited business activities. In January 2009, following the acquisition of Comfort Life Medical Supply, LLC, we initiated our direct-to-consumer marketing strategy and began selling Inogen One systems directly to patients and building our Medicare rental business in the United States. In April 2009, we became a Durable, Medical Equipment, Prosthetics, Orthotics, and Supplies accredited Medicare supplier by the Accreditation Commission for Health Care for our Goleta, California facility for Home/Durable Medical Equipment Services for oxygen equipment and supplies. In addition, in May 2015, we again received notice of accreditation approval from the Accreditation Commission for Health Care for all six locations in which we conduct business, effective from May 8, 2015 through May 7, 2018. We believe we are the only portable oxygen concentrator manufacturer that employs a direct-to-consumer marketing strategy in the United States, meaning we advertise directly to patients, process their physician paperwork, provide clinical support as needed and bill Medicare or insurance on their behalf.

We derive a majority of our revenue from the sale and rental of our Inogen One systems and related accessories to patients, insurance carriers, home healthcare providers and distributors. We sell multiple configurations of our Inogen One systems with various batteries, accessories, warranties, power cords and language settings. We also rent our products to Medicare beneficiaries and patients with other insurance coverage to support their oxygen needs as prescribed by a physician as part of a care plan. Our goal is to design, build and market oxygen solutions that redefine how oxygen therapy is delivered. To accomplish this goal and to grow our revenue, we intend to continue to:

- Expand our sales and marketing channels. During the year ended December 31, 2015, we increased our internal sales representatives from 129 to 166. Typically, we expect new sales representatives to take 4-6 months to reach full productivity. Additionally, we are building a physician referral channel that consists of 14 sales representatives as of December 31, 2015 up from 12 as of December 31, 2014. Lastly, we are focused on building our international and domestic business-to-business partnerships, including relationships with distributors, key accounts, resellers, and private label partners.
- Invest in our product offerings to develop innovative products. We expended \$1.2 million and \$0.9 million for the three months ended March 31, 2016 and March 31, 2015, respectively, in research and development expenses, and we intend to continue to make such investments in the foreseeable future. We launched our upgraded Inogen One G3 product in December 2015, which has 25% increased oxygen output (1,050 ml/minute versus 840 ml/minute previously), is less expensive to manufacture than our current Inogen One G3 product, and features improvements in sound level (from 42 dBA to 39 dBA). We also expect to launch our fourth-generation portable oxygen concentrator, the Inogen One G4, by the end of May 2016 and we expect this product to weigh approximately 2.8 pounds versus 4.8 pounds for our Inogen One G3 at approximately half the size compared to the Inogen One G3. The sound level is approximately 40 dBA at setting 2 and it produces up to 630 ml/minute of oxygen output. We estimate that it will be suitable for more than 85% of supplemental long-term ambulatory oxygen therapy patients who contact us. We also expect the Inogen One G4 to be less expensive to manufacture than our Inogen One G3 product.
- Secure contracts with healthcare payors and insurers. Based on our patient population, we estimate that at least 30% of oxygen therapy patients are covered by non-Medicare payors, and that these patients often represent a younger, more active patient segment. By becoming an in-network provider with more insurance companies, we can reduce the patients' co-insurance and deductible obligations on their oxygen services, which we believe will allow us to attract additional patients to our Inogen One and Inogen At Home solutions.

We have been developing and refining the manufacturing of our Inogen One systems over the past eleven years. While nearly all of our manufacturing and assembly processes were originally outsourced, assembly of the manifold, compressor, sieve bed and concentrator is now conducted in-house in order to improve quality control and reduce cost. Additionally, we use lean manufacturing practices to maximize manufacturing efficiency. We rely on third-party manufacturers to supply several components of our Inogen One systems and Inogen At Home systems. We typically enter into supply agreements for these components that specify quantity and quality requirements and delivery terms. In certain cases, these agreements can be terminated by either party upon relatively short notice. We have elected to source certain key components from single sources of supply, including our batteries, motors, valves, and some molded plastic components. While alternative sources of supply are readily available for these components, we believe that maintaining a single source of supply allows us to control production costs and inventory levels and to manage component quality.

Historically, we have generated a majority of our revenue from sales and rentals to customers in the United States. For the three months ended March 31, 2016 and March 31, 2015, approximately 23.2% and 24.9%, respectively, of our total revenue was from customers outside the United States, primarily in Europe. Approximately 68.3% and 22.0% of the non-U.S. revenue for the three months ended March 31, 2016 and March 31, 2015, respectively, was invoiced in Euros with the remainder invoiced in United States dollars. As of March 31, 2016, we sold our products in 44 countries outside the United States through distributors or directly to large "house" accounts, which include gas companies, home oxygen providers, and resellers. In those instances, we sell to and bill the distributor or "house" accounts directly, leaving responsibility for the patient billing, support and clinical setup to the local provider.

Edgar Filing: Inogen Inc - Form 10-Q

Our total revenue increased \$9.2 million to \$43.0 million for the three months ended March 31, 2016 from \$33.8 million for the three months ended March 31, 2015, primarily due to growth in sales revenue associated with the increases in business-to-business sales and direct-to-consumer sales of our Inogen One systems and Inogen At Home systems, and partially offset by a decline in rental revenue associated with decreased reimbursement rates. We generated net income of \$2.4 million and \$1.6 million for the three months ended March 31, 2016 and March 31, 2015, respectively. We generated Adjusted EBITDA of \$8.1 million and \$6.4 million for the three months ended March 31, 2016 and March 31, 2015, respectively (see “Non-GAAP financial measures” for reconciliations between U.S. GAAP and non-GAAP results). As of March 31, 2016, our accumulated deficit was \$42.7 million.

Sales revenue

Our future financial performance will be driven in part by the growth in sales of our Inogen One systems, and, to a lesser extent, sales of batteries, other accessories, and sales of our Inogen At Home stationary oxygen concentrators. We plan to grow our system sales in the coming years through multiple strategies including: expanding our direct-to-consumer sales efforts through hiring additional sales representatives, investing in consumer awareness, expanding our sales infrastructure and efforts outside of the United States, expanding our business-to-business sales through key partnerships, and enhancing our product offerings through additional product launches. As our product offerings grow, we solicit feedback from our customers and focus our research and development efforts on continuing to improve patient preference and reduce the total cost of the product, in order to further drive sales of our products.

Our direct-to-consumer sales process involves numerous interactions with the individual patient, the physician and the physician's staff, and includes an in-depth analysis and review of our product, the patient's diagnosis and prescribed oxygen therapy, including procuring an oxygen prescription. The patient may consider whether to finance the product through an Inogen-approved third-party or purchase the equipment. Product is not deployed until both the prescription and payment are received. Once product is deployed, the patient has 30 days to return the product, subject to the payment of a minimal processing and handling fee. Approximately 10-13% of consumers who purchase a system return the system during this 30-day return period.

Our business-to-business efforts are focused on selling to home medical equipment distributors, oxygen providers, resellers, and private label partners who are based inside and outside of the United States. This process involves interactions with various key customer stakeholders, including sales, purchasing, product testing, and clinical personnel. Businesses that have patient demand that can be met with our oxygen concentrator systems place purchase orders to secure product deployment. This may be influenced based on outside factors, including the result of tender offerings, changes in insurance plan coverage, and overall changes in the net oxygen therapy patient population. Products are shipped freight on board (FOB) Inogen dock domestically, and based on financial history and profile, businesses may either prepay or receive extended terms. Products are shipped both FOB Inogen dock and DDP (Delivery Duty Paid) for certain international shipments depending on the shipper used. DDP shipments are Inogen's property until title has changed which is upon duty being paid. As a result of these factors, product purchases can be subject to changes in demand by customers.

We sold approximately 17,000 systems in the three months ended March 31, 2016 compared to 11,000 systems for the same period in 2015. Management focuses on system sales as an indicator of current business success.

Rental revenue

Our direct-to-consumer rental process involves numerous interactions with the individual patient, the physician and the physician's staff. The process includes an in-depth analysis and review of our product, the patient's diagnosis and prescribed oxygen therapy, and their medical history to confirm the appropriateness of our product for the patient's oxygen therapy and compliance with Medicare and private payor billing requirements, which often necessitates additional physician evaluation and/or testing as well as a Certificate of Medical Necessity. Once the product is deployed, the patient receives direction on product use and receives a clinical titration from our licensed staff to confirm the product meets the patient's medical oxygen needs prior to billing. As a result, the time from initial contact with a customer to billing can vary significantly and be up to one month or longer.

We plan to grow our rental revenue in the coming years through multiple strategies, including expanding our direct-to-consumer marketing efforts through hiring additional sales representatives and investing in patient and physician awareness, securing additional insurance contracts and continuing to enhance our product offerings through additional product launches. However, we expect declining rental revenue in 2016 associated with reimbursement rate

declines, partially offset by increased net patients on service. In addition, patients may come off of our services due to death, a change in their condition, a change in location, a change in provider or other factors. In each case, we maintain asset ownership and can redeploy assets as appropriate following such events. Given the length and uncertainty of our patient acquisition cycle and potential returns we have in the past experienced, and likely will in the future experience, fluctuations in our net new patient setups will occur on a period-to-period basis.

As the rental patient base increases, this rental model generates recurring revenue with minimal additional sales and general and administrative expenses. A portion of rentals include a capped rental period when no additional reimbursement will be allowed unless additional criteria are met. In this scenario, the ratio of billable patients to patients on service is critical to maintaining rental revenue growth as patients on service increases. Medicare has noted a certain percentage of beneficiaries, approximately 25%, based on their review of Medicare claims, reach the 36th month and enter the capped rental period. Our capped patients as a percentage of total patients on service was approximately 12.9% as of March 31, 2016, which is slightly lower than the capped patients as a percentage of total patients on service of approximately 15.3% as of March 31, 2015. The percentage of capped patients may fluctuate over time as new patients come on service, patients come off of service before and during the capped rental period, and existing patients enter the capped rental period.

As of March 31, 2016, we had approximately 33,200 oxygen rental patients, an increase from approximately 30,000 oxygen rental patients as of March 31, 2015. Management focuses on rental revenue as an indicator of current business success and a leading indicator of likely future rental revenue; however, actual rental revenue recognized is subject to a variety of other factors, including reimbursement levels by payor, patient zip code, the number of capped patients, write-offs for uncollectable balances, and adjustments for patients in transition.

Reimbursement

We rely heavily on reimbursement from Medicare, and secondarily, from private payors, Medicaid and patients, for our rental revenue. For the three months ended March 31, 2016, approximately 82.2% of our rental revenue was derived from Medicare's service reimbursement programs. The U.S. list price for our stationary oxygen rentals (HCPCS E1390) is \$260 per month and for our oxygen generating portable equipment (OGPE) rentals (HCPCS E1392) is \$70 per month. The current standard Medicare allowable effective January 1, 2016 now varies by state instead of the one national standard allowable for previous years. The national standard allowable in 2015 for stationary oxygen rentals (E1390) was \$180.92 per month and for OGPE rentals (E1392) was \$51.63 per month. Effective January 1, 2016, the Medicare allowable for stationary oxygen rentals (E1390) ranges from \$135.14 to \$145.61 per month and the OGPE rentals (E1392) ranges from \$46.69 to \$49.52 per month. These are the two primary codes that we bill to Medicare and other payors for our oxygen product rentals. These rates are subject to additional cuts effective July 1, 2016, per competitive bidding guidelines. In these areas covered under the re-bid of round two competitive bidding effective July 1, 2016, the Medicare allowable, for stationary oxygen rentals (E1390) ranges from \$70.00 to \$89.86 per month and the OGPE rentals (E1392) ranges from \$33.97 to \$42.00 per month.

As of January 1, 2011, Medicare has phased in a program called competitive bidding. Competitive bidding impacts the amount Medicare reimburses suppliers of durable medical equipment rentals, including portable oxygen concentrators. The program is defined geographically, with suppliers submitting bids to provide medical equipment for a specific product category within that geography. Once bids have been placed, an individual company's bids across products within the category are aggregated and weighted by each product's market share in the category. The weighted-average price is then indexed against competitors. Medicare determines a "clearing price" out of these weighted-average prices, at which, sufficient suppliers have indicated they will support patients in the category, and this threshold is typically designed to generate theoretical supply that is twice the expected demand. Bids for each modality among the suppliers that made the cut are then arrayed to determine what Medicare will reimburse for each product category and geographic area. The program has strict anti-collusion guidelines to ensure bidding is truly competitive. Competitive bidding contracts last up to three years once implemented, after which they are subject to a new round of bidding. Discounts off the standard Medicare allowable occur in competitive bidding Metropolitan Statistical Areas where contracts have been awarded as well as in cases where private payors pay less than this allowable. Competitive bidding rates are based on the zip code where the patient resides. Rental revenue includes payments for product, disposables, and customer service/support.

As of January 1, 2016, competitive bidding was nationalized. All areas previously not subject to bidding had rate reductions applied instead of doing another bidding process. The fee schedules in the un-bid areas are adjusted based on regional averages of the single payment amounts for areas already under competitive bidding. The regional prices are limited by a national ceiling (110% of the average of the regional prices) and a floor (90% of the average regional prices). Since January 1, 2016, the reimbursement rates for these un-bid areas (with dates of services from January 1, 2016 to June 30, 2016) are based on 50% of the un-adjusted (current) fee schedule amount and 50% of the adjusted (reduced) fee schedule amount which is based on the regional competitive bidding rates. Starting on July 1, 2016, reimbursement rates will be 100% of the adjusted fee schedule amount which will be based on regional competitive bidding rates, including the adjustments associated with competitive bidding round two re-compete effective July 1, 2016.

The regions are defined as follows:

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

The Centers for Medicare and Medicaid Services (CMS) defines frontier states as states where more than 50% of the counties in the state have a population density of 6 people or less per square mile and rural states are defined as states where more than 50% of the population lives in rural areas per census data. Current frontier states include MT, ND, SD and WY; rural states include ME, MS, VT and WV; and non-contiguous United States areas include AK, HI, Guam and Puerto Rico. For frontier and rural states, and frontier and rural zip codes in non-frontier/rural states, the single payment amount will be the national ceiling (110% of the average of the regional prices) to account for higher servicing costs in these areas. For non-contiguous United States areas, single payment amounts will be the higher of the national ceiling, or the average of competitive bidding pricing from these areas, if the areas had been bid through competitive bidding. We estimate that less than 10% of our patients would be eligible to receive the 110% of the regional prices for rural and frontier areas based on the geographic locations of our current patient population.

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

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

The following table sets forth the current Medicare standard allowable reimbursement rates and the weighted-average of reimbursement rates applicable in Metropolitan Statistical Areas covered by rounds one and two of competitive bidding. The round one re-compete was completed in the same Metropolitan Statistical Areas as round one for the next three-year period starting January 1, 2014 when the original contracts expired.

	Round two weighted- average 7/1/13- 6/30/16	Round one re-compete weighted- average 1/1/14- 12/31/16	Round two re-compete weighted- average 7/1/16- 12/31/18
E1390 (stationary oxygen rentals)	\$ 93.07	\$ 95.74	\$ 76.84
E1392 (portable oxygen rentals)	42.72	38.08	37.90
Total	\$ 135.79	\$ 133.82	\$ 114.74

In addition to reducing the Medicare reimbursement rates in the Metropolitan Statistical Areas, the competitive bidding program has effectively reduced the number of oxygen suppliers that can participate in the Medicare program.

We believe that more than 75% of existing oxygen suppliers were eliminated in round one of competitive bidding, which was implemented January 1, 2011 in 9 Metropolitan Statistical Areas. Round two of competitive bidding was implemented July 1, 2013 in 91 Metropolitan Statistical Areas and we believe the impact on the number of oxygen suppliers was similar to round one. We believe that approximately 59% of the market was covered by round one and round two of competitive bidding.

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

Following round one of competitive bidding, we were excluded from the Kansas City-MO-KS, Miami-Fort Lauderdale-Pompano-FL, and Orlando-Kissimmee-FL competitive bidding areas and Honolulu-Hawaii, where we have never maintained a license. After round one re-compete of competitive bidding, we gained access to Kansas City-MO-KS and were excluded from the following competitive bidding areas: Cleveland-Elyria-Mentor-OH, Cincinnati-Middletown-OH, Miami-Fort Lauderdale-Pompano-

FL, Orlando-Kissimmee-FL, Pittsburg-PA, and Riverside-San Bernardino-Ontario-CA. After round two of competitive bidding, we were excluded from an additional 10 competitive bidding areas, including Akron-OH, Cape Coral-Fort Myers-FL, Deltona-Daytona Beach-Ormond Beach-FL, Jacksonville-FL, Lakeland-Winter Haven-FL, North Port-Bradenton-Sarasota-FL, Ocala, Palm Bay-Melbourne-Titusville-FL, Tampa-St. Petersburg-Clearwater-FL and Toledo-OH. After round two re-compete of competitive bidding, we gained access to Cape-Coral-Fort Myers-FL, Deltona-Daytona Beach-Ormond Beach-FL, Jacksonville-FL, Lakeland-Winter Haven-FL, North Port-Sarasota-Bradenton-FL, Ocala-FL, Palm Bay-Melbourne-Titusville-FL, and Tampa-St. Petersburg-Clearwater-FL. We were excluded from the following competitive bidding areas that we had previously won under competitive bidding round two in the round two re-compete: Allentown-Bethlehem-Easton-PA, Asheville,-NC, Augusta-Richmond County-GA, Camden-NJ, Catoosa-Dade-Walker Counties-GA, Elizabeth-Lakewood-New Brunswick,-NJ, Flint-MI, Greensboro-High Point-NC, Greenville-Anderson-Mauldin-SC, Jersey City-Newark-NJ, Las Vegas-Henderson-Paradise-NV, Little Rock-North Little Rock-Conway-AR, Louisville-Jefferson County-KY, Mercer County-PA, Poughkeepsie-Newburgh-Middletown-NY, Raleigh-NC, Scranton-Wilkes-Barre-Hazleton-PA, Stockton-Lodi-CA, Syracuse-NY, Wilmington-DE, and Youngstown-Warren-Boardman-OH, and were excluded from the following in both round two and round two re-compete competitive bidding rounds: Akron-OH, and Toledo-OH.

On a going forward basis, effective July 1, 2016, we believe we will continue to have access to over 90% of the Medicare market based on our analysis of the 96 competitive bidding areas that we have won out of the 126 competitive bidding areas, representing 59% of the market, with the remaining 41% of the market not subject to competitive bidding rounds. Instead in these areas, the rates are applied as discussed above. The loss of access to the competitive bidding areas where we were not awarded contracts is not expected to lead to a material adverse impact on our rental business. Medicare revenue, including patient co-insurance and deductible obligations, represented 21.0% of our total revenue in 2015 and 19.5% of our total revenue in the three months ended March 31, 2016. We expect the decline in total revenue resulting from the loss of competitive bidding contracts in the areas that we were excluded from to be partially offset by the “grandfathering” of existing Medicare patients, direct sales to former Medicare patients with third-party insurance coverage, or Medicare patients paying out-of-pocket to purchase our products. Our revenue from Medicare in the 30 competitive bidding areas where we were not offered contracts as of July 1, 2016 was approximately \$0.6 million in the three months ended March 31, 2016 and \$0.5 million in the three months ended March 31, 2015.

Under the Medicare competitive bidding program, providers may “grandfather” existing patients on service up to the effective date of the competitive bidding round. This means providers may retain all existing patients and continue to receive reimbursement for them, so long as the new reimbursement rate is accepted and the applicable beneficiary chooses to continue to receive equipment from the provider. Providers must either keep or release all patients under this “grandfathering” arrangement in each competitive bidding area; specific individual selection of patients for retention or release is not allowed. Providers can continue to sell equipment in competitive bid areas where they were not awarded contracts to patients paying out-of-pocket or with third-party insurance coverage.

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

Medicare reimbursement for oxygen rental equipment is limited to a maximum of 36 months within a 60-month period and the equipment is always owned by the home oxygen provider. The provider that billed Medicare for the 36th month continues to be responsible for the patient’s oxygen therapy needs for months 37 through 60, and there is generally no additional reimbursement for oxygen generating portable equipment for these later months. CMS does not separately reimburse suppliers for oxygen tubing, cannulas and supplies that may be required for the patient. The provider is required to keep the equipment provided in working order and in some cases, CMS will reimburse for

repair costs. After the five-year useful life is reached, the patient may request replacement equipment and, if he or she can be re-qualified for the Medicare benefit: a new maximum 36-month payment cycle out of the next 60 months of service would begin. The provider may not arbitrarily issue new equipment. We have analyzed the potential impact to revenue associated with patients in the capped rental period and have deferred \$0 associated with the capped rental period for the three months ended March 31, 2016 and March 31, 2015, respectively.

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

In addition to the adoption of the competitive bidding program, from 2010 through 2015, reimbursable fees for oxygen rental services in non-competitive bidding areas were eligible to receive mandatory annual updates based upon the Consumer Price Index for all Urban Consumers, or CPI-U. For 2014, the CPI-U was +1.8%, but the multi-factor productivity adjustment, “adjustment”, was -0.8%, so the net result was a 1.0% increase in fee schedule payments in 2014 for items and services not included in an area subject to competitive bidding. However, the stationary oxygen equipment, codes payment amounts, as required by statute, must be adjusted on an annual basis, as necessary, to ensure budget neutrality of the new payment class for oxygen generating portable equipment. Thus, the increase in allowable payment amounts for stationary oxygen equipment codes increased 0.5% from 2013 to 2014. For 2015, the CPI-U was +2.1%, but the adjustment was -0.6%, so the net result was a 1.5% increase in fee schedule payments in 2015 for stationary oxygen equipment for items and services not included in an area subject to competitive bidding. Beginning in 2016, the standard allowable for all areas is set based on regional averages of the competitive bidding prices as described previously and no fees are based on non-competitive bidding. Accordingly, we do not anticipate future adjustments to the reimbursable fees based upon changes in CPI-U.

In addition, the President’s proposed federal budget for fiscal year 2017 includes multiple provisions that could impact the Company if they were enacted. The budget proposed eliminating the 36-month cap for oxygen equipment, and reducing the monthly payment amount for oxygen and oxygen equipment by the necessary percentage to be budget neutral. The Company’s patient population may materially differ from the Medicare population, which could lead to either more or less revenue if this is enacted. In addition, this change would likely also impact the number of patients interested in a cash purchase and could shift patients from out-of-pocket purchases toward renting units instead. The proposed budget also proposes to extend the authority to require prior authorization to all Medicare fee-for-service items and services, particularly those that are at the highest risk for improper payment. The proposed budget also contains multiple provisions related to the Medicare appeals process including establishing a refundable filing fee (non-refundable if denied), providing the Office of Medicare Hearings and Appeals and Department Appeals Board Authority to use Recover Audit Contractor collections, and increase minimum amount in controversy for administrative law judge adjudication of claims to equal the amount required for judicial review. In addition, this proposal includes the ability to remand appeals to the redetermination level with the introduction of new evidence and the ability to sample and consolidate similar claims for administrative efficiency.

A ruling from CMS has outlined the expansion of competitive bidding to certain previously unbid areas by applying regional pricing averages to unbid areas with 110% of regional prices to be paid for defined rural and frontier areas. We believe that the net effect of the ruling would be an approximately 3.5-4.0% decrease in 2016 total revenue since this pricing is being applied partially from January 1, 2016 to June 30, 2016 and will be applied completely starting on July 1, 2016. Medicare represented 21.0% of our total revenue in the year ended December 31, 2015, and we estimate that 41% of the Medicare markets will be subject to this reimbursement reduction. We also estimate that on average the rates will be reduced to the weighted-average of the regional prices under round one re-compete and round two re-compete. We estimate that less than 10% of our patients would be eligible to receive the 110% of the regional prices for rural and frontier areas based on the geographic locations of our current patient population. CMS has also re-bid the round two re-compete for contracts from July 1, 2016 through December 31, 2018 as discussed previously. CMS has begun the re-bid process for the round one re-compete for contracts from January 1, 2017 through December 31, 2018. There are multiple legislative efforts to delay the next round of bidding-derived reimbursement cuts for rural and non-bid areas that are currently expected to be implemented July 1, 2016. If these delay efforts are successful, this will reduce the impact of competitive bidding in the period of the delay. For additional discussion of the impact of the recent competitive bidding proposals, see “Risk Factors” herein.

As of March 31, 2016, we had 84 contracts with Medicaid and private payors. These contracts qualify us as an in-network provider for these payors. As a result, patients can rent or purchase our systems at the same patient obligation as other in-network oxygen providers. Based on our patient population, we believe at least 30% of all oxygen therapy patients are covered by private payors. Private payors typically provide reimbursement at 60% up to

and above 100% of Medicare allowables for in-network plans, and private payor plans can have 36-month capped rental periods similar to Medicare although they typically do not. We anticipate that private payor reimbursement levels will generally be reset in accordance with Medicare payment amounts established through competitive bidding.

We cannot predict the full extent to which reimbursement for our products will be affected by competitive bidding, the proposed budget for 2017, or by initiatives to reduce costs for private payors. We believe that we are well positioned to respond to the changing reimbursement environment because our product offerings are innovative, patient-focused and cost-effective. We have historically been able to reduce our costs through scalable manufacturing, better sourcing, continuous innovation, and reliability improvements, as well as innovations that reduce our product service costs by minimizing exchanges, such as user replaceable batteries and oxygen filtration cartridges. As a result of bringing manufacturing and assembly largely in-house and our commitment to driving efficient manufacturing processes, we have reduced our overall system cost by 46% from 2009 to the first quarter of 2016. We intend to continue to seek ways to reduce our cost of revenue through manufacturing and design improvements.

Basis of presentation

The following describes the line items set forth in our statements of comprehensive income.

Revenue

We classify our revenue in two main categories: sales revenue and rental revenue. There will be fluctuations in mix between business-to-business sales, direct-to-consumer sales and rentals from period-to-period. Inogen One system and Inogen At Home system selling prices and gross margins for our systems may fluctuate as we introduce new products, reduce our product costs, have changes in purchase volumes, and as currency variations occur. For example, the gross margin for our Inogen One G3 is higher than our Inogen One G2 due to lower manufacturing costs and similar average selling prices. Thus, to the extent our sales of our Inogen One G3 systems are higher than sales of our Inogen One G2 systems, our overall gross margins should improve and, conversely, to the extent our sales of our Inogen One G2 systems are higher than sales of our Inogen One G3 systems, our overall gross margins should decline. Quarter over quarter results may vary due to seasonality in both the international and domestic markets. For example, we typically experience higher sales in the second and third quarters, as a result of consumers traveling and vacationing during warmer weather in the spring and summer months.

Sales revenue

Our sales revenue is derived from the sale of our Inogen One systems, Inogen At Home systems, and related accessories to patients in the United States and to home healthcare providers, distributors, private label partners and resellers worldwide. Sales revenue is classified into two areas: business-to-business sales and direct-to-consumer sales. For the three months ended March 31, 2016 and March 31, 2015, business-to-business sales as a percentage of total sales revenue were 59.3% and 61.9%, respectively. Generally, our direct-to-consumer sales have higher gross margins than our business-to-business sales.

We also offer a lifetime warranty for direct-to-consumer sales. For a fixed price, we agree to provide a fully functional oxygen concentrator for the remaining life of the patient. Lifetime warranties are only offered to patients upon the initial sale of oxygen equipment by us and are non-transferable. Product sales with lifetime warranties are considered to be multiple element arrangements within the scope of the Accounting Standards Codification (ASC) 605-25—Revenue Recognition-Multiple-Element Arrangements.

There are two deliverables when a product that includes a lifetime warranty is sold. The first deliverable is the oxygen concentrator equipment which comes with a standard warranty of three years. The second deliverable is the lifetime warranty that provides for a functional oxygen concentrator for the remaining life of the patient. These two deliverables qualify as separate units of accounting.

The revenue is allocated to the two deliverables on a relative selling price method. We have vendor-specific objective evidence of selling price for the equipment including the standard warranty. To determine the selling price of the lifetime warranty, we use our best estimate of the selling price for that deliverable as the lifetime warranty is neither separately priced nor is selling price available through third-party evidence. To calculate the selling price associated with the lifetime warranties, management considered the profit margins of the overall business, the average estimated cost of lifetime warranties and the price of extended warranties. A significant estimate used to calculate the price and expense of lifetime warranties is the life expectancy of patients. Based on clinical studies, we estimate that 60% of patients will succumb to their disease within three years. Given the approximate mortality rate of 20% per year, we estimate on average all patients will succumb to their disease within five years. We have taken into consideration that when patients decide to buy an Inogen portable oxygen concentrator with a lifetime warranty, they typically have already been on oxygen for a period of time, which can have a large impact on their life expectancy from the time our

product is deployed.

After applying the relative selling price method, revenue from equipment sales is recognized when all other revenue recognition criteria for product sales are met. Lifetime warranty revenue is deferred for the first three years and is recognized using the straight-line method during the fourth and fifth year after the delivery of the equipment which is the estimated usage period of the contract based on the average patient life expectancy.

Freight revenue consists of fees associated with the deployment of products internationally or domestically, when expedited freight options or minimum order quantities are not met. Freight revenue is a percentage markup of freight costs.

Rental revenue

Our rental revenue is primarily derived from the rental of our Inogen One systems and Inogen At Home systems to patients through reimbursement from Medicare, private payors and Medicaid, which typically also includes a patient responsibility component for patient co-insurance and deductibles. We expect our rental revenue per patient to decline in future periods due to lower reimbursement rates due to competitive bidding reimbursement declines, the nationalization of competitive bidding, continued reimbursement declines across third-party payors and increases in capped patients on service.

We recognize equipment rental revenue over the non-cancelable lease term, which is one month, less estimated adjustments, per ASC 840 — Leases. We have a separate contract with each patient that is not subject to a master lease agreement with any payor. The lease term begins on the date products are shipped to patients and is recorded at amounts estimated to be received under reimbursement arrangements with third-party payors, including Medicare, private payors, and Medicaid. Due to the nature of the industry and the reimbursement environment in which we operate, certain estimates are required to record net revenue and accounts receivable at their net realizable values. Inherent in these estimates is the risk that they will have to be revised or updated as additional information becomes available. Specifically, the complexity of many third-party billing arrangements and the uncertainty of reimbursement amounts for certain services from certain payors may result in adjustments to amounts originally recorded. Such adjustments are typically identified and recorded at the point of cash application, claim denial or account review. Amounts billed but not earned due to the timing of the billing cycle are deferred and recognized in revenue on a straight-line basis over the monthly billing period. For example, if the first day of the billing period does not fall on the first of the month, then a portion of the monthly billing period will fall in the subsequent month and the related revenue and cost would be deferred based on the service days in the following month. Included in rental revenue are unbilled amounts for which the revenue recognition criteria had been met as of period-end but were not billed. The estimate of unbilled rental revenue accrual is reported net of adjustments that are based on historical trends and estimates of future collectability.

Cost of revenue

Cost of sales revenue

Cost of sales revenue consists primarily of costs incurred in the production process, including costs of component materials, assembly labor and overhead, warranty, provisions for slow-moving and obsolete inventory, rework and delivery costs for items sold. Labor and overhead expenses consist primarily of personnel-related expenses, including wages, bonuses, benefits, and stock-based compensation for manufacturing, logistics, repair, quality assurance, and facility costs. They also include manufacturing freight in, materials, temporary labor, outside services, consulting, facility costs, and depreciation expense. We provide a three-year or lifetime warranty on Inogen One systems sold and a three-year warranty on Inogen At Home systems sold. We established a reserve for warranty repairs based on historical warranty repair costs incurred. Provisions for warranty obligations, which are included in cost of sales revenue, are provided for at the time of revenue recognition.

We expect the average unit costs of our Inogen One systems and Inogen At Home systems to continue to decline in future periods as a result of our ongoing efforts to develop lower-cost systems and to improve our manufacturing processes, and increase production volume and yields.

Cost of rental revenue

Cost of rental revenue consists primarily of depreciation expense and service costs for rental patients, including rework costs, material, labor, freight, consumable disposables and logistics costs.

We expect the average rental service costs per patient to decline in future periods as a result of our ongoing efforts to reduce average unit costs of our systems, including reductions in logistics costs, material, labor and depreciation.

Operating expense

Research and development

Our research and development expense consists primarily of personnel-related expenses, including wages, bonuses, benefits and stock-based compensation for research and development and engineering employees, allocated facility costs, laboratory supplies, product development materials, consulting fees and related costs, and testing costs for new product launches. We have made substantial investments in research and development since our inception. Our research and development efforts have focused primarily on the tasks required to enhance our technologies and to support development and commercialization of new and existing products. We expect research and development expense to increase in absolute dollars in future periods as we continue to invest in our engineering and technology teams to support our new and enhanced product research and development efforts and manufacturing line support, including our efforts related to the upcoming Inogen One G4. We plan to continue to invest in research and development activities to stay at the forefront of patient preference in oxygen therapy devices and as a result expect our research and development expense to increase in future periods.

Sales and marketing

Our sales and marketing expense primarily supports our direct-to-consumer strategy. Our sales and marketing expense consists primarily of personnel-related expenses, including wages, bonuses, commissions, benefits, and stock-based compensation for sales, marketing, customer service and clinical service employees, and allocated facilities costs. They also include expenses for media and advertising, printing, informational kits, dues and fees, including credit card fees, sales promotional and marketing activities, travel and entertainment expenses as well as customer service and clinical services. Sales and marketing expenses increased throughout 2014, 2015, and the first quarter of 2016, primarily due to an increase in the sales force and the increasing number of rental patients, and we expect a further increase in 2016 as we continue to increase sales and marketing activities.

General and administrative

Our general and administrative expense consists primarily of personnel-related expenses, including wages, bonuses, benefits, and stock-based compensation for employees in our compliance, finance, medical billing, human resources, information technology, business development and general management functions, consulting fees, facilities costs, bad debt expense, and board of directors expenses, including stock-based compensation. In addition, general and administrative expense includes professional services, such as legal, patent registration and defense costs, insurance, consulting and accounting services, including audit and tax services, and travel and entertainment expenses. We expect general and administrative expenses to increase in future periods as the number of administrative personnel grows and we continue to introduce new products, broaden our customer base and grow our business. We also expect legal, accounting and compliance costs to increase due to costs associated with being a public company.

Other income (expense), net

Our other income (expense), net consisted primarily of foreign currency translation losses, and interest income driven by the interest accruing on cash, cash equivalents and short-term investments.

Results of operations

Comparison of three months ended March 31, 2016 and March 31, 2015

Revenue

Edgar Filing: Inogen Inc - Form 10-Q

(amounts in thousands)	Three months ended		Change 2016		% of Revenue	
	March 31,		vs. 2015		2016	2015
	2016	2015	\$	%		
Sales revenue	\$32,811	\$23,049	\$9,762	42.4%	76.3 %	68.3 %
Rental revenue	10,178	10,703	(525)	-4.9 %	23.7 %	31.7 %
Total revenue	\$42,989	\$33,752	\$9,237	27.4%	100.0%	100.0%

Sales revenue increased \$9.8 million to \$32.8 million for the three months ended March 31, 2016 from \$23.0 million for the three months ended March 31, 2015, or an increase of 42.4% over the comparable period. The increase was primarily attributable to a 6,000-unit increase in the number of oxygen systems sold. We sold approximately 17,000 oxygen systems during the three months ended March 31, 2016 compared to approximately 11,000 oxygen systems sold during the three months ended March 31, 2015, or an increase of 54.5% over the comparable period. In addition, the increase in the number of systems sold resulted from an increase in direct-to-consumer sales in the United States due to increased sales and marketing efforts and an increase in business-to-business sales worldwide.

Rental revenue decreased \$0.5 million to \$10.2 million for the three months ended March 31, 2016 from \$10.7 million for the three months ended March 31, 2015, or a decrease of 4.9% over the comparable period. The decrease in rental revenue was primarily related to a 3% year-over-year decline in per patient rental rates due to Medicare reimbursement cuts and an increase in reserves and adjustment rates.

	Three months ended		Change 2016 vs. 2015		% of Revenue	
	March 31, 2016	2015	\$	%	2016	2015
(amounts in thousands)						
Revenue by region and category						
Business-to-business domestic sales	\$9,478	\$5,880	\$3,598	61.2%	22.0%	17.4%
Business-to-business international sales	9,965	8,398	1,567	18.7%	23.2%	24.9%
Direct-to-consumer domestic sales	13,368	8,771	4,597	52.4%	31.1%	26.0%
Direct-to-consumer domestic rentals	10,178	10,703	(525)	-4.9%	23.7%	31.7%
Total revenue	\$42,989	\$33,752	\$9,237	27.4%	100.0%	100.0%

Domestic sales in both business-to-business and direct-to-consumer increased 61.2% and 52.4%, respectively, for the three months ended March 31, 2016 compared to the three months ended March 31, 2015. The increase in domestic business-to-business sales was primarily the result of increased demand from our private label distributor, home medical equipment provider, resellers, as well as increased consumer demand for our products due to our marketing efforts and the marketing efforts of our business partners. The increase in direct-to-consumer sales was primarily due to the hiring of the additional internal sales representatives in the fourth quarter of 2015 and in the first quarter of 2016, our expansion of marketing strategies, and our continued focus on direct-to-consumer sales with more selective new rental patient set-ups.

Business-to-business international sales increased 18.7% for the three months ended March 31, 2016 compared to the three months ended March 31, 2015, primarily due to continued demand in Europe. As of March 31, 2016, we sold our products in 44 countries outside of the United States, and we plan to continue to expand our presence in other countries as the opportunities present themselves. Of our international sales revenue in the three months ended March 31, 2016, 90.8% was sold in Europe, compared to 87.7% in the comparative period in 2015.

In future periods, revenue may be impacted by seasonality resulting in higher sales in the warmer weather spring and summer months due to patients traveling in those periods and lower revenue in the low travel and colder weather months. We also will be impacted by lower Medicare and third-party reimbursement rates, including competitive bidding, the number of sales representatives, the level of and response from potential customers to direct-to-consumer marketing spend, the number and demand of business-to-business partners and distributors, product launches, and

other uncontrollable factors such as changes in the market and competition. We expect our rental revenue per patient to decline in future periods due to competitive bidding reimbursement declines, lower reimbursement rates in connection with the nationalization of competitive bidding, continued reimbursement declines across third-party payors and increases in capped patients on service. While we are monitoring the implementation of competitive bidding pricing changes in 2016, we believe that the net effect would be an approximately 3.5-4.0% decrease in 2016 total revenue since this pricing is being applied partially from January 1, 2016 to June 30, 2016 and will be applied completely starting on July 1, 2016.

Cost of revenue and gross profit

(amounts in thousands)	Three months ended		Change 2016 vs. 2015		% of Revenue	
	March 31, 2016	2015	\$	%	2016	2015
Cost of sales revenue	\$16,507	\$12,589	\$3,918	31.1 %	38.4 %	37.3 %
Cost of rental revenue	5,203	5,140	63	1.2 %	12.1 %	15.2 %
Total cost of revenue	\$21,710	\$17,729	\$3,981	22.5 %	50.5 %	52.5 %
Gross profit - sales revenue	\$16,304	\$10,460	\$5,844	55.9 %	37.9 %	31.0 %
Gross profit - rental revenue	4,975	5,563	(588)	-10.6 %	11.6 %	16.5 %
Total gross profit	\$21,279	\$16,023	\$5,256	32.8 %	49.5 %	47.5 %
Gross margin percentage - sales revenue	49.7 %	45.4 %				
Gross margin percentage- rental revenue	48.9 %	52.0 %				
Total gross margin percentage	49.5 %	47.5 %				

We manufacture our products in our Goleta, California and Richardson, Texas facilities. Our manufacturing process includes final assembly, testing, and packaging to quality and customer specifications. The cost of sales revenue increased \$3.9 million to \$16.5 million for the three months ended March 31, 2016 from \$12.6 million for the three months ended March 31, 2015, or an increase of 31.1% over the comparable period. The increase in cost of sales revenue was primarily attributable to an increase in the number of systems sold, partially offset by reduced bill of material costs for our products associated with design changes, better sourcing and increased volumes. We expect the cost of sales revenue as a percentage of sales revenue in future periods to fluctuate based on customer mix, product mix, and changes in sales prices and cost of goods sold.

The cost of rental revenue increased \$0.1 million to \$5.2 million for the three months ended March 31, 2016 from \$5.1 million for the three months ended March 31, 2015, or an increase of 1.2% over the comparable period. The increase in cost of rental revenue was primarily attributable to an increase of rental patients and related repair costs, disposables, product exchange and logistics costs. Cost of rental revenue included \$2.9 million of rental asset depreciation for the three months ended March 31, 2016 versus \$3.0 million for the three months ended March 31, 2015. Rental asset depreciation expense declined in the first quarter of 2016 versus the first quarter of 2015 primarily due to lower equipment costs due to lower materials and labor costs per unit.

Gross margin is defined as revenue less costs of revenue divided by revenue. Sales revenue gross margin increased to 49.7% for the three months ended March 31, 2016 from 45.4% for the three months ended March 31, 2015. The increase in sales gross margin was primarily related to lower cost of goods sold per unit due to lower materials and labor costs associated with the Inogen One G3 upgrade product launched in the fourth quarter of 2015. In addition, an increase in sales mix toward higher margin direct-to-consumer sales, which accounted for 40.7% of total sales revenue in the first quarter of 2016 versus 38.1% in the first quarter of 2015, improved sales gross margin.

Rental revenue gross margin decreased to 48.9% for the three months ended March 31, 2016 from 52.0% for the three months ended March 31, 2015, primarily due to lower net revenue per rental patient resulting from the reimbursement reductions and increased provisions for rental adjustments in the first quarter of 2016, partially offset by lower cost of

rental revenues associated with lower depreciation and servicing costs per patient.

Research and development expense

(amounts in thousands)	Three months ended		Change		% of	
	March 31, 2016	March 31, 2015	2016 vs. 2015	%	Revenue 2016	Revenue 2015
Research and development expense	\$1,168	\$863	\$305	35.3%	2.7%	2.6%

Research and development expense increased \$0.3 million to \$1.2 million for the three months ended March 31, 2016 from \$0.9 million for the three months ended March 31, 2015, or an increase of 35.3% over the comparable period. The increase was primarily attributable to a \$0.2 million increase in personnel-related expenses for engineering projects and \$0.1 million for product development expense.

We expect research and development expense to increase in absolute dollars in future periods as we continue to invest in our engineering and technology teams to support our new and enhanced product research and development efforts and manufacturing line support, including our efforts related to the new Inogen One G4.

Sales and marketing expense

(amounts in thousands)	Three months ended		Change 2016 vs. 2015		% of Revenue	
	March 31,		\$	%	2016	2015
	2016	2015				
Sales and marketing expense	\$8,965	\$6,924	\$2,041	29.5%	20.9%	20.5%

Sales and marketing expense increased \$2.0 million to \$9.0 million for the three months ended March 31, 2016 from \$6.9 million for the three months ended March 31, 2015, or an increase of 29.5% over the comparable period. The increase was primarily attributable to \$1.0 million of sales and marketing personnel-related expenses as a result of increased headcount to support the growth of our business (which included \$0.5 million of wages and payroll tax expense, \$0.4 million of commissions expense, and \$0.1 million additional stock compensation expense), \$0.4 million of additional media/printing expenses and \$0.2 million in higher credit card processing fees. We also incurred an additional \$0.1 million for non-warranty repair costs done as an accommodation to our customers. In the three months ended March 31, 2016, we spent \$1.5 million in media and advertising costs compared to \$1.1 million in the comparative period in 2015.

We expect sales and marketing expenses to increase in absolute dollars in future periods as we continue to invest in our business, including expanding our sales and sales support team, increasing media spend to drive consumer awareness, and increasing patient support costs as our patient base increases.

General and administrative expense

(amounts in thousands)	Three months ended		Change 2016 vs. 2015		% of Revenue	
	March 31,		\$	%	2016	2015
	2016	2015				
General and administrative expense	\$7,869	\$5,718	\$2,151	37.6%	18.3%	16.9%

General and administrative expense increased \$2.2 million to \$7.9 million for the three months ended March 31, 2016 from \$5.7 million for the three months ended March 31, 2015, or an increase of 37.6% over the comparable period. The increase was primarily attributable to a \$1.0 million litigation settlement accrual, \$1.2 million of personnel-related expenses as a result of increased headcount in executive administration, billing, finance, information technology, human resources and compliance (which included an additional \$0.6 million of stock compensation expense and an additional \$0.6 million of wages and payroll tax expense), \$0.5 million of bad debt expense primarily related to our rental receivables and \$0.2 million of patent defense costs. These increases were partially offset by

Edgar Filing: Inogen Inc - Form 10-Q

decreases of \$0.7 million in audit/tax/legal fees (primarily due to the audit committee investigation expense of \$0.9 million in the first quarter of 2015) and \$0.2 million of bonus expense. Bad debt expense, expressed as a percentage of total revenue, was 2.0% and 0.9% in the three months ended March 31, 2016 and March 31, 2015, respectively.

We expect general and administrative expense to increase in absolute dollars as we continue to invest in corporate infrastructure to support our growth and our operation as a public company, including personnel-related expenses, professional services fees and compliance costs associated with operating as a public company. In addition, as our patient base increases, we expect our billing and administration costs to increase in absolute dollars and our bad debt expense to increase in absolute dollars as our revenue increases.

Other income (expense), net

(amounts in thousands)	Three months ended		Change 2016 vs. 2015		% of Revenue	
	March 31, 2016	March 31, 2015	\$	%	2016	2015
Interest expense	\$(3)	\$(7)	\$4	-57.1 %	0.0%	0.0 %
Interest income	29	12	17	141.7%	0.1%	0.0 %
Other income (expense)	97	(105)	202	192.4%	0.2%	-0.3 %
Total other income (expense), net	\$123	\$(100)	\$223	223.0%	0.3%	-0.3 %

Total other income (expense), net, increased to \$0.1 million for the three months ended March 31, 2016 from \$(0.1) million for the three months ended March 31, 2015. The increase was primarily due to gains on foreign currency sales transactions as the U.S. dollar stabilized.

Income tax expense

(amounts in thousands)	Three months ended		Change		% of	
	March 31, 2016	March 31, 2015	2016 vs. 2015	%	2016	2015
Income tax expense	\$1,035	\$846	\$189	22.3%	2.4%	2.5%
Effective income tax rate	30.4%	35.0%				

The increase in the provision for income taxes for the three months ended March 31, 2016 compared to the prior year period was primarily due to an increase in income before provision for income taxes to \$3.4 million for the three months ended March 31, 2016 compared to \$2.4 million for the three months ended March 31, 2015, partially offset by a decrease in the effective tax rate to 30.4% for the three months ended March 31, 2016, compared to 35.0% for the three months ended March 31, 2015. This decrease in the effective rates was primarily associated with a decreased valuation allowance on net operating losses in California.

Net income

(amounts in thousands)	Three months ended		Change		% of	
	March 31, 2016	March 31, 2015	2016 vs. 2015	%	2016	2015
Net income	\$2,365	\$1,572	\$793	50.4%	5.5%	4.7%

The increase in net income was primarily related to the increase in revenues of 27.4% over the prior year and the decrease in the effective tax rate to 30.4% for the three months ended March 31, 2016 compared to 35.0% for the three months ended March 31, 2015.

Contractual obligations

We obtain individual components for our products from a wide variety of individual suppliers. Consistent with industry practice, we acquire components through a combination of purchase orders, supplier contracts, and open orders based on projected demand information. Where appropriate, the purchases are applied to inventory component

prepayments that are outstanding with the respective supplier. As of March 31, 2016, we had purchase obligations of \$23.0 million of which the timing varies depending on demand, current supply on hand and other factors. The obligations normally do not extend beyond twelve month time-frames.

Except as indicated above, there have been no other material changes, outside of the ordinary course of business, in our outstanding contractual obligations from those disclosed within “Management’s Discussion and Analysis of Financial Condition and Results of Operations” section contained in our Annual Report on Form 10-K filed with the SEC on March 14, 2016.

Off-balance sheet arrangements

We do not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or for any other contractually narrow or limited purpose. However, from time to time we enter into certain types of contracts that contingently require us to indemnify parties against third-party claims including certain real estate leases, supply purchase agreements, and directors and officers. The terms of such obligations vary by contract and in most instances a maximum dollar amount is not explicitly stated therein.

Generally, amounts under these contracts cannot be reasonably estimated until a specific claim is asserted thus no liabilities have been recorded for these obligations on our balance sheets for any of the periods presented.

Liquidity and capital resources

As of March 31, 2016, we had cash and cash equivalents of \$72.4 million, which consisted of highly-liquid investments with a maturity of three months or less. In addition, we held \$13.7 million in certificates of deposits which had maturities greater than three months, but less than twelve months, and which were classified as short-term investments. Since inception, we have financed our operations primarily through cash from operations, the sale of equity securities and, to a lesser extent, from borrowings. As of March 31, 2016, we had \$0.2 million outstanding in patent licensing debt. Since inception, we have received net proceeds of \$91.7 million from the issuance of redeemable convertible preferred stock and convertible preferred stock, and \$52.5 million (\$49.7 million net proceeds) in connection with the sale of common stock in our initial public offering. Since 2013, we have received \$4.3 million from proceeds related to stock option exercises and employee stock purchase plans. For the three months ended March 31, 2016 and March 31, 2015, we received \$0.6 million and \$0.5 million, respectively, in proceeds related to these stock programs.

In November 2014, we secured a primary banking relationship that provides access to a \$15.0 million working capital revolving line of credit and treasury and cash management services through commercial banking with JPMorgan Chase Bank. This agreement is a three-year working capital revolving line of credit which replaced the previous loan facility we maintained with Comerica Bank. The interest rate on outstanding debt balances is the London Interbank Offer Rate (LIBOR) plus 1.25%.

Pursuant to the revolving credit agreement, we are subject to certain financial covenants relating to our net worth and EBITDA. Tangible net worth under the revolving credit agreement is calculated by subtracting the sum of intangible assets and total liabilities from total assets. EBITDA is defined in the revolving credit agreement as our net income plus interest expense, plus depreciation expense, plus amortization expense, plus income tax expense, plus non-cash expense, plus extraordinary losses, minus non-cash income, and minus extraordinary gains, as computed during certain test periods provided in the revolving credit agreement. We are required to maintain at all times a tangible net worth of \$90.0 million and EBITDA (i) of \$10.0 million for any period of four consecutive quarters commencing with the four-quarter test period ended September 30, 2014 through the four-quarter test period ended March 31, 2016 and (ii) of \$12.5 million for any four-quarter test period commencing with the four-quarter test period ending June 30, 2016 and continuing thereafter.

The agreement contains events of default customary for transactions of this type, including nonpayment, misrepresentation, breach of covenants, and bankruptcy. In the event we fail to satisfy our covenants, or otherwise go into default, JPMorgan Chase Bank 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 March 31, 2016, in order to be in compliance with the EBITDA and tangible net worth requirements, we were required to maintain \$10.0 million in EBITDA for the preceding test period, and we had \$34.2 million in EBITDA for that period. In addition, we were required to maintain a tangible net worth of \$90.0 million and we had a tangible net worth of \$138.0 million. As of March 31, 2016, we had \$15.0 million in available debt capacity under the revolving facility.

Our principal uses of cash in the three months ended March 31, 2016 consisted of the funding of our capital expenditures including additional rental equipment and other property, plant and equipment of \$2.2 million, which were more than offset by net maturities of available-for-sale investments of \$3.1 million. We believe that our current cash, cash equivalents, short-term investments, available borrowings under our revolving credit and term loan agreement and the cash to be generated from expected product sales and rentals will be sufficient to meet our projected operating and investing requirements for at least the next 12 months. However, our liquidity assumptions may prove to be incorrect, and we could utilize our available financial resources sooner than we currently expect. Our future capital requirements and the adequacy of available funds will depend on many factors, including those set forth

in the section of this Quarterly Report on Form 10-Q entitled “Risk Factors.”

If we require additional funds in the future, we may not be able to obtain such funds on acceptable terms, or at all. In the future, we may also attempt to raise additional capital through the sale of equity securities or through equity-linked or debt financing arrangements. If we raise additional funds by issuing equity or equity-linked securities, the ownership of our existing stockholders will be diluted. If we raise additional financing by the incurrence of indebtedness, we will be subject to increased fixed payment obligations and could also be subject to restrictive covenants, such as limitations on our ability to incur additional debt, and other operating restrictions that could adversely impact our ability to conduct our business. Any future indebtedness we incur may result in terms that could be unfavorable to equity investors. There can be no assurances that we will be able to raise additional capital, which would adversely affect our ability to achieve our business objectives. In addition, if our operating performance during the next twelve months is below our expectations, our liquidity and ability to operate our business could be adversely affected.

40

Edgar Filing: Inogen Inc - Form 10-Q

The following tables show a summary of our cash flows and working capital for the periods indicated:

(amounts in thousands)	Three months ended		Change 2016 vs. 2015	
	March 31, 2016	March 31, 2015	\$	%
Summary of cash flows				
Cash provided by operating activities	\$4,777	\$6,061	\$(1,284)	-21.2 %
Cash provided by (used in) investing activities	942	(4,040)	4,982	-123.3 %
Cash provided by financing activities	515	2,245	(1,730)	-77.1 %
Effect of exchange rates on cash	60	—	60	—
Net increase in cash and cash equivalents	\$6,294	\$4,266	\$2,028	47.5 %

(amounts in thousands)	March 31, 2016	December 31, 2015
Working capital		
Cash and cash equivalents	\$72,400	\$66,106
Short-term investments	13,694	16,793
Accounts receivable, net	23,748	19,872
Inventories, net	10,275	8,648
Deferred cost of revenue	520	397
Income tax receivable	2,158	2,158
Prepaid expenses and other current assets	1,185	870
Total current assets	123,980	114,844
Accounts payable and accrued expenses	17,220	12,867
Accrued payroll	3,017	5,271
Current portion of long-term debt	238	315
Warranty reserve	1,351	1,226
Deferred revenue	2,212	2,323
Income tax payable	6	11
Total current liabilities	24,044	22,013
Net working capital	\$99,936	\$92,831

Operating activities

We derive operating cash flows from cash collected from the sales and rental of our products and services. These cash flows received are partially offset by our use of cash for operating expenses to support the growth of our business. Net income in each period has increased associated with increased sales, improving product mix and lower costs of revenues. In addition, operating expense leverage has increased as expenses have not grown as quickly as revenues due to improved operating efficiencies. The changes in cash related to operating assets and liabilities discussed below were primarily due to the following factors that occurred across all periods: an increase in cash used related to inventory to support our growth in revenue; an increase in cash used by accounts receivable resulting from growth in rental receivables which typically have a longer collection cycle; and an increase in cash provided by accounts

payable resulting from the higher level of operating expenses needed to support the higher sales level.

Net cash provided by operating activities for the three months ended March 31, 2016 consisted primarily of our net income of \$2.4 million adjusted for non-cash expense items such as depreciation and amortization of our equipment and leasehold improvements of \$3.4 million, provision for rental revenue adjustments of \$2.6 million, provision for sales returns of \$2.1 million, stock-based compensation expense of \$1.3 million, deferred tax assets of \$1.0 million, provision for doubtful accounts of \$0.8 million and loss on disposal of rental units of \$0.3 million. The net changes in operating assets and liabilities resulted in a net decrease in cash of \$9.2 million, of which \$12.0 million was due to a net increase in accounts receivable, inventory, and other current assets during this period, and \$2.3 million was due to a net decrease in accrued payroll. These were partially offset by a net increase of \$4.3 million of accounts payable, \$0.5 million of deferred revenue, and \$0.5 million of the warranty reserve.

Investing activities

Net cash provided by or used in investing activities for each of the periods presented was primarily related to the production and purchase of rental assets, manufacturing tooling, and computer equipment and software to support our expanding business. Beginning in the second quarter of 2015, net cash used in investing activities also included the net purchase of available-for-sale investments.

For the three months ended March 31, 2016, we had \$10.1 million in maturities of available-for-sale investments, partially offset by \$7.0 million of purchases that we invested in certificates of deposits with maturities greater than three months and less than twelve months that were classified as short-term investments. In addition, we invested \$1.5 million in rental assets and \$0.7 million in other property, equipment, and leasehold improvements.

We expect to continue investing in property and equipment as we expand our operations. Our business is inherently capital intensive. For example, we expend significant manufacturing and production expense in connection with the development and production of our oxygen concentrator products and, in connection with our rental business, we incur expense in the deployment of rental products to our patients. Investments will continue to be required in order to grow our revenue.

Financing activities

Historically, we have funded our operations through our sales and rental revenue, the issuance of preferred and common stock, and the incurrence of indebtedness.

For the three months ended March 31, 2016, net cash provided by financing activities consisted primarily of \$0.6 million from the proceeds of purchases under our employee stock purchase program, and stock options that were exercised, partially offset by \$0.1 million of payments on our contractual obligation.

Non-GAAP financial measures

EBITDA and Adjusted EBITDA are financial measures that are not calculated in accordance with U.S. GAAP. We define EBITDA as net income 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, the most directly comparable financial measure calculated and presented in accordance with U.S. GAAP. EBITDA and Adjusted EBITDA should not be considered alternatives to net income or any other measure of financial performance calculated and presented in accordance with U.S. GAAP. Our EBITDA and Adjusted EBITDA may not be comparable to similarly titled measures of other organizations because other organizations may not calculate EBITDA and Adjusted EBITDA in the same manner as we calculate these measures.

We include EBITDA and Adjusted EBITDA in this Quarterly Report on Form 10-Q 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 re-measurements of our preferred stock warrants, 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 uses 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 U.S. GAAP. Some of these limitations are:

Edgar Filing: Inogen Inc - Form 10-Q

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.

42

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 certain expenses. When evaluating our performance, you should consider EBITDA and Adjusted EBITDA alongside other financial performance measures, including other U.S. GAAP results.

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

	Three months ended March	
(amounts in thousands)	31, 2016	2015
EBITDA and Adjusted EBITDA	2016	2015
Net income (U.S.GAAP)	\$2,365	\$1,572
Non-GAAP adjustments:		
Interest expense	3	7
Interest income	(29)	(12)
Provision for income taxes	1,035	846
Depreciation and amortization	3,448	3,444
EBITDA (Non-GAAP)	6,822	5,857
Stock-based compensation	1,295	518
Adjusted EBITDA (Non-GAAP)	\$8,117	\$6,375

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to various market risks, including fluctuation in interest rates, foreign currency, and exchange rates. Market risk is the potential loss arising from adverse changes in market rates and prices. We do not hold or issue financial instruments for trading purposes.

Interest rate fluctuation risk

The principal market risk we face is interest rate risk. We had cash and cash equivalents of \$72.4 million as of March 31, 2016, which consisted of highly-liquid investments with a maturity of three months or less, and \$13.7 million of short-term investments with original maturity dates of greater than three months and less than twelve months. The primary goals of our investment policy are liquidity and capital preservation. We do not enter into investments for trading or speculative purposes. We believe that we do not have any material exposure to changes in the fair value of these assets as a result of changes in interest rates due to the short-term nature of our cash and cash equivalents. Declines in interest rates, however, would reduce future investment income. If overall interest rates had decreased by 10% during the periods presented, our interest income would not have been materially affected.

As of March 31, 2016, we did not have outstanding borrowings under our JPMorgan Chase Bank credit facility. If overall interest rates had increased by 10% during the periods presented, our interest expense would not have been affected.

In November 2014, we secured a primary banking relationship that provides access to a \$15.0 million working capital revolving line of credit and treasury and cash management services through commercial banking with JPMorgan Chase Bank. This agreement is a three year working capital revolving line of credit which replaces the previous loan facility we maintained with Comerica Bank. The interest rate on outstanding debt balances will be LIBOR plus 1.25%.

Pursuant to the revolving credit agreement, we are subject to certain financial covenants relating to our net worth and EBITDA. Tangible net worth under the revolving credit agreement is calculated by subtracting the sum of intangible assets and total liabilities from total assets. EBITDA is defined in the revolving credit agreement as our net income plus interest expense, plus depreciation expense, plus amortization expense, plus income tax expense, plus non-cash expense, plus extraordinary losses, minus non-cash income, and minus extraordinary gains, as computed during certain test periods provided in the revolving credit agreement. We are required to maintain at all times a tangible net worth of \$90.0 million and EBITDA (i) of \$10.0 million for any period of four consecutive quarters commencing with the four-quarter test period ended September 30, 2014 through the four-quarter test period ended March 31, 2016 and (ii) of \$12.5 million for any four-quarter test period commencing with the four-quarter test period ending June 30, 2016 and continuing thereafter.

The agreement contains events of default customary for transactions of this type, including nonpayment, misrepresentation, breach of covenants, and bankruptcy. In the event we fail to satisfy our covenants, or otherwise go into default, JPMorgan Chase Bank 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 March 31, 2016, in order to be in compliance with the EBITDA and tangible net worth requirements, we were required to maintain \$10.0 million in EBITDA for the preceding test period, and we had \$34.2 million in EBITDA for that period. As of March 31, 2016, we were also required to maintain a tangible net worth of \$90.0 million, and we had a tangible net worth of \$138.0 million.

Foreign currency exchange risk

Prior to the fourth quarter of 2014, our international customer and distributor agreements had been denominated almost exclusively in U.S. dollars. In the fourth quarter of 2014, we began receiving VAT refunds in Euro currency, and had an exchange translation loss of \$0.1 million during that period. The effect of a 10% adverse change in exchange rates on foreign denominated cash, receivables and payables as of March 31, 2016 would not have been material. As our operations in countries outside of the United States grow, our results of operations and cash flows will be subject to fluctuations due to changes in foreign currency exchange rates, which could harm our business in the future.

We entered into foreign exchange forward contracts to protect our forecasted U.S. dollar-equivalent earnings from adverse change in foreign currency exchange rates in December 2015. These hedging contracts reduce, but will not entirely eliminate, the impact of adverse currency exchange rate movements. We designate these forward contracts as cash flow hedges for accounting purposes. The fair value of the forward contract is separated into intrinsic and time values. The fair value of forward currency-exchange contracts is sensitive to changes in currency exchange rates. Changes in the time value are coded in other income (expense), net. Changes in the intrinsic value are recorded as a component of accumulated other comprehensive income and subsequently reclassified into revenue to offset the hedged exposures as they occur.

Inflation risk

We do not believe that inflation has had a material effect on our business, financial condition or results of operations. If our costs were to become subject to significant inflationary pressures, we might not be able to fully offset such higher costs through price increases. Our inability or failure to do so could harm our business, financial condition and results of operations.

Item 4. Controls and Procedures

Evaluation of disclosure controls and procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2016. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation,

controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of March 31, 2016, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in internal controls over financial reporting

There has been no change in our internal control over financial reporting during the three months ended March 31, 2016 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Limitations on effectiveness of controls

In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Part II. OTHER INFORMATION

Item 1. Legal Proceedings

Inova Labs litigation

On November 4, 2011, we filed a lawsuit in the United States District Court for the Central District of California against Inova Labs Inc., or Defendant, for infringement of two of our patents. The case, Inogen Inc. v. Inova Labs Inc., Case No. 8:11-cv-01692-JGB-AN, or the Inova Labs Lawsuit, involves U.S. Patent Nos. 7,841,343, entitled “Systems and Methods For Delivering Therapeutic Gas to Patients,” or the ’343 patent, and 6,605,136 entitled “Pressure Swing Adsorption Process Operation And Optimization,” or the ’136 patent. We alleged in the Inova Labs Lawsuit that certain of Defendant’s oxygen concentrators infringe various claims of the ’343 and ’136 patents. The Inova Labs Lawsuit seeks damages, injunctive relief, costs and attorneys’ fees.

The Defendant has answered the complaint, denying infringement and asserting various sets of defenses including non-infringement, invalidity and unenforceability, patent misuse, unclean hands, laches and estoppel. The Defendant also filed counterclaims against us alleging patent invalidity, non-infringement and inequitable conduct. We denied the allegations in the Defendant’s counterclaims and filed a motion to dismiss Defendant’s inequitable conduct counterclaim.

The Defendant filed requests with the U.S. Patent and Trademark Office seeking an inter partes reexamination of the ’343 and ’136 patents. The Defendant also filed a motion to stay the Inova Labs Lawsuit pending outcome of the reexamination. On March 20, 2012, the Court granted the Defendant’s motion to stay the Inova Labs Lawsuit pending outcome of the reexamination and also granted our motion to dismiss the Defendant’s inequitable conduct counterclaim. On December 7, 2015, the U.S. Patent and Trademark Office issued an inter partes Reexamination Certificate for the ’343 patent. Reexamination proceedings for the ’136 patent have not concluded.

On February 4, 2016, ResMed announced the completion of the acquisition of Inova Labs Inc.

Separation Design Group litigation

On October 23, 2015, Separation Design Group IP Holdings, LLC (SDGIP) filed a lawsuit against Inogen in the United States District Court for the Central District of California. On December 7, 2015, the SDGIP filed a First Amended Complaint in the SDGIP Lawsuit.

SDGIP alleges that we willfully infringe U.S. Patent Nos. 8,894,751 and 9,199,055, both of which are titled “Ultra Rapid Cycle Portable Oxygen Concentrator.” SDGIP also alleges misappropriation of trade secrets and breach of contract stemming from a meeting in September 2010. We never received any communication from SDGIP related to patent infringement, misuse of trade secrets, or breach of the mutual non-disclosure agreement prior to SDGIP filing the lawsuit. SDGIP seeks to recover an unspecified amount of damages (including compensatory and treble damages), costs and expenses (including attorneys’ fees), pre-judgment and post-judgment interest, and other relief that the Court deems proper. SDGIP also seeks a permanent injunction against us.

We have and continue to vigorously contest SDGIP’s claims. We have answered SDGIP’s First Amended Complaint, denying SDGIP’s allegations of patent infringement, trade secret misappropriation, and breach of contract and

asserting several affirmative defenses.

Labor law dispute

On April 13, 2016, Ryan Casper and Shane Hofer (Plaintiffs) filed a lawsuit against Inogen on behalf of themselves and all other similarly situated employees in the Superior Court for Santa Barbara County, California. The complaint alleges failure to pay overtime wages, failure to allow and pay for meal periods, and other alleged violations of California wage and hour law. The Plaintiffs and class members are seeking compensatory damages in the amount of all wages, interest, and penalties allegedly due, as well as liquidated damages, attorney's fees and other relief. The parties successfully mediated the claims and reached a settlement in April 2016. While we dispute the claims, we agreed to the settlement with no admission of liability to avoid the risks and costs associated with litigating the claims. As of March 31, 2016, we have accrued approximately \$980 for the settlement costs.

Other litigation

In the normal course of business, we are from time to time involved in various other legal proceedings or potential legal proceedings, including matters involving employment, intellectual property, or others. We carry insurance, subject to specified deductibles under our policies, to protect against losses from certain types of legal claims. At this time, we do not anticipate that any of these proceedings will have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources, and other factors.

Item 1A. Risk Factors

We operate in a rapidly changing environment that involves numerous uncertainties and risks. In addition to the other information included in this Quarterly Report on Form 10-Q, the following risks and uncertainties may have a material and adverse effect on our business, financial condition, results of operations, or stock price. You should consider these risks and uncertainties carefully, together with all of the other information included or incorporated by reference in this Quarterly Report on Form 10-Q. If any of the risks or uncertainties we face were to occur, the trading price of our securities could decline, and you may lose all or part of your investment. This Quarterly Report on Form 10-Q also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this report.

Risks related to our business and strategy

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

As a provider of oxygen product rentals, we depend heavily on Medicare reimbursement as a result of the higher proportion of elderly persons suffering from chronic respiratory conditions. Medicare Part B, or Supplementary Medical Insurance Benefits, provides coverage to eligible beneficiaries that include items of durable medical equipment for use in the home, such as oxygen equipment and other respiratory devices. We believe that more than 60% of oxygen therapy patients in the United States have primary coverage under Medicare Part B. For the three months ended March 31, 2016 and March 31, 2015, we derived 19.5% and 26.0%, respectively, of our total revenue from Medicare's program or beneficiaries (including patient co-insurance obligations). There are increasing pressures on Medicare to control healthcare costs and to reduce or limit reimbursement rates for home medical products.

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

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

The Deficit Reduction Act of 2005 limited the total number of continuous rental months for which Medicare will pay for oxygen equipment to 36 months, after which time there is generally no additional reimbursement to the supplier (other than for periodic, in-home maintenance and servicing). The Deficit Reduction Act of 2005 also provided that title of the equipment would transfer to the beneficiary, which was later repealed by the Medicare Improvements for Patients and Providers Act of 2008. For purposes of the rental cap, the Deficit Reduction Act of 2005 provided for a new 36-month rental period that began January 1, 2006 for all oxygen equipment. After the 36th continuous month during which payment is made for the oxygen equipment, the supplier is generally required to continue to furnish the equipment during the period of medical need for the remainder of the useful lifetime of the equipment, provided there are no breaks in service due to medical necessity that exceed 60 days. The reasonable useful lifetime for portable oxygen equipment is 60 months. After 60 months, if the patient requests, and the patient meets Medicare coverage criteria, the rental cycle starts over and a new 36-month 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 capped rental period in month thirty-seven, resulting in potentially two or more years without rental income from these customers. Our capped patients as a percentage of total patients on service was approximately 12.9% as of March 31, 2016, which is slightly lower than the capped patients as a percentage of total patients on service of

approximately 15.3% as of March 31, 2015. The percentage of capped patients may fluctuate over time as new patients come on service, patients come off of service before and during the capped rental period, and existing patients enter the capped rental period. We cannot predict the potential impact to rental revenues in future periods associated with patients in the capped rental period.

The Medicare Improvements for Patients and Providers Act of 2008 retroactively delayed the implementation of competitive bidding for 18 months from previously established dates and decreased the 2009 fee schedule payment amounts by 9.5% for product categories included in competitive bidding. In addition to the 9.5% reduction under Medicare Improvements for Patients and Providers Act of 2008, the Centers for Medicare and Medicaid Services (CMS) implemented a reduction to the monthly payment amount for stationary oxygen equipment. The monthly payment rate for non-delivery ambulatory oxygen in the relevant period was flat at \$51.63. The table below summarizes the increases and decreases in the monthly payment amounts for stationary oxygen equipment. This does not apply for 2016 as the standard allowables were set based on regional averages of the competitive bidding prices as described in the “Business” section and below in this “Risk Factors” section.

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

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, includes, among other things, 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.

In addition, the President’s proposed federal budget for fiscal year 2017 includes multiple provisions that could impact the Company if they were enacted. The budget proposed eliminating the 36-month cap for oxygen equipment, and reducing the monthly payment amount for oxygen and oxygen equipment by the necessary percentage to be budget neutral. The Company’s patient population may materially differ from the Medicare population, which could lead to either more or less revenue per patient on service if this is enacted. For example, the Company’s patient population is more heavily weighted towards ambulatory patients versus stationary/nocturnal patients seen in the overall Medicare market. In addition, this would likely also impact the number of patients interested in a cash purchase and could increase rental patients and decrease out-of-pocket purchases. The proposed budget also proposes to extend the authority to require prior authorization to all Medicare fee-for-service items and services, particularly those that are at the highest risk for improper payment. The proposed budget also contains multiple provisions related to the Medicare appeals process including establishing a refundable filing fee (non-refundable if denied), providing the Office of Medicare Hearings and Appeals and Department Appeals Board Authority to use Recover Audit Contractor collections, and increase minimum amount in controversy for administrative law judge adjudication of claims to equal the amount required for judicial review. In addition, this proposal includes the ability to remand appeals to the redetermination level with the introduction of new evidence and the ability to sample and consolidate similar claims for administrative efficiency.

The Health and Human Services (HHS) Office of Inspector General (OIG) has recommended states to review Medicaid reimbursement for durable medical equipment (DME) and supplies. The OIG cites an earlier report estimating that four states (California, Minnesota, New York, and Ohio) could have saved more than \$18.1 million on selected DME items if their Medicaid prices were comparable to those under Round one of the Medicare competitive bidding program. Since issuing those reports, the OIG identified \$12 million in additional savings that the four states

could have obtained on the selected items by using pricing similar to the Medicare Round two competitive bidding and national mail-order programs. In light of varying Medicaid provider rates for DME and the potential for lower spending, the OIG recommends the CMS (1) seek legislative authority to limit state Medicaid DME reimbursement rates to Medicare program rates, and (2) encourage further reduction of Medicaid reimbursement rates through competitive bidding or manufacturer rebates (the OIG did not determine the cost of implementing a rebate or competitive bidding program in each state). CMS concurred with the OIG's recommendations, observing that the President's fiscal year 2016 budget recommended limiting Medicaid reimbursement of DME to Medicare rates. In December 2015, the Omnibus bill passed that will require state Medicaid agencies to match Medicare fee schedule reimbursement rates (including single payment amounts in applicable areas) beginning January 1, 2019, including for oxygen. CMS also noted that it communicates frequently with states to inform them of available options for their DME purchasing programs, including manufacturer rebates and competitive bidding.

On January 28, 2016, the Department of Health and Human Services (DHHS) published a final rule to implement Medicare’s face-to-face provisions for home health and DME under the Medicaid program, effective July 1, 2016. Medicaid programs are run by state agencies that must coordinate with state legislative bodies, therefore the state agencies have until July 1, 2017 or July 1, 2018 (depending on the timing of their legislative sessions) to allow state agencies to publish compliant initiatives on this rule. The Medicaid definition of medical supplies, equipment and appliances were aligned with the Medicare definitions. In addition, the DHHS is implementing the requirement for a face-to-face visit related to the beneficiary’s primary need for medical equipment within 6 months prior to the start of durable medical equipment services, including oxygen. These legislative provisions, when enacted, could have an adverse impact on our business, financial conditions and operating results.

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

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

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

As of January 1, 2016, competitive bidding has been nationalized. All areas previously not subject to bidding have had rate reductions applied instead of doing another bidding process. The fee schedules in the un-bid areas are adjusted based on regional averages of the single payment amounts for areas already under competitive bidding. The regional prices are limited by a national ceiling (110% of the average of the regional prices) and a floor (90% of the average regional prices). Since January 1, 2016, the reimbursement rates for these un-bid areas (with dates of services from January 1, 2016 to June 30, 2016) are based on 50% of the un-adjusted (current) fee schedule amount and 50% of the adjusted (reduced) fee schedule amount which is based on the regional competitive bidding rates. Starting on July 1, 2016, reimbursement rates will be 100% of the adjusted fee schedule amount which will be based on regional competitive bidding rates.

The regions are defined as follows:

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

CMS defines frontier states as states where more than 50% of the counties in the state have a population density of 6 people or less per square mile and rural states are defined as states where more than 50% of the population lives in rural areas per census data. Current frontier states include MT, ND, SD and WY; rural states include ME, MS, VT and

WV; and non-contiguous United States areas include AK, HI, Guam and Puerto Rico. For frontier and rural states, and frontier and rural zip codes in non-frontier/rural states, the single payment amount will be the national ceiling (110% of the average of the regional prices) to account for higher servicing costs in these areas. For non-contiguous United States areas, single payment amounts will be the higher of the national ceiling, or the average of competitive bidding pricing from these areas, if the areas had been bid through competitive bidding. We estimate that less than 10% of our patients would be eligible to receive the 110% of the regional prices for rural and frontier areas based on the geographic locations of our current patient population.

A ruling from CMS has outlined the expansion of competitive bidding to certain previously unbid areas by applying regional pricing averages to unbid areas with 110% of regional prices to be paid for defined rural and frontier areas. We believe that the net effect of the ruling would be an approximately 3.5-4.0% decrease in 2016 total revenue since this pricing is being applied partially from January 1, 2016 to June 30, 2016 and will be applied completely starting on July 1, 2016. Medicare was 21.0% of our total revenue in the year ended December 31, 2015, and we estimate that 41% of the Medicare markets will be subject to this reimbursement reduction. We also estimate that on average the rates will be reduced to the weighted-average of the regional prices under round one re-compete and round two re-compete. We estimate that less than 10% of our patients would be eligible to receive the 110% of the regional prices for rural and frontier areas based on the geographic locations of our current patient population. CMS has

also re-bid the round two re-compete for contracts from July 1, 2016 through December 31, 2018 as discussed previously. CMS has begun the re-bid process for the round one re-compete for contracts from January 1, 2017 through December 31, 2018.

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

CMS has begun the bidding process for the round one 2017 for contracts effective January 1, 2017 through December 31, 2018. Bids were due by December 16, 2015. In round one 2017, there are 9 metropolitan statistical areas and 13 CBAs to make sure each CBA does not cross state boundaries. We estimate approximately 9% of the Medicare market will be impacted by these contracts set to begin January 1, 2017 and continue through December 31, 2018. To the extent that we are not successful in future competitive bidding rounds, we may lose access to patients in CBAs in which we are not awarded contracts, which would adversely affect our business, financial condition and results of operation.

On April 16, 2015, the Medicare Access and CHIP Reauthorization Act of 2015 was signed into law which requires Medicare suppliers that bid under the DMEPOS competitive bidding program to obtain a \$50,000 to \$100,000 bid surety bond for each CBA. The provision is intended to prevent suppliers from submitting not-binding, "low-ball" bids that artificially drive down prices and jeopardize beneficiary access to equipment. If the supplier bids at or lower than the median composite bid rate and does not accept a contract offered for a CBA, the bid bond would be forfeited. The Act also codifies that competitive bidding contracts can only be awarded to suppliers that meet applicable state licensure requirements. We will incur additional expense to obtain the appropriate surety bonds in the CBAs where we win contracts in future competitive bidding rounds. There are currently 9 CBAs under contract in round one re-compete and 117 CBAs under contract in round two re-compete. CBAs are defined by Medicare and are subject to change at each new bidding period. This cost is not expected to be material to our financial results.

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

The implementation of prior authorization rules for DMEPOS under Medicare could negatively affect our business and financial condition.

CMS has issued a final rule to require Medicare prior authorization (PA) for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) that the agency characterizes as frequent subject to unnecessary

utilization. The final rule was published on December 30, 2015 and specifies a master list of 135 items that could potentially be subject to PA, including stationary oxygen rentals (E1390). The master list will be updated annually and published in the Federal Register. The presence of an item on the master list does not automatically mean that a PA is required. CMS will select a subset of these master list items for its “Required Prior Authorization List”, which has not yet been published in the Federal Register. There will be a notice period of at least 60 days prior to implementation. The ruling does not create any new clinical documentation requirements; instead the same information necessary to support Medicare payment will be required prior to the item being furnished to the beneficiary. CMS has proposed that reasonable efforts are made to provide a PA decision within 10 days of receipt of all applicable information, unless this timeline could seriously jeopardize the life or health of the beneficiary or the beneficiary’s ability to regain maximum function, in which case the proposed PA decision would be 2 business days. CMS will issue additional subregulatory guidance on these timelines in the future. CMS has announced that two power mobility codes (HCPCS K0856 and K0861) will be considered for prior approval as CMS moves forward with the implementation of this final rule. No other codes have been publicly discussed at this time. If our products are subject to prior authorization, it could reduce the number of patients qualified to come on service using their Medicare benefits, it could delay the start of those patients while we wait for the prior authorization to be received, and/or it could decrease sales productivity. As a result, this could adversely affect our business, financial conditions and results of operations.

The Medicare Fee-For-Service (FFS) sequestration reduction has and may continue to negatively impact our revenue and profits.

Medicare FFS claims with dates of service on or after April 1, 2013 are subject to a 2% reduction in Medicare payment, including claims for DMEPOS, including in competitive bidding areas. The claims payment adjustment is applied to all claims after determining coinsurance, any applicable deductible, and any applicable Medicare secondary payment adjustments. These reductions are included in rental revenue adjustments. This sequestration reduction will continue until further notice. As a result, this could adversely affect our financial conditions and results of operations.

We face intense international, 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, Respirationics (a subsidiary of Koninklijke Philips N.V.), AirSep Corporation and SeQual Technologies (subsidiaries of Chart Industries, Inc.), Inova Labs, Inc. (a subsidiary of ResMed), DeVilbiss Healthcare (a subsidiary of Drive Medical) and O2 Concepts. Given the relatively straightforward regulatory path in the oxygen therapy device manufacturing market, we expect that the industry will become increasingly competitive in the future. Manufacturing companies compete for sales to providers primarily on the basis of product features, service and price.

For many years, Lincare, Inc. (subsidiary of the Linde Group), Apria Healthcare, Inc., Rotech Healthcare, Inc. and American HomePatient, Inc. (now a subsidiary of Lincare, Inc.) have been among the market leaders in providing oxygen therapy, 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 relationships with healthcare professionals, customers and third-party payors;
- established distribution networks;
- additional lines of products, and the ability to offer rebates or bundle products to offer higher discounts or other incentives to gain a competitive advantage;
- greater history in conducting research and development, manufacturing, marketing and obtaining regulatory approval for oxygen device products; and
- greater financial and human resources for product development, sales and marketing, patent litigation and customer financing.

As a result, our competitors may be able to respond more quickly and effectively than we can to new or changing opportunities, technologies, standard regulatory and reimbursement development and customer requirements. In light of these advantages that our competitors maintain, even if our technology and direct-to-consumer distribution strategy is more effective than the technology and distribution strategy of our competitors, current or potential customers might

accept competitor products and services in lieu of purchasing our products. We anticipate that we will face increased competition in the future as existing companies and competitors develop new or improved products and distribution strategies and as new companies enter the market with new technologies and distribution strategies. We may not be able to compete effectively against these organizations. Our ability to compete successfully and to increase our market share is dependent upon our reputation for providing responsive, professional and high-quality products and services and achieving strong customer satisfaction. Increased competition in the future could adversely affect our revenue, revenue growth rate, margins and market share.

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

In the United States, the legislative landscape, particularly as it relates to healthcare regulation and reimbursement coverage, continues to evolve. In March 2010, the Patient Protection and Affordable Care Act was passed, which has the potential to substantially change healthcare financing by both governmental and private insurers, and significantly impact the U.S. medical device industry. In addition, as discussed above, the Patient Protection and Affordable Care Act also expands the round two of competitive bidding to a total of 117 competitive bidding areas, and in 2016, prices in non-competitive bidding areas will be adjusted to match competitive bidding prices.

In addition, other legislative changes have been proposed and adopted in the United States since the Patient Protection and Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, which went into effect on April 1, 2013, and will remain in effect through 2024 unless additional Congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012 which, among other things, further reduced Medicare payments to certain providers, including physicians, hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressures.

In addition to the legislative changes discussed above, the Patient Protection and Affordable Care Act also requires healthcare providers to voluntarily report and return an identified overpayment within 60 days after identifying the overpayment. Failure to repay the overpayment within 60 days will result in the claim being considered a "false claim" and the healthcare provider will be subject to False Claims Act liability.

State legislative bodies also have the right to enact legislation that would impact requirements of home medical equipment providers, including oxygen therapy providers. Some states have already enacted legislation that would require in-state facilities. Additional states such as Idaho, Arizona, Virginia, and North Carolina are considering such legislation. Idaho is considering Senate Bill 1387, which would require any durable medical equipment supplier selling products including oxygen to have at least one accredited physical facility that meets federal supplier standards under 42 CFR 424.57 and is either located in Idaho or is within 150 miles of any customer located in Idaho served by the supplier, and to maintain sufficient inventory and staff to service or repair such products. Arizona is currently considering HB 2266, which would require any durable medical equipment supplier to have at least one accredited physical facility that is staffed during reasonable business hours per accreditation guidelines and that is located in Arizona or within 100 miles of any resident Medicare beneficiary in Arizona who is being served by the supplier. Virginia is considering HB 527 which would require nonresident medical equipment suppliers to register with the Board of Pharmacy. North Carolina is considering House Bill 623, which would require home medical equipment providers to maintain at least one physical location within North Carolina or within 40 miles of the border of North Carolina and with sufficient inventory to respond to orders or requests within North Carolina in a timely manner. We do not have facilities in these states and as such would be required to incur costs to comply with these requirements. We are monitoring all state requirements to maintain compliance with state-specific legislation and access to service patients in these states. To the extent such legislation is enacted, it could result in increased administrative costs or otherwise exclude us from doing business, which would adversely impact our business, financial condition and operating results.

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 \$1.2 million and \$0.9 million for the three months ended March 31, 2016 and March 31, 2015, respectively, for research and development efforts, 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, or obtain necessary regulatory clearances or approvals for such product improvements or new products in a timely manner, or at all. Our competitors' new products may enter the market before our new products reach 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, Medicaid and patients for a significant portion of our revenue, and if we fail to manage the complex and lengthy reimbursement process, our business and operating results could 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 direct from patients under co-insurance provisions. For the three months ended March 31, 2016 and March 31, 2015, approximately 23.7% and 31.7%, respectively, of our total revenue was derived from Medicare, private payors, Medicaid, and individual patients who directly receive reimbursement from third-party payors.

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

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

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

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

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

Edgar Filing: Inogen Inc - Form 10-Q

- our suppliers may encounter financial hardships as a result of unfavorable economic and market conditions unrelated to our demand for components, which could inhibit their ability to fulfill our orders and meet our requirements;
 - suppliers may fail to comply with regulatory requirements, be subject to lengthy compliance, validation or qualification periods, or make errors in manufacturing components that could negatively affect the performance or safety of our products or cause delays in supplying of our products to our customers;
 - newly identified suppliers may not qualify under the stringent quality regulatory standards to which our business is subject;
 - we or our suppliers may not be able to respond to unanticipated changes in customer orders, and if orders do not match forecasts, we or our suppliers may have excess or inadequate inventory of materials and components;
 - we may be subject to price fluctuations due to a lack of long-term supply arrangements for key components;
 - we may experience delays in delivery by our suppliers due to changes in demand from us or their other customers;
-

- we or our suppliers may lose access to critical services and components, resulting in an interruption in the manufacture, assembly and shipment of our systems;
- our suppliers may be subject to allegations by other parties of misappropriation of proprietary information in connection with their supply of products to us, which could inhibit their ability to fulfill our orders and meet our requirements;
- fluctuations in demand for products that our suppliers manufacture for others may affect their ability or willingness to deliver components to us in a timely manner;
- our suppliers may wish to discontinue supplying components or services to us; and
- we may not be able to find new or alternative components or reconfigure our system and manufacturing processes in a timely manner if the necessary components become unavailable.

In addition, we may be deemed to manufacture or contract to manufacture products that contain certain minerals that have been designated as “conflict minerals” under the Dodd-Frank Wall Street Reform and Consumer Protection Act. As a result, in future periods, we may be required to perform due diligence to determine the origin of such minerals, and disclose and report whether or not such minerals originated in the Democratic Republic of the Congo or adjoining countries. The implementation of these new requirements could adversely affect the sourcing, availability, and pricing of minerals used in the manufacture of our products. In addition, we may incur additional costs to comply with the disclosure requirements, including costs related to determining the source of any of the relevant minerals and metals used in our products. If any of these risks materialize, costs could significantly increase and our ability to meet demand for our products could be impacted. If we are unable to satisfy commercial demand for our Inogen One systems and Inogen At Home systems in a timely manner, our ability to generate revenue would be impaired, market acceptance of our products could be adversely affected, and customers may instead purchase or use alternative products. In addition, we could be forced to secure new or alternative components and subassemblies through a replacement supplier. Finding alternative sources for these components and subassemblies could be difficult in certain cases and may entail a significant amount of time and disruption. In some cases, we would need to change the components or subassemblies if we sourced them from an alternative supplier. This, in turn, could require a redesign of our Inogen One systems and Inogen At Home systems and, potentially, require additional FDA clearance or approval before we could use any redesigned product with new components or subassemblies, thereby causing further costs and delays that could adversely affect our business, financial condition and operating results.

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

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

If our manufacturing facilities become unavailable or inoperable, we will be unable to continue manufacturing our Inogen One systems and Inogen At Home systems and, as a result, our business, financial condition, and operating results will be harmed until we are able to secure a new facility.

We manufacture our Inogen One systems and Inogen At Home systems at our facility in Richardson, Texas and compressors at our facility in Goleta, California. No other manufacturing facilities are currently available to us, particularly facilities of the size and scope of our Texas facility. Our facilities and the equipment we use to manufacture our Inogen One systems and Inogen At Home systems would be costly to replace and could require

substantial lead time to repair or replace. Our facilities may be harmed or rendered inoperable by natural or man-made disasters, including fire, flood, earthquakes and power outages, which may render it difficult or impossible for us to manufacture our products for some period of time. If any of our facilities become unavailable to us, we cannot provide assurances that we will be able to secure a new manufacturing facility on acceptable terms, in a timely manner. The inability to manufacture our products, combined with delays in replacing parts inventory and manufacturing supplies and equipment, may result in the loss of customers and/or harm our reputation, and we may be unable to reestablish relationships with those customers in the future. Although we have insurance coverage for certain types of disasters which may help us recover some of the costs of damage to our property and lost income from the disruption of our business, this insurance is limited and may not be sufficient to cover any or all of our potential losses and may not continue to be available to us on acceptable terms, or at all. If our manufacturing capabilities are impaired, we may not be able to manufacture, store, and ship our products in a cost effective or timely manner, which would adversely impact our business, financial condition, and operating results.

We may experience manufacturing problems or delays that could limit our growth or adversely affect our operating results.

Our Inogen One systems and Inogen At Home systems are manufactured using complex processes, sophisticated equipment and strict adherence to specifications and quality standards. Any unforeseen manufacturing problems, such as contamination of our facility, equipment malfunction, regulatory findings, or failure to strictly follow procedures or meet specifications, could result in delays or shortfalls in production of our products. Identifying and resolving the cause of any such manufacturing issues could require substantial time and resources. If we are unable to keep up with demand for our products by successfully manufacturing and shipping our products in a timely and quality manner, our operating results could be impaired, market acceptance for our products could be adversely affected and our customers might instead purchase our competitors' products.

In addition, the introduction of new products may require the development of new manufacturing processes and procedures. While all of our products are assembled using the same basic processes, significant changes in technology, programming, and other variations may be required to meet product specifications. Developing new processes can be very time consuming and affect quality, as such any unexpected difficulty in doing so could delay the introduction of a new product and our ability to produce sufficient quantities of existing products.

Failure to comply with anti-bribery, anti-corruption, and anti-money laundering laws, including the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, and similar laws associated with our activities outside of the United States could subject us to penalties and other adverse consequences.

We are subject to the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, the United Kingdom Bribery Act of 2010 and possibly other anti-corruption, anti-bribery and anti-money laundering laws in the more than forty countries around the world where we conduct activities and sell our products. We face significant risks and liability if we fail to comply with the FCPA and other anti-corruption and anti-bribery laws that prohibit companies and their employees and third-party business partners, such as distributors or resellers, from authorizing, offering or providing, directly or indirectly, improper payments or benefits to foreign government officials, political parties or candidates, employees of public international organizations including healthcare professionals, or private-sector recipients for the corrupt purpose of obtaining or retaining business, directing business to any person, or securing any advantage.

We leverage various third parties to sell our products and conduct our business abroad. We, our distributors and channel partners, and our other third-party intermediaries may have direct or indirect interactions with officials and employees of government agencies or state-owned or affiliated entities (such as in the context of obtaining government approvals, registrations, or licenses) and may be held liable for the corrupt or other illegal activities of these third-party business partners and intermediaries, our employees, representatives, contractors, partners, and agents, even if we do not explicitly authorize such activities. In many foreign countries, particularly in countries with developing economies, it may be a local custom that businesses engage in practices that are prohibited by the FCPA or other applicable laws and regulations. As such, we intend to continue to implement an FCPA/anti-corruption compliance program to ensure compliance with such laws but cannot assure you that all of our employees and agents, as well as those companies to which we outsource certain of our business operations, will not take actions in violation of our policies and applicable law, for which we may be ultimately held responsible.

Any violation of the FCPA, other applicable anti-bribery, anti-corruption laws, and anti-money laundering laws could result in whistleblower complaints, adverse media coverage, investigations, loss of export privileges, severe criminal or civil sanctions and, in the case of the FCPA, suspension or debarment from U.S. government contracts, which could have a material and adverse effect on our reputation, business, operating results and prospects. In addition, responding to any enforcement action or related investigation may result in a materially significant diversion of management's

attention and resources and significant defense costs and other professional fees.

If we fail to comply with U.S. 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.

We may also be subject to other types of claims arising from our normal business activities. These may include claims, suits, and proceedings involving labor and employment, wage and hour, commercial, alleged securities laws violations or other investor claims and other matters. The outcome of any litigation, regardless of its merits, is inherently uncertain. Any claims and lawsuits, and the disposition of such claims and lawsuits, could be time-consuming and expensive to resolve, divert management attention and resources, and lead to attempts on the part of other parties to pursue similar claims. Any adverse determination related to litigation could require us to change our technology or our business practices, pay monetary damages or enter into royalty or licensing arrangements, which could adversely impact our business, financial condition, and operating results.

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

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

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

Our success depends upon the skills, experience and efforts of our senior executives and other key technical personnel, including certain members of our engineering staff and our sales and marketing executives. Much of our corporate expertise is concentrated in relatively few employees, the loss of which for any reason could negatively

affect our business. Competition for our highly skilled employees is intense and we cannot prevent the resignation of any employee. We do not maintain “key man” life insurance on any of our senior executives. None of our senior executive team is bound by written employment contracts to remain with us for a specified period. In addition, we have not entered into non-compete agreements with members of our senior management team. The loss of any member of our senior management team could harm our ability to implement our business strategy and respond to the market conditions in which we operate.

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

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

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

We have a limited operating history and incurred significant net losses in each fiscal year until fiscal year 2012, when we achieved positive net income. As of March 31, 2016, we had an accumulated deficit of \$42.7 million. These net losses have resulted principally from costs incurred from our selling, general and administrative expenses and to a lesser extent in our research and development programs. We expect to incur significant expansion of our sales and marketing expenses and increases in expenses for research and development to a lesser extent. Additionally, since completing our initial public offering, we expect that our general and administrative expenses will increase due to the additional operational and reporting costs associated with being a public company. Because of the numerous risks and uncertainties associated with our commercialization efforts and future product development, we are unable to predict if we will maintain or increase our net income.

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

Our quarterly revenue and results of operations have varied in the past and may continue to vary significantly from quarter-to-quarter. This variability may lead to volatility in our stock price as research analysts and investors respond to these quarterly fluctuations. These fluctuations are due to numerous factors, including: fluctuations in consumer demand for our products; seasonal cycles in consumer spending; our ability to design, manufacture and deliver products to our consumers in a timely and cost-effective manner; quality control problems in our manufacturing operations; our ability to timely obtain adequate quantities of the components used in our products; new product introductions and enhancements by us and our competitors; unanticipated increases in costs or expenses; and fluctuations in foreign currency exchange rates. For example, we typically experience higher sales in the second quarter, as a result of consumers traveling and vacationing during warmer weather in the spring and summer months. The foregoing factors are difficult to forecast, and these, as well as other factors, could materially and adversely affect our quarterly and annual results of operations. In addition, a significant amount of our operating expenses are relatively fixed due to our manufacturing, research and development and sales and general administrative efforts. Any failure to adjust spending quickly enough to compensate for a revenue shortfall could magnify the adverse impact of such revenue shortfall on our results of operations. Our results of operations may not meet the expectations of research analysts or investors, in which case the price of our common stock could decrease significantly.

If the market opportunities for our products are smaller than we believe they are, our revenues may be adversely affected and our business may suffer.

Our projections regarding (i) the size of the oxygen therapy market, both in the United States and internationally, (ii) the size and percentage of the oxygen therapy market that is subject to competitive bidding in the United States, (iii) the number of oxygen therapy patients, (iv) the number of patients requiring ambulatory and stationary oxygen, (v) the number of patients who rely on the delivery model, and (vi) the share of portable oxygen concentrators as a percentage of the total oxygen therapy spend are based on estimates that we believe are reliable. These estimates may prove to be incorrect, new data or studies may change the estimated incidence or prevalence of patients requiring oxygen therapy, or the type of oxygen therapy patients. The number of patients in the United States and internationally may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our products, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business.

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

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

Pursuant to the revolving credit agreement, we are subject to certain financial covenants relating to our net worth and EBITDA. Tangible net worth under the revolving credit agreement is calculated by subtracting the sum of intangible assets and total liabilities from total assets. EBITDA is defined in the revolving credit agreement as our net income plus interest expense, plus depreciation expense, plus amortization expense, plus income tax expense, plus non-cash expense, plus extraordinary losses, minus non-cash income, and minus extraordinary gains, as computed during certain test periods provided in the revolving credit agreement. We are required to maintain at all times a tangible net worth of \$90.0 million and EBITDA (i) of \$10.0 million for any period of four consecutive quarters commencing with the four-quarter test period ended September 30, 2014 through the four-quarter test period ending March 31, 2016 and (ii) of \$12.5 million for any four-quarter test period commencing with the four-quarter test period ending June 30, 2016 and continuing thereafter.

The agreement contains events of default customary for transactions of this type, including non-payment, misrepresentation, breach of covenants, and bankruptcy. In the event we fail to satisfy our covenants, or otherwise go into default, JPMorgan Chase 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 March 31, 2016, in order to be in compliance with the EBITDA and tangible net worth requirements, we were required to maintain \$10.0 million in EBITDA for the preceding test period, and we had \$34.2 million in EBITDA for that period. As of March 31, 2016, we were also required to maintain a tangible net worth of \$90.0 million, and we had a tangible net worth of \$138.0 million.

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

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

Changes in accounting principles, or interpretations thereof, could have a significant impact on our financial position and results of operations.

We prepare our financial statements in accordance with accounting principles generally accepted in the United States of America, referred to as U.S. GAAP. These principles are subject to interpretation by the Securities and Exchange Commission (SEC) and various bodies formed to interpret and create appropriate accounting principles. A change in these principles can have a significant effect on our reported results and may even retroactively affect previously reported transactions. Additionally, the adoption of new or revised accounting principles may require that we make significant changes to our systems, processes and controls.

For example, the U.S.-based Financial Accounting Standards Board, referred to as FASB, is currently working together with the International Accounting Standards Board, referred to as IASB, on several projects to further align accounting principles and facilitate more comparable financial reporting between companies who are required to follow U.S. GAAP under SEC regulations and those who are required to follow International Financial Reporting Standards outside of the United States. These efforts by the FASB and IASB may result in different accounting principles under U.S. GAAP that may result in materially different financial results for us in areas including, but not limited to, principles for recognizing revenue and lease accounting. Additionally, significant changes to U.S. GAAP resulting from the FASB's and IASB's efforts may require that we change how we process, analyze and report financial information and that we change financial reporting controls.

It is not clear if or when these potential changes in accounting principles may become effective, whether we have the proper systems and controls in place to accommodate such changes and the impact that any such changes may have on our financial position and results of operations.

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

Our existing net operating losses (NOLs) are subject to limitations arising from ownership changes subject to the provisions of Section 382 of the Internal Revenue Code of 1986, as amended. If we undergo one or more future ownership changes our ability to utilize NOLs could be further limited.

Risks related to the regulatory environment

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

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

As a healthcare provider participating in governmental healthcare programs, we are subject to laws directed at preventing fraud and abuse, which subject our marketing, billing, documentation and other practices to strict government scrutiny. To ensure compliance with Medicare, Medicaid and other regulations, government agencies or their contractors often conduct routine audits and request customer records and other documents to support our claims submitted for payment of services rendered. Government agencies or their contractors also periodically open investigations and obtain information from healthcare providers. Violations of federal and state regulations can result in severe criminal, civil and administrative penalties and sanctions, including debarment, suspension or exclusion from Medicare, Medicaid and other government reimbursement programs, any of which would have a material adverse effect on our business.

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

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

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

Current law provides for a significant expansion of the government's auditing and oversight of suppliers who care for patients covered by various government healthcare programs. Examples of this expansion include audit programs being implemented by the Durable Medical Equipment Medicare Administrative Contractors, the Zone Program

Integrity Contractors, the Recovery Audit Contractors, and the Comprehensive Error Rate Testing contractors, operating under the direction of the Centers for Medicare and Medicaid Services, and the various state Medicaid Fraud Control Units.

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

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

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

- design, development and manufacturing;
- testing, labeling, content and language of instructions for use and storage;
- clinical trials;
- product safety;
- marketing, sales and distribution;
- pre-market clearance and approval;
- record keeping;
- 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 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.

All of our commercial products have received 510(k) clearance by the FDA. If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, our product introductions or modifications could be delayed or canceled, which 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, or do so in a timely fashion.

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 Quality System requirements.

Medical devices may only be promoted and sold for the indications for which they are approved or cleared. In addition, even if the FDA has approved or cleared a product, it can take action affecting such product approvals or

clearances if serious safety or other problems develop in the marketplace. Delays in obtaining clearances or approvals could adversely affect our ability to introduce new products or modifications to our existing products in a timely manner, which would delay or prevent commercial sales of our products. Additionally, the FDA and other regulatory authorities have broad enforcement powers. Regulatory enforcement or inquiries, or other increased scrutiny on us, could affect the perceived safety and performance of our products and dissuade our customers from using our products.

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

Any modification we make to our Inogen One systems and Inogen At Home system that could significantly affect its safety or performance, 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 and disagree with any manufacturer's decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. We have modified some of our 510(k) cleared products, and have determined that in certain instances new 510(k) clearances or pre-market approval are not required. 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.

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

Even after we have obtained regulatory clearance or approval to market a product, we have ongoing responsibilities under FDA regulations. The FDA and state authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state agencies, which may include any of the following sanctions:

- adverse publicity, warning letters, fines, injunctions, consent decrees and civil penalties;
- recalls, termination of distribution, or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- delays in the introduction of products into the market;
- refusal to grant our requests for future 510(k) clearances or approvals of new products, new intended uses, or modifications to existing products;
- withdrawals or suspensions of current 510(k) clearances or approvals, resulting in prohibitions on sales of our products; and
- criminal prosecution.

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

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

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design, labeling or manufacture of a product or in the event that a product poses an unacceptable risk to health. Manufacturers may also, under their own initiative, recall a product if any material deficiency in a device is found or withdraw a product to improve device performance or for other reasons. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Similar regulatory agencies in other countries have similar authority to recall devices because of material deficiencies or defects in design or manufacture that could endanger health. Any recall would divert management attention and financial resources, could cause the price of our stock to decline and expose us to product liability or other claims and harm our reputation with customers. A recall involving our Inogen concentrators could be particularly harmful to our business, financial and operating results.

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

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

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

We and our component manufacturers are required to comply with the FDA's Quality System Regulation, or QSR, which covers the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, 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 prompt and satisfactory corrective action in response to an adverse inspection, the FDA could take enforcement action, including any of the following sanctions:

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

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

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

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

Approximately 23.2% and 24.9% of our revenue was from sales outside of the United States for the three months ended March 31, 2016 and March 31, 2015, respectively. As of March 31, 2016, we sold our products in 44 countries outside of the United States through distributors or directly to large "house" accounts. In order to market our products in the European Union or other foreign jurisdictions, we must obtain and maintain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies from country to country and can involve additional testing. The time required to obtain approval abroad may be longer than the time required to obtain FDA clearance. The foreign regulatory approval process includes many of the risks associated with obtaining FDA clearance and we may not obtain foreign regulatory approvals on a timely basis, if at all. FDA clearance does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries. However, the failure to obtain clearance or

approval in one jurisdiction may have a negative impact on our ability to obtain clearance or approval elsewhere. If we do not obtain or maintain necessary approvals to commercialize our products in markets outside the United States, it would negatively affect our overall market penetration.

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

Our promotional materials and training methods must comply with the FDA and other applicable laws and regulations, including the prohibition of the promotion of a medical device for a use that has not been cleared or approved by the FDA. 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 that is either false or misleading, 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 could result in significant penalties.

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

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

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

The 2013 final HITECH omnibus rule modifies the breach reporting standard in a manner that will likely make more data security incidents qualify as reportable breaches. Any liability from a failure to comply with the requirements of HIPAA or the HITECH Act could adversely affect our financial condition. The costs of complying with privacy and security related legal and regulatory requirements are burdensome and could have a material adverse effect on our results of operations.

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

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

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

If we fail to comply with state and federal fraud and abuse laws, including anti-kickback, Stark, 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 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.

The “Stark Law” prohibits a physician from referring Medicare or Medicaid patients to an entity providing “designated health services,” which includes durable medical equipment, if the physician or immediate family member of the physician, has an ownership or investment interest or compensation arrangement with such entity that does not comply with the requirements of a Stark exception. Violation of the Stark Law could result in denial of payment, disgorgement of reimbursements received under a non-compliant arrangement, civil penalties, and exclusion from Medicare, Medicaid or other governmental programs. Although we believe that we have structured our provider arrangements to comply with current Stark Law requirements, these arrangements may not expressly meet the requirements for applicable exceptions from the law.

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 and self-referral laws 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 annual reporting and disclosure requirements on device and drug manufacturers for “transfers of value” made or distributed to licensed physicians and teaching hospitals. Device and drug manufacturers are also required to report and disclose annually any investment interests held by physicians and their immediate family members during the preceding calendar year. Failure to submit required information may result in civil monetary penalties of up to an aggregate of \$.15 million per year (and up to an aggregate of \$1.0 million per year for “knowing failures”), for all payments, transfers of value or ownership or investment interests not reported in an annual submission.

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

The Federal Civil Monetary Penalties Law prohibits the offering or giving of remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of items or services reimbursable by a Federal or state governmental healthcare program. We sometimes offer customers various discounts and other financial incentives in connection with the sales of our products. While it is our intent to comply with all applicable laws, the government may find that our marketing activities violate the Civil Monetary Penalties Law. If we are found to be in non-compliance, we could be subject to civil money penalties of up to \$.01 million for each wrongful act, assessment of three times the amount claimed for each item or service and exclusion from the federal or state healthcare programs.

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

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

As of March 31, 2016 we sold our products in 44 countries outside the United States through distributors or directly to large "house" accounts. In some foreign countries, particularly in the European Union, the pricing of medical devices is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to supply data that compares the cost-effectiveness of our Inogen One systems and our Inogen At Home to other available oxygen therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, it may not be profitable to sell our products in certain foreign countries, which would negatively affect the long-term growth of our business.

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

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

Risks related to our intellectual property

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

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

- prevent our competitors from duplicating our products;

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

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

As of March 31, 2016, we had two pending U.S. patent applications, thirty 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 reexamination, inter partes review, post-grant review, and derivation proceedings in the U.S. Patent and Trademark Office. Foreign patents may be subject to opposition or comparable proceedings in the corresponding foreign patent offices. Any of these proceedings could result in loss of the patent or

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

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

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

The medical device industry in general has been characterized by extensive litigation and administrative proceedings regarding patent infringement and intellectual property rights. Our competitors hold a significant number of patents relating to oxygen therapy devices and products. Third parties have asserted and may in the future assert that we are employing their proprietary technology without authorization. For example, Separation Design Group IP Holdings, LLC (“SDGIP”) filed a lawsuit against us on October 23, 2015 in the United States District Court for the Central District of California. SDGIP alleges that we willfully infringe U.S. Patent Nos. 8,894,751 and 9,199,055, both of which are titled “Ultra Rapid Cycle Portable Oxygen Concentrator.” SDGIP also alleges misappropriation of trade secrets and breach of contract stemming from a meeting in September 2010. SDGIP seeks to recover an unspecified amount of damages (including compensatory and treble damages), costs and expenses (including attorneys’ fees), pre-judgment and post-judgment interest, and other relief that the Court deems proper. SDGIP also seeks a permanent injunction against us. While we have and continue to vigorously contest SDGIP’s claims, we cannot predict the outcome of the SDGIP lawsuit. Any adverse determination in the SDGIP lawsuit could have a material adverse effect on our business and operating results.

From time to time, we have also commenced litigation to enforce our intellectual property rights. For example, we have pursued litigation against Inova Labs Inc. (subsidiary of ResMed) for infringement of two of our patents seeking damages, injunctive relief, costs, and attorneys’ fees. An adverse decision in this action or in any other legal action could limit our ability to assert our intellectual property rights, limit the value of our technology or otherwise negatively impact our business, financial condition and results of operations.

Monitoring unauthorized use of our intellectual property is difficult and costly. Unauthorized use of our intellectual property may have occurred or may occur in the future. Although we have taken steps to minimize the risk of this occurring, any such failure to identify unauthorized use and otherwise adequately protect our intellectual property

would adversely affect our business. Moreover, if we are required to commence litigation, whether as a plaintiff or defendant as has occurred with Inova Labs Inc. and SDGIP, not only will this be time-consuming, but we will also be forced to incur significant costs and divert our attention and efforts of our employees, which could, in turn, result in lower revenue and higher expenses.

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

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

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

- cease selling or using any of our products that incorporate the asserted intellectual property, which would adversely affect our revenue;
- pay damages for past use of the asserted intellectual property, which may be substantial;
- obtain a license from the holder of the asserted intellectual property, which license may not be available on reasonable terms, if at all, and which could reduce profitability; and
- redesign or rename, in the case of trademark claims, our products to avoid infringing the intellectual property rights of third parties, which may not be possible and could be costly and time-consuming if it is possible to do so.

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

We rely on a combination of trade secrets, copyrights, trademarks, confidentiality agreements and other contractual provisions and technical security measures to protect certain aspects of our technology, especially where we do not believe that patent protection is appropriate or obtainable. We require our employees and consultants to execute confidentiality agreements in connection with their employment or consulting relationships with us. We also require our employees and consultants to disclose and assign to us all inventions conceived during the term of their employment or engagement while using our property or that relate to our business. We also require our corporate partners, outside scientific collaborators and sponsored researchers, advisors and others with access to our confidential information to sign confidentiality agreements. We also have taken precautions to initiate reasonable safeguards to protect our information technology systems. However, these measures may not be adequate to safeguard our proprietary intellectual property and conflicts may, nonetheless, arise regarding ownership of inventions. Such conflicts may lead to the loss or impairment of our intellectual property or to expensive litigation to defend our rights

against competitors who may be better funded and have superior resources. Our employees, consultants, contractors, outside clinical collaborators and other advisors may unintentionally or willfully disclose our confidential information to competitors. In addition, confidentiality agreements may be unenforceable or may not provide an adequate remedy in the event of unauthorized disclosure. Enforcing a claim that a third-party illegally obtained and is using our trade secrets is expensive and time-consuming, and the outcome is unpredictable. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary, and in such cases we could not assert any trade secret rights against such party. As a result, other parties may be able to use our proprietary technology or information, and our ability to compete in the market would be harmed.

“Inogen,” “Inogen One,” “Inogen One G2,” “Inogen One G3,” “G4,” “Oxygenation,” “Live Life in Moments, not Minutes,” “N Run Out of Oxygen,” “Oxygen Therapy on Your Terms,” “Oxygen.Anytime.Anywhere,” “Reclaim Your Independence,” “Intelligent Delivery Technology,” “Inogen At Home,” and the Inogen design are pending applications and/or registered trademarks with the United States Patent and Trademark Office of Inogen, Inc. We own trademark registrations for the mark “Inogen” in Australia, Canada, South Korea, Mexico, and Europe (European Union registration). We own pending applications for “Inogen” in Japan and South Korea, and we own a pending application for “ ” in Japan. We own trademark registrations for the mark “Inogen One” in Australia, Canada, China, South Korea, Mexico, and Europe (European Union registration). We own trademark registrations for the mark “Satellite Conserver” in Canada and China. We own a trademark registration for the mark “Inogen At Home” in Europe (European Union Registration). Other service marks, trademarks, and trade names referred to in this Quarterly Report on Form 10-Q are the property of their respective owners.

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

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

Risks related to being a public company

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

On February 20, 2014 we completed our initial public offering. As a public company, and increasingly after we are no longer an “emerging growth company,” we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act and rules subsequently implemented by the SEC and the NASDAQ Global Select Market impose numerous requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Also, the Securities Exchange Act of 1934, as amended, or the Exchange Act, requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. Our management and other personnel will need to devote a substantial amount of time to compliance with these laws and regulations. These requirements have increased and will continue to increase our legal, accounting, and financial compliance costs and have made and will continue to make some activities more time consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to incur substantial costs to maintain the same or similar coverage. These rules and regulations could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or our board committees or as executive officers.

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

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), requires us to perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting. Section 404(b) of Sarbanes-Oxley Act, or Section 404(b), also requires our independent registered public accounting firm to attest to the effectiveness of our internal control over financial reporting. As an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012 (the “JOBS Act”), we are availing 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.

Failure to maintain effective internal controls could cause our investors to lose confidence in us and adversely affect the market price of our common stock. If our internal controls are not effective, we may not be able to accurately report our financial results or prevent fraud.

Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, requires that we maintain internal control over financial reporting that meets applicable standards. We may err in the design or operation of our controls, and all internal control systems, no matter how well designed and operated, can provide only reasonable assurance that the objectives of the control system are met. Because there are inherent limitations in all control systems, there can be no absolute assurance that all control issues have been or will be detected. If we are unable, or are perceived as unable, to produce reliable financial reports due to internal control deficiencies, investors could lose confidence in our reported financial information and operating results, which could result in a negative market reaction.

We are required to disclose changes made in our internal controls and procedures on a quarterly basis. However, our independent registered public accounting firm will not be required to report on the effectiveness of our internal control over financial reporting pursuant to Section 404 until the later of the year following our first annual report required to be filed with the SEC, or the date we are no longer an “emerging growth company” as defined in the JOBS Act since we are availing ourselves of the exemptions contained in the JOBS Act. At such time, our independent registered public accounting firm may issue a report that is adverse in the event it is not satisfied with the level at which our controls are documented, designed or operating. Our remediation efforts may not enable us to avoid a material weakness in the future. Additionally, to comply with the requirements of being a public company, we may need to undertake various actions, such as implementing new internal controls and procedures and hiring accounting or internal audit staff, which may adversely affect our operating results and financial condition.

As we disclosed in our Annual Report on Form 10-K for the period ended December 31, 2014, and our Quarterly Reports on Forms 10-Q for the periods ended March 31, 2015, June 30, 2015 and September 30, 2015, we identified a material weakness with respect to internal control over the review of sales order documentation supporting our direct-to-customer sales and rentals prior to revenue recognition. We commenced measures to remediate this material weakness during the first quarter of 2015, and remediation has been completed as of December 31, 2015. Steps we have taken to remediate the material weakness in our internal control over financial reporting of revenue include: implementation of more extensive random and data analytics driven quarterly medical documentation audits, supervisor facsimile and call monitoring, and additional independent scrutiny of medical documentation authenticity. However, we cannot assure you that our internal controls will continue to operate properly or that our financial statements will be free from error. There may be undetected material weaknesses in our internal control over financial reporting, as a result of which we may not detect financial statement errors on a timely basis. Moreover, in the future we may implement new offerings and engage in business transactions, such as acquisitions, reorganizations or implementation of new information systems that could require us to develop and implement new controls and could negatively affect our internal control over financial reporting and result in material weaknesses.

If we identify new material weaknesses in our internal control over financial reporting, if we are unable to comply with the requirements of Section 404 in a timely manner, if we are unable to assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting, we may be late with the filing of our periodic

reports, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be negatively affected. As a result of such failures, we could also become subject to investigations by the stock exchange on which our securities are listed, the SEC, or other regulatory authorities, and become subject to litigation from investors and stockholders, which could harm our reputation, financial condition or divert financial and management resources from our core business.

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

We are an “emerging growth company,” as defined in the JOBS Act, and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced financial disclosure obligations, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a non-binding advisory vote on executive compensation and any golden parachute payments not previously approved. We may take advantage of these provisions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company upon the earliest to occur of: the last day of the fiscal year in which we have more than \$1.0 billion in annual revenue; the date we qualify as a large accelerated filer, with at least \$700 million of equity securities held by non-affiliates; the issuance, in any three-year period, by us of more than \$1.0 billion in non-convertible debt securities; and the last day of the fiscal year ending after the fifth anniversary of our initial public offering. We may choose to take advantage of some but not all of these reduced reporting burdens. If we take advantage of any of these reduced reporting burdens in future filings, the information that we provide our security holders may be different than you might get from other public companies in which you hold equity interests. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards, delaying the adoption of these accounting standards until they would apply to private companies. We have elected to avail ourselves of this exemption and, as a result, our financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be reduced or more volatile.

Risks related to our common stock

We expect that our stock price will fluctuate significantly, you may have difficulty selling your shares, and you could lose all or part of your investment.

Our stock is currently traded on NASDAQ, but we can provide no assurance that we will be able to maintain an active trading market on NASDAQ or any other exchange in the future. If an active trading market does not develop, you may have difficulty selling any of our shares of common stock that you buy. In addition, the trading price of our common stock may be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These factors include:

- actual or anticipated quarterly variation in our results of operations or the results of our competitors;
- announcements of secondary offerings;
- announcements by us or our competitors of new commercial products, significant contracts, commercial relationships or capital commitments;
- issuance of new or changed securities analysts’ reports or recommendations for our stock;
- 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;
 - the other factors described in this “Risk Factors” section; and
 - general economic conditions and slow or negative growth of our markets.
-

The stock market in general and market prices for the securities of technology-based companies like ours in particular, have from time to time experienced volatility that often has been unrelated to the operating performance of the underlying companies. 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 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.

Future sales of shares could cause our stock price to decline.

Our stock price could decline as a result of sales of a large number of shares of our common stock or the perception that these sales could occur. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate.

As of March 31, 2016, one holder of approximately 3.5 million shares, or approximately 17.9%, of our outstanding shares, has rights, subject to some conditions, to require us to file registration statements covering the sale of their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have also registered the offer and sale of all shares of common stock that we may issue under our equity compensation plans.

In addition, in the future, we may issue additional shares of common stock or other equity or debt securities convertible into common stock in connection with a financing, acquisition, litigation settlement, and employee arrangements or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause our stock price to decline.

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

As of March 31, 2016, our executive officers, directors and stockholders who owned more than 5% of our outstanding common stock and their respective affiliates beneficially owned or controlled approximately 36.2% of the outstanding shares of our common stock. Accordingly, these executive officers, directors and stockholders who owned more than 5% of our outstanding common stock and their respective affiliates, acting as a group, have substantial influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of our assets or any other significant corporate transactions. These stockholders may also delay or prevent a change of control of us, even if such a change of control would benefit our other stockholders. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

Edgar Filing: Inogen Inc - Form 10-Q

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

Provisions in our certificate of incorporation and bylaws may have the effect of delaying or preventing a change of control or changes in our management. Our amended and restated certificate of incorporation and amended and restated bylaws include provisions that:

- authorize our board of directors to issue, without further action by the stockholders, up to 10,000,000 shares of undesignated preferred stock;
 - require that any action to be taken by our stockholders be 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.

We continue to retain broad discretion in the use of the net proceeds from our initial public offering and may not use them effectively.

We continue to retain broad discretion in the application of the net proceeds from our initial public 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 might not be able to yield a significant return, if any, on any investment of these net proceeds from the initial public offering. Stockholders will not have the opportunity to influence our management's decisions on how to use the net proceeds, 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 of more than \$1 million in any fiscal year 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.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Unregistered Sales of Equity Securities

None.

Issuer Purchases of Equity Securities

We did not repurchase any shares of our common stock during the three months ended March 31, 2016 and March 31, 2015.

Use of Proceeds from Initial Public Offering, or (IPO), of Common Stock

On February 20, 2014, we sold 3,529,411 shares in our IPO at a price to the public of \$16.00 per share. Additionally, the selling stockholders sold 981,902 shares of common stock (882,352 upon the IPO, and 99,550 of which were sold pursuant to a 30-day option granted to the underwriters). The offering closed on February 20, 2014, as a result of which we received net proceeds of approximately \$52.5 million after underwriting discounts of approximately \$3.9 million, but before offering expenses of approximately \$2.8 million. We did not receive any proceeds from the shares sold by the selling stockholders. J.P. Morgan acted as sole book-running manager for the offering, Leerink Partners acted as lead manager, and William Blair and Stifel acted as co-managers. No payments for such expenses were made directly or indirectly to (i) any of our officers or directors or their associates, (ii) any persons owning 10% or more of any class of our equity securities, or (iii) any of our affiliates. There has been no material change in the planned use of proceeds from our initial public offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b) under the Securities Act on Use of Proceeds from Initial Public Offering of Common Stock.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit Number	Description
31.1	Certification Pursuant to Exchange Act Rules 13a - 14(a) and 15d - 14(a), as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 of Chief Executive Officer
31.2	Certification Pursuant to Exchange Act Rules 13a - 14(a) and 15d - 14(a), as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 of Chief Financial Officer
32.1(1)	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 of Chief Executive Officer
32.2(1)	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 of Chief Financial Officer
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Document

(1)The Certifications attached as Exhibits 32.1 and 32.2 that accompany this Quarterly Report on Form 10-Q are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of Inogen, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

inogen, inc.

Dated: May 9, 2016 By: /s/ Raymond Huggenberger
Raymond Huggenberger
Chief Executive Officer

(Principal Executive Officer)

Dated: May 9, 2016 By: /s/ Alison Bauerlein
Alison Bauerlein
Chief Financial Officer

Executive Vice President, Finance

Secretary and Treasurer

(Principal Financial and Accounting Officer)