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 June 30, 2020

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, CA	**93117**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (805) 562-0500

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value	**INGN**	**The NASDAQ Stock Market LLC (NASDAQ Global Select Market)**

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 every Interactive Data File required to be submitted 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 such files). Yes ☒ No ☐

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

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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 July 31, 2020, the registrant had 22,066,049 shares of common stock, par value $0.001, outstanding.

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INOGEN, INC.

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

Inogen, Inc.
Consolidated Balance Sheets
(amounts in thousands)

	June 30, 2020	December 31, 2019
	(unaudited)	
Assets		
Current assets		
Cash and cash equivalents	$ 214,086	$ 198,037
Marketable securities	4,549	11,057
Accounts receivable, net	28,422	34,325
Inventories, net	36,180	35,664
Income tax receivable	2,984	2,976
Prepaid expenses and other current assets	16,544	10,160
Total current assets	302,765	292,219
Property and equipment		
Rental equipment, net	40,614	39,308
Manufacturing equipment and tooling	10,351	9,704
Computer equipment and software	7,841	7,266
Furniture and equipment	2,269	1,730
Leasehold improvements	4,607	4,388
Land and building	125	125
Construction in process	1,104	1,773
Total property and equipment	66,911	64,294
Less accumulated depreciation	(45,381)	(44,856)
Property and equipment, net	21,530	19,438
Goodwill	32,957	32,954
Intangible assets, net	73,253	77,533
Operating lease right-of-use asset	9,454	5,855
Deferred tax asset - noncurrent	13,768	14,452
Other assets	4,394	4,888
Total assets	$ 458,121	$ 447,339

See accompanying condensed notes to the consolidated financial statements.

Inogen, Inc.
Consolidated Balance Sheets (continued)
(amounts in thousands, except share and per share amounts)

	June 30, 2020	December 31, 2019
	(unaudited)	
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable and accrued expenses	$ 29,363	$ 30,730
Accrued payroll	6,405	6,215
Warranty reserve - current	5,769	4,923
Operating lease liability - current	1,823	2,014
Deferred revenue - current	6,266	5,478
Income tax payable	988	821
Total current liabilities	50,614	50,181
Long-term liabilities		
Warranty reserve - noncurrent	8,039	7,648
Operating lease liability - noncurrent	8,693	4,702
Earnout liability - noncurrent	26,539	26,559
Deferred revenue - noncurrent	13,035	13,541
Deferred tax liability - noncurrent	87	87
Total liabilities	107,007	102,718
Commitments and contingencies (Note 10)		
Stockholders' equity		
Common stock, $0.001 par value per share; 200,000,000 authorized; 22,065,961 and 22,031,410 shares issued and outstanding as of June 30, 2020 and December 31, 2019, respectively	22	22
Additional paid-in capital	268,349	263,252
Retained earnings	82,425	81,434
Accumulated other comprehensive income (loss)	318	(87)
Total stockholders' equity	351,114	344,621
Total liabilities and stockholders' equity	$ 458,121	$ 447,339

See accompanying condensed notes to the consolidated financial statements.

Inogen, Inc.
Consolidated Statements of Comprehensive Income
(unaudited)
(amounts in thousands, except share and per share amounts)

	Three months ended June 30, 2020	Three months ended June 30, 2019	Six months ended June 30, 2020	Six months ended June 30, 2019
Revenue				
Sales revenue	$ 65,612	$ 95,863	$ 148,752	$ 180,681
Rental revenue	6,079	5,200	11,428	10,584
Total revenue	71,691	101,063	160,180	191,265
Cost of revenue				
Cost of sales revenue	36,082	47,230	83,200	89,297
Cost of rental revenue, including depreciation of $1,221 and $1,594, for the three months ended and $2,520 and $3,299 for the six months ended, respectively	2,860	3,618	5,865	7,344
Total cost of revenue	38,942	50,848	89,065	96,641
Gross profit				
Gross profit-sales revenue	29,530	48,633	65,552	91,384
Gross profit-rental revenue	3,219	1,582	5,563	3,240
Total gross profit	32,749	50,215	71,115	94,624
Operating expense				
Research and development	3,290	1,468	6,895	3,137
Sales and marketing	22,086	27,758	49,249	55,959
General and administrative	9,724	8,844	19,501	18,525
Total operating expense	35,100	38,070	75,645	77,621
Income (loss) from operations	(2,351)	12,145	(4,530)	17,003
Other income (expense)				
Interest income	176	1,394	728	2,728
Other income	5,700	145	5,640	25
Total other income, net	5,876	1,539	6,368	2,753
Income before provision for income taxes	3,525	13,684	1,838	19,756
Provision for income taxes	945	3,524	847	4,294
Net income	2,580	10,160	991	15,462
Other comprehensive income (loss), net of tax				
Change in foreign currency translation adjustment	178	106	20	(31)
Change in net unrealized gains (losses) on foreign currency hedging	(417)	(618)	244	(534)
Less: reclassification adjustment for net (gains) losses included in net income	134	282	146	458
Total net change in unrealized gains (losses) on foreign currency hedging	(283)	(336)	390	(76)
Change in net unrealized gains (losses) on marketable securities	1	23	(5)	36
Total other comprehensive income (loss), net of tax	(104)	(207)	405	(71)
Comprehensive income	$ 2,476	$ 9,953	$ 1,396	$ 15,391
Basic net income per share attributable to common stockholders (Note 7)	$ 0.12	$ 0.47	$ 0.05	$ 0.71
Diluted net income per share attributable to common stockholders (Note 7)	$ 0.12	$ 0.45	$ 0.04	$ 0.69
Weighted-average number of shares used in calculating net income per share attributable to common stockholders:				
Basic common shares	21,963,472	21,815,634	21,939,919	21,783,150
Diluted common shares	22,221,356	22,359,679	22,229,744	22,459,101

See accompanying condensed notes to the consolidated financial statements.

Inogen, Inc.
Consolidated Statements of Stockholders' Equity
(amounts in thousands, except share amounts)

Three months ended June 30, 2020 and June 30, 2019	Common stock Shares	Common stock Amount	Additional paid-in capital	Retained earnings	Accumulated other comprehensive income (loss)	Total stockholders' equity
Balance, March 31, 2019 (unaudited)	21,931,342	$ 22	$ 255,226	$ 65,786	$ 860	$ 321,894
Stock-based compensation	—	—	1,779	—	—	1,779
Restricted stock awards issued, net of forfeitures	(12,342)	—	—	—	—	—
Vesting of restricted stock units	10,111	—	(8)	—	—	(8)
Shares withheld related to net restricted stock settlement	(978)	—	(63)	—	—	(63)
Stock options exercised	5,536	—	243	—	—	243
Net income	—	—	—	10,160	—	10,160
Other comprehensive loss	—	—	—	—	(207)	(207)
Balance, June 30, 2019 (unaudited)	21,933,669	$ 22	$ 257,177	$ 75,946	$ 653	$ 333,798
Balance, March 31, 2020 (unaudited)	22,044,527	$ 22	$ 267,011	$ 79,845	$ 422	$ 347,300
Stock-based compensation	—	—	1,277	—	—	1,277
Vesting of restricted stock units	20,049	—	(4)	—	—	(4)
Shares withheld related to net restricted stock settlement	(1,605)	—	(61)	—	—	(61)
Stock options exercised	2,990	—	126	—	—	126
Net income	—	—	—	2,580	—	2,580
Other comprehensive loss	—	—	—	—	(104)	(104)
Balance, June 30, 2020 (unaudited)	22,065,961	$ 22	$ 268,349	$ 82,425	$ 318	$ 351,114

Six months ended June 30, 2020 and June 30, 2019	Common stock Shares	Common stock Amount	Additional paid-in capital	Retained earnings	Accumulated other comprehensive income (loss)	Total stockholders' equity
Balance, December 31, 2018	21,778,632	$ 22	$ 249,194	$ 60,484	$ 724	$ 310,424
Stock-based compensation	—	—	5,365	—	—	5,365
Employee stock purchases	16,767	—	1,525	—	—	1,525
Restricted stock awards issued, net of forfeitures	54,602	—	—	—	—	—
Vesting of restricted stock units	21,376	—	(67)	—	—	(67)
Shares withheld related to net restricted stock settlement	(13,023)	—	(718)	—	—	(718)
Stock options exercised	75,315	—	1,878	—	—	1,878
Net income	—	—	—	15,462	—	15,462
Other comprehensive loss	—	—	—	—	(71)	(71)
Balance, June 30, 2019 (unaudited)	21,933,669	$ 22	$ 257,177	$ 75,946	$ 653	$ 333,798
Balance, December 31, 2019	22,031,410	$ 22	$ 263,252	$ 81,434	$ (87)	$ 344,621
Stock-based compensation	—	—	4,061	—	—	4,061
Employee stock purchases	27,954	—	1,088	—	—	1,088
Restricted stock awards issued, net of forfeitures	(27,729)	—	—	—	—	—
Vesting of restricted stock units	30,216	—	(11)	—	—	(11)
Shares withheld related to net restricted stock settlement	(5,214)	—	(227)	—	—	(227)
Stock options exercised	9,324	—	186	—	—	186
Net income	—	—	—	991	—	991
Other comprehensive income	—	—	—	—	405	405
Balance, June 30, 2020 (unaudited)	22,065,961	$ 22	$ 268,349	$ 82,425	$ 318	$ 351,114

See accompanying condensed notes to the consolidated financial statements.

Inogen, Inc.
Consolidated Statements of Cash Flows
(unaudited)
(amounts in thousands)

	Six months ended June 30, 2020	Six months ended June 30, 2019
Cash flows from operating activities		
Net income	$ 991	$ 15,462
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	8,942	5,554
Loss on rental units and other fixed assets	279	323
Gain on sale of former rental assets	(74)	(46)
Provision for sales revenue returns and doubtful accounts	5,694	8,890
Provision for rental revenue adjustments	1,548	1,227
Provision for inventory losses	626	410
Stock-based compensation expense	4,061	5,365
Deferred income taxes	684	4,067
Change in fair value of earnout liability	(20)	—
Changes in operating assets and liabilities:		
Accounts receivable	(1,399)	(19,735)
Inventories	(3,327)	1,536
Income tax receivable	(8)	(95)
Prepaid expenses and other current assets	(6,385)	(3,154)
Operating lease right-of-use asset	(3,599)	(5,461)
Other noncurrent assets	1,509	(1,926)
Accounts payable and accrued expenses	(1,124)	223
Accrued payroll	190	(4,436)
Warranty reserve	1,237	795
Deferred revenue	282	1,959
Income tax payable	163	15
Operating lease liability	3,800	6,462
Other noncurrent liabilities	—	(832)
Net cash provided by operating activities	14,070	16,603
Cash flows from investing activities		
Purchases of marketable securities	(4,554)	(38,601)
Maturities of marketable securities	11,057	40,150
Investment in intangible assets	(215)	(31)
Investment in property and equipment	(2,329)	(1,973)
Production and purchase of rental equipment	(3,227)	(1,481)
Proceeds from sale of former assets	119	104
Net cash provided by (used in) investing activities	851	(1,832)

(continued on next page)

See accompanying condensed notes to the consolidated financial statements.

Inogen, Inc.
Consolidated Statements of Cash Flows (continued)
(unaudited)
(amounts in thousands)

	Six months ended June 30,	
	2020	**2019**
Cash flows from financing activities		
Proceeds from stock options exercised	186	1,878
Proceeds from employee stock purchases	1,088	1,525
Payment of employment taxes related to release of restricted stock	(238)	(785)
Net cash provided by financing activities	1,036	2,618
Effect of exchange rates on cash	92	(76)
Net increase in cash and cash equivalents	16,049	17,313
Cash and cash equivalents, beginning of period	198,037	196,634
Cash and cash equivalents, end of period	$ 214,086	$ 213,947
Supplemental disclosures of cash flow information		
Cash paid during the period for income taxes, net of refunds received	$ 132	$ 208
Supplemental disclosure of non-cash transactions		
Property and equipment in accounts payable and accrued liabilities	146	242

See accompanying condensed notes to the consolidated financial statements.

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 (POCs) 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 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.

Since adopting the Company's direct-to-consumer rental strategy in 2009, the Company has directly sold or rented more than875,000 of its Inogen oxygen concentrators as of June 30, 2020.

The Company incorporated Inogen Europe Holding B.V., a Dutch limited liability company, on April 13, 2017. On May 4, 2017, Inogen Europe Holding B.V. acquired all issued and outstanding capital stock of MedSupport Systems B.V. (MedSupport) and began operating under the name Inogen Europe B.V. The Company merged Inogen Europe Holding B.V. and Inogen Europe B.V. on December 28, 2018. Inogen Europe B.V. is the remaining legal entity. Inogen completed the acquisition of New Aera, Inc. (New Aera) on August 9, 2019.

2. Basis of presentation and summary of significant accounting policies

The consolidated financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP).

The results of operations for the three months and six months ended June 30, 2020 shown in this report are not necessarily indicative of results to be expected for the full year ending December 31, 2020. In the opinion of the Company's management, the information contained herein reflects all adjustments, consisting of only normal recurring adjustments, necessary for a fair presentation of the Company's results of operations, financial position, cash flows and stockholders' equity. Certain footnote disclosures normally included in annual consolidated financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to Securities and Exchange Commission (SEC) rules and regulations relating to interim financial statements. The accompanying consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto contained in the Company's Annual Report on Form 10-K filed with the SEC on February 25, 2020. Except as further described below, 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 February 25, 2020.

Basis of consolidation

The consolidated financial statements include the accounts of Inogen, Inc. and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated.

Use of estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. 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 and determining the stand-alone selling price (SSP) of performance obligations, inventory and rental asset valuations and write-downs, accounts receivable allowances for bad debts, returns and adjustments, warranty expense, stock compensation expense, depreciation and amortization, income tax provision and uncertain tax positions, fair value of financial instruments, fair value of acquired intangible assets and goodwill and fair value of earnout liabilities. Actual results could differ from these estimates.

Government grants

The Company may receive cash payments from government grants during a public health emergency (PHE). The Company considers the nature and substance of the government grant and records the cash payment in accordance with the terms and conditions of the grant. Income is deferred until all considerations required for receiving the grant are met and is recognized in the consolidated statements of comprehensive income based on the nature of the terms and conditions of the grant. In the three months ended June 30, 2020, the Company received a grant of $6,200 from the Public Health and Social Services Emergency Fund (Relief Fund), which was among the provisions of the Coronavirus Aid, Relief, and Economic Security Act (CARES) Act signed into law on March 27, 2020. During the three months ended June 30, 2020, the Company recorded $5,600 in other income, which was associated with lost revenues from the COVID-19 PHE, and a $600 benefit in general and administrative expense due to COVID-19 PHE related costs incurred in the quarter.

Recently issued accounting pronouncements not yet adopted

In December 2019, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes.* The new guidance simplifies the accounting for income taxes by removing certain exceptions to the general principles in Topic 740. The new guidance also improves consistent application of and simplifies U.S. GAAP for other areas of Topic 740 by clarifying and amending the existing guidance. The ASU is effective for fiscal years beginning after December 15, 2020, with early adoption permitted. The Company is currently evaluating the effect of the new guidance.

Recently adopted accounting pronouncements

In June 2016, the FASB issued ASU No. 2016-13, *Accounting for Credit Losses (Topic 326).* The new standard requires the use of an "expected loss" model on certain types of financial instruments. The standard also amends the impairment model for available-for-sale debt securities and requires estimated credit losses to be recorded as allowances instead of reductions to amortized cost of the securities. The Company adopted this standard on January 1, 2020, and adoption of this standard did not have a material impact on the Company's consolidated financial statement presentation or results.

In January 2017, the FASB issued ASU No. 2017-04, *Simplifying the Test for Goodwill Impairment.* The new guidance eliminates step two of the goodwill impairment test. Under the new guidance, an entity should recognize an impairment charge for the amount by which a reporting unit's carrying value exceeds its fair value. The Company adopted this standard on January 1, 2020, and adoption of this standard did not have a material impact on the Company's consolidated financial statement presentation or results.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement*. The new guidance modifies the disclosure requirements on fair value measurements. The Company adopted this standard on January 1, 2020, and adoption of this standard did not have a material impact on the Company's consolidated financial statement presentation or results.

Business segments

The Company operates and reports in only one operating and reportable segment – development, manufacturing, marketing, sales, and rental of respiratory products. Management reports financial information on a consolidated basis to the Company's chief operating decision maker.

3. Acquisitions

On August 6, 2019, the Company entered into an Agreement and Plan of Merger (Merger Agreement) by and among the Company, New Aera, Inc., a Delaware corporation, Move Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of the Company, and Gregory J. Kapust, as stockholder representative. On August 9, 2019, the Company completed the acquisition of New Aera pursuant to and on the terms set forth in the Merger Agreement. In connection with the Merger Agreement, the Company also separately acquired certain intellectual property assets from Silverbow Development, LLC, an affiliate of New Aera (Silverbow). New Aera is an innovative developer and manufacturer of portable non-invasive ventilators for people suffering from various chronic lung diseases. Under the terms of the Merger Agreement, all outstanding shares of capital stock of New Aera were cancelled and converted into the right to receive merger consideration with a value equal to up to $101,923 in cash in the aggregate (inclusive of payments to Silverbow) comprised of $70,523 of cash paid at closing and up to $31,400 in earnout payments if certain performance targets are achieved. Goodwill associated with this acquisition is not expected to be deductible for income tax purposes.

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

Assets and liabilities of the acquired company were recorded at their estimated fair values at the date of acquisition. The excess purchase price over the fair value of net tangible assets and identifiable intangible assets acquired has been allocated to goodwill. Goodwill represents the expected synergies with the existing business, the acquired assembled workforce, and future cash flows after the acquisition. The fair value assigned to the identifiable intangible asset was determined primarily by usingthe excess earnings method. The key assumptions included in the excess earnings method included revenue recognized, cost of revenue and the discount rate. The fair value of the earnout liability was measured using a Monte Carlo simulation and was discounted using a rate that appropriately captures the risk associated with the obligation. The key assumption included in the simulation included revenue recognized.

Preliminary fair values of assets acquired and liabilities assumed have been updated for deferred taxes. The purchase accounting for this acquisition has been finalized.

The following table summarizes the purchase price allocation for the acquisition of New Aera:

Cash	$	122
Inventories		140
Other current assets		8
Property and equipment		224
Goodwill		30,742
Intangible assets		77,700
Total assets acquired	$	108,936
Deferred tax liability - noncurrent	$	12,664
Earnout liability - noncurrent		25,749
Total liabilities assumed		38,413
Total purchase price	$	70,523

The consolidated financial and operating results reflect the New Aera operations beginning August 9, 2019. The following unaudited pro forma information for the three months and six months ended June 30, 2019 presents the revenue and net income assuming the acquisition of New Aera had occurred as of January 1, 2018.

	Three months ended June 30, 2019		Six months ended June 30, 2019	
Total revenue	$	101,068	$	191,275
Net income	$	7,359	$	10,009

4. Fair value measurements

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 is to estimate the price at which an orderly transaction to sell an asset or to transfer the liability would take place between market participants at the measurement date under current market conditions. 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.

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

The Company's financial instruments consist of cash and cash equivalents, marketable securities, accounts receivable, accounts payable and accrued expenses. The carrying values of its financial instruments approximate fair value based on their short-term nature.

Cash, cash equivalents and marketable securities

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 marketable securities within Level 2 of the fair value hierarchy.

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 marketable securities:

	As of June 30, 2020				
	Adjusted cost	Gross unrealized gains	Fair value	Cash and cash equivalents	Marketable securities
Cash	$ 54,332	$ —	$ 54,332	$ 54,332	$ —
Level 1:					
Money market accounts	159,754	—	159,754	159,754	—
Level 2:					
Corporate bonds	4,547	2	4,549	—	4,549
U.S. Treasury securities	—	—	—	—	—
Total	$ 218,633	$ 2	$ 218,635	$ 214,086	$ 4,549

	As of December 31, 2019				
	Adjusted cost	Gross unrealized gains	Fair value	Cash and cash equivalents	Marketable securities
Cash	$ 51,560	$ —	$ 51,560	$ 51,560	$ —
Level 1:					
Money market accounts	146,477	—	146,477	146,477	—
Level 2:					
Corporate bonds	2,011	2	2,013	—	2,013
U.S. Treasury securities	9,038	6	9,044	—	9,044
Total	$ 209,086	$ 8	$ 209,094	$ 198,037	$ 11,057

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 has entered 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 consolidated statements of comprehensive income (loss) 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 expense, net in the consolidated 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.

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

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 consolidated balance sheet. The Company had a related receivable of $64 and a related payable of $514 as of June 30, 2020 and December 31, 2019, respectively.

The Company classifies the foreign currency derivative instruments within Level 2 in the fair value hierarchy as the valuation inputs are based on quoted prices and market observable data of whether it is designated and qualifies for hedge accounting.

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 (loss) and reclassified into earnings in the same 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 other comprehensive income (loss) related to the hedging relationship.

Accumulated other comprehensive income (loss)

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

	Foreign currency translation adjustments	Unrealized gains (losses) on marketable securities	Unrealized gains (losses) on cash flow hedges	Accumulated other comprehensive income (loss)
Balance as of December 31, 2019	$ 271	$ 6	$ (364)	$ (87)
Other comprehensive income (loss)	20	(5)	390	405
Balance as of June 30, 2020	$ 291	$ 1	$ 26	$ 318

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, the Company does not have any transactions or other economic events that qualify as comprehensive income (loss).

Earnout liability

The Company has obligations to pay up to $31,400 in earnout payments in cash if certain future financial results are met.The earnout liability was valued using Level 3 inputs. The fair value of the earnout was determined by employing a Monte Carlo simulation in a risk-neutral framework. The underlying simulated variable includes recognized revenue. The recognized revenue volatility estimate was based on a study of historical asset volatility for a set of comparable public companies. The model includes other assumptions including the market price of risk, which was calculated as the weighted average cost of capital (WACC) less the long-term risk free rate. The earnout period for recognized revenue is each calendar year beginning with calendar year 2019 and ending on the calendar year in which the earnout consideration equals the earnout cap.

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

The following table provides quantitative information about Level 3 inputs for fair value measurement of the earnout liability as of June 30, 2020 and December 31, 2019. Significant increases or decreases in these inputs in isolation could result in a significant impact on our fair value measurement:

Simulation input	**As of June 30, 2020**	**As of December 31, 2019**
Revenue volatility	35.00 %	35.00 %
WACC	12.00 %	13.00 %
20-year risk free rate	1.18 %	2.25 %
Market price of risk	8.00 %	10.00 %

The reconciliation of the earnout liability measured and carried at fair value on a recurring basis is as follows:

	Three months ended June 30, 2020	**Six months ended June 30, 2020**
Balance at beginning of period	$ 25,607	$ 26,559
Change in fair value	932	(20)
Balance at end of period	$ 26,539	$ 26,539

5. Balance sheet components

Cash, cash equivalents and marketable securities

The Company considers all short-term highly liquid investments with a maturity of three months or less to be cash equivalents. The Company's marketable debt securities are classified and accounted for as available-for-sale. Cash equivalents are recorded at cost plus accrued interest, which is considered adjusted cost, and approximates fair value. Marketable debt securities are included in cash equivalents and marketable securities based on the maturity date of the security. Short-term investments are included in marketable securities in the current period presentation.

The Company considers investments with maturities greater than three months, but less than one year, to be marketable securities. Investments are reported at fair value with realized and unrealized gains or losses reported in other income (expense), net.

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. Cash, cash equivalents, and marketable securities consist of the following:

Cash and cash equivalents	**June 30, 2020**	**December 31, 2019**
Cash	$ 54,332	$ 51,560
Money market accounts	159,754	146,477
Total cash and cash equivalents	$ 214,086	$ 198,037
Marketable securities		
Corporate bonds	$ 4,549	$ 2,013
U.S. Treasury securities	—	9,044
Total marketable securities	$ 4,549	$ 11,057

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

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 general and administrative expense for sales revenue and as a reduction of rental revenue in the periods in which they become known. The allowance is increased by bad debt provisions, net of recoveries, 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 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, audit adjustments, 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 for sales revenue, 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 allowances for rental reserve adjustments and doubtful accounts, the rental revenue adjustments account (contra rental revenue account) is charged.

As of June 30, 2020 and December 31, 2019, included in accounts receivable on the consolidated balance sheets were earned but unbilled receivables of $1,520 and $590, 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.

Gross accounts receivable balance concentrations by major category as of June 30, 2020 and December 31, 2019 were as follows:

Gross accounts receivable		**June 30, 2020**		**December 31, 2019**
Rental (1)	$	3,960	$	3,003
Business-to-business and other receivables (2)		25,815		33,101
Total gross accounts receivable	$	29,775	$	36,104

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

Net accounts receivable (gross accounts receivable, net of allowances) balance concentrations by major category as of June 30, 2020 and December 31, 2019 were as follows:

Net accounts receivable	**June 30, 2020**	**December 31, 2019**
Rental (1)	$ 3,314	$ 2,464
Business-to-business and other receivables (2)	25,108	31,861
Total net accounts receivable	$ 28,422	$ 34,325

(1) Rental includes Medicare, Medicaid/other government, private insurance and patient pay.

(2) Business-to-business receivables included one customer with a gross accounts receivable balance of $5,866 and $10,695 as of June 30, 2020 and December 31, 2019, respectively. This customer received extended payment terms through a direct financing plan offered. The Company also has a credit insurance policy in place, which allocated up to $20,000 in coverage as of June 30, 2020 and allocated up to $20,000 in coverage as of December 31, 2019 for this customer with a $400 deductible and 10% retention.

The following tables set forth the accounts receivable allowances as of June 30, 2020 and December 31, 2019:

Allowances - accounts receivable	**June 30, 2020**	**December 31, 2019**
Doubtful accounts	$ 141	$ 205
Rental revenue adjustments	544	411
Sales returns	668	1,163
Total allowances - accounts receivable	$ 1,353	$ 1,779

Concentration of credit risk

Financial instruments that potentially subject the Company to concentration of credit risk consist principally of cash, cash equivalents, marketable securities 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 also 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 traditional home medical equipment providers, distributors, and resellers in the United States and in foreign countries primarily on a credit basis. The Company also sells its products direct-to-consumers on a primarily prepayment basis. One single customer represented more than 10% of the Company's total revenue for the six months ended June 30, 2020, and no single customer represented more than 10% of the Company's total revenue for the six months ended June 30, 2019. Two customers each represented more than 10% of the Company's net accounts receivable balance with accounts receivable balances of $5,866 and $8,900, respectively, as of June 30, 2020, and $10,695 and $5,228, respectively, as of December 31, 2019.

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 six months ended June 30, 2020, the Company's three major vendors accounted for 21.4%, 10.6%, and 10.4%, respectively, of total raw material purchases. For the six months ended June 30, 2019, the Company's three major vendors accounted for 21.5%, 13.1% and 9.3%, respectively, of total raw material purchases.

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

A portion of revenue is earned from sales outside the United States. Approximately77.2% and 71.8% of the non-U.S. revenue for the three months ended June 30, 2020 and June 30, 2019, respectively, were invoiced in Euros. Approximately 72.2% and 71.6% of the non-U.S. revenue for the six months ended June 30, 2020 and June 30, 2019, respectively, were invoiced in Euros. A breakdown of the Company's revenue from U.S. and non-U.S. sources for the three and six months ended June 30, 2020 and June 30, 2019, respectively, is as follows:

	Three months ended June 30,		Six months ended June 30,	
	2020	2019	2020	2019
U.S. revenue	$ 57,817	$ 78,499	$ 126,223	$ 148,898
Non-U.S. revenue	13,874	22,564	33,957	42,367
Total revenue	$ 71,691	$ 101,063	$ 160,180	$ 191,265

Inventories

Inventories are stated at the lower of cost and net realizable value. 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. The Company records adjustments at least quarterly to inventory for potentially excess, obsolete, slow-moving or impaired items. The Company recorded noncurrent inventory related to inventories that are expected to be realized or consumed after one year of $2,091 and $1,076 as of June 30, 2020 and December 31, 2019, respectively. Noncurrent inventories are primarily related to raw materials purchased in bulk to support long-term expected repairs to reduce costs and are classified in other assets. During the six months ended June 30, 2020 and June 30, 2019, $1,193 and $670, respectively, of inventory was transferred to rental equipment and was considered a noncash transaction in the production and purchase of rental equipment on the consolidated statements of cash flow. Inventories that are considered current consist of the following:

	June 30, 2020	December 31, 2019
Raw materials and work-in-progress	$ 31,925	$ 31,676
Finished goods	5,085	5,174
Less: reserves	(830)	(1,186)
Inventories, net	$ 36,180	$ 35,664

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	3-5 years
Computer equipment and software	2-3 years
Furniture and equipment	3-5 years
Leasehold improvements	Lesser of estimated useful life or remaining lease term

Expenditures for additions, improvements and replacements are capitalized and depreciated to a salvage value of $0. Repair and maintenance costs on rental equipment are included in cost of rental revenue on the consolidated statements of comprehensive income. Repair and maintenance expense, which includes labor, parts and freight, for rental equipment was $598 and $701 for the three months ended June 30, 2020 and June 30, 2019, respectively, and $1,123 and $1,363 for the six months ended June 30, 2020 and June 30, 2019, respectively.

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.

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

Depreciation and amortization expense related to rental equipment and other property and equipment are summarized below for the three and six months ended June 30, 2020 and June 30, 2019, respectively.

	Three months ended June 30,		Six months ended June 30,	
	2020	2019	2020	2019
Rental equipment	$ 1,221	$ 1,594	$ 2,520	$ 3,299
Other property and equipment	1,009	842	1,930	1,603
Total depreciation and amortization	$ 2,230	$ 2,436	$ 4,450	$ 4,902

Property and equipment and rental equipment with associated accumulated depreciation is summarized below as of June 30, 2020 and December 31, 2019, respectively.

	June 30, 2020	December 31, 2019
Property and equipment		
Rental equipment, net of allowances of $355 and $395, respectively	$ 40,614	$ 39,308
Other property and equipment	26,297	24,986
Property and equipment	66,911	64,294
Accumulated depreciation		
Rental equipment	30,678	30,984
Other property and equipment	14,703	13,872
Accumulated depreciation	45,381	44,856
Property and equipment, net		
Rental equipment, net of allowances of $355 and $395, respectively	9,936	8,324
Other property and equipment	11,594	11,114
Property and equipment, net	$ 21,530	$ 19,438

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 as of June 30, 2020 and June 30, 2019.

Goodwill

The changes in the carrying amount of goodwill for the six months ended June 30, 2020 were as follows:

Balance as of December 31, 2019	$ 32,954
Translation adjustment	3
Balance as of June 30, 2020	$ 32,957

Intangible assets

There were no impairments recorded related to the Company's intangible assets as of June 30, 2020 and June 30, 2019. Amortization expense for intangible assets for the three months ended June 30, 2020 and June 30, 2019 was $2,250 and $324, respectively, and for the six months ended June 30, 2020 and June 30, 2019 was $4,492 and $652, respectively.

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

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

June 30, 2020	Average estimated useful lives (in years)	Gross carrying amount	Accumulated amortization	Net amount
Technology	10	$ 77,700	$ 6,799	$ 70,901
Licenses	10	185	169	16
Patents and websites	5	4,490	2,658	1,832
Customer relationships	4	1,347	1,067	280
Commercials	2-3	777	553	224
Total		$ 84,499	$ 11,246	$ 73,253

December 31, 2019	Average estimated useful lives (in years)	Gross carrying amount	Accumulated amortization	Net amount
Technology	10	$ 77,700	$ 2,914	$ 74,786
Licenses	10	185	165	20
Patents and websites	5	4,274	2,308	1,966
Customer relationships	4	1,346	897	449
Commercials	2-3	777	465	312
Total		$ 84,282	$ 6,749	$ 77,533

Annual estimated amortization expense for each of the succeeding fiscal years is as follows:

	June 30, 2020
Remaining 6 months of 2020	$ 4,506
2021	8,723
2022	8,410
2023	7,835
2024	7,830
Thereafter	35,949
	$ 73,253

Current liabilities

Accounts payable and accrued expenses as of June 30, 2020 and December 31, 2019 consisted of the following:

	June 30, 2020	December 31, 2019
Accounts payable	$ 13,189	$ 16,399
Accrued inventory (in-transit and unvouchered receipts) and trade payables	6,992	11,124
Accrued purchasing card liability	2,132	1,675
Accrued franchise, sales and use taxes	408	713
Other accrued expenses	6,642	819
Accounts payable and accrued expenses	$ 29,363	$ 30,730

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

Accrued payroll as of June 30, 2020 and December 31, 2019 consisted of the following:

	June 30, 2020	December 31, 2019
Accrued bonuses	$ 4	$ 87
Accrued wages and other payroll related items	3,157	3,158
Accrued vacation	2,488	2,169
Accrued employee stock purchase plan deductions	756	801
Accrued payroll	$ 6,405	$ 6,215

6. Leases

The Company has entered into operating leases primarily for commercial buildings. These leases have terms which range from 2 years to 8 years, some of which include options to extend the leases for up to 5 years. There are no economic penalties for the Company to extend the lease, and it is not reasonably assured that the Company will exercise the extension options. Operating lease right-of-use assets and liabilities commencing after January 1, 2019 are recognized at commencement date based on the present value of lease payments over the lease term. The operating leases do not contain material residual value guarantees or material restrictive covenants.

The Company leases a property owned by a related party. Operating lease cost for the property was $8 and $16 for the three and six months ended June 30, 2020, respectively, which was included in the total operating lease cost.

Information related to the Company's right-of-use assets and related operating lease liabilities were as follows:

	Six months ended June 30, 2020	Six months ended June 30, 2019
Cash paid for operating lease liabilities	$ 1,183	$ 1,164
Operating lease cost	1,344	1,087
Non-cash right-of-use assets obtained in exchange for new operating lease obligations	4,667	6,418
Weighted-average remaining lease term	2.9 years	2.8 years
Weighted-average discount rate	3.7 %	3.8 %
Maturities of lease liabilities due in the 12-month period ending June 30,		
2021		$ 2,143
2022		1,971
2023		1,752
2024		1,757
2025		846
Thereafter		3,344
		11,813
Less imputed interest		(1,297)
Total lease liabilities		$ 10,516
Operating lease liability - current		$ 1,823
Operating lease liability - noncurrent		$ 8,693
Total lease liabilities		$ 10,516

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

As of June 30, 2020, the Company has additional operating leases for its corporate headquarters in California and industrial space in Texas that have not yet commenced, with total minimum lease payments of $21,548. Lease payments for its corporate headquarters will increase annually by the lesser of the change, if any, in the Consumer Price Index of the Bureau of Labor Statistics of the U.S. Department of Labor or three and one-half percent (3.5%) at each annual adjustment date thereafter. Lease payments for the Company's industrial space in Texas will increase annually by two and one-half percent (2.5%) at each annual adjustment date thereafter. These operating leases are estimated to commence in the first quarter of 2021 with a lease term of 10 to 11 years. The table above excludes lease payments that were not fixed at commencement or modification.

7. 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, restricted stock units and restricted stock awards) 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 other dilutive awards 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 the Company's weighted-average outstanding common shares. Diluted earnings per share is calculated using the Company's weighted-average outstanding common shares including the dilutive effect of stock awards as determined under the treasury stock method.

The computation of EPS is as follows:

	Three months ended June 30,		Six months ended June 30,	
	2020	2019	2020	2019
Numerator—basic and diluted:				
Net income	$ 2,580	$ 10,160	$ 991	$ 15,462
Denominator:				
Weighted-average common shares - basic common stock (1)	21,963,472	21,815,634	21,939,919	21,783,150
Weighted-average common shares - diluted common stock	22,221,356	22,359,679	22,229,744	22,459,101
Net income per share - basic common stock	$ 0.12	$ 0.47	$ 0.05	$ 0.71
Net income per share - diluted common stock	$ 0.12	$ 0.45	$ 0.04	$ 0.69
Denominator calculation from basic to diluted:				
Weighted-average common shares - basic common stock (1)	21,963,472	21,815,634	21,939,919	21,783,150
Stock options and other dilutive awards	257,884	544,045	289,825	675,951
Weighted-average common shares - diluted common stock	22,221,356	22,359,679	22,229,744	22,459,101
Shares excluded from diluted weighted-average shares:				
Stock options	476,385	66,485	252,842	—
Restricted stock units and restricted stock awards	224,860	158,680	47,870	165,060
Shares excluded from diluted weighted-average shares	701,245	225,165	300,712	165,060

(1) Unvested restricted stock units and restricted stock awards are not included as shares outstanding in the calculation of basic earnings per share. Vested restricted stock units and restricted stock awards are included in basic earnings per share if all vesting and performance criteria have been met. Performance-based restricted stock units and restricted stock awards are included in the number of shares used to calculate diluted earnings per share as long as all applicable performance criteria are met, and their effect is dilutive. Restricted stock awards are eligible to receive all dividends declared on the Company's common shares during the vesting period; however, such dividends are not paid until the restrictions lapse.

The computations of diluted net income attributable to common stockholders exclude common stock options, restricted stock units, and restricted stock awards, which were anti-dilutive for the three and six months ended June 30, 2020 and June 30, 2019.

8. 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 consolidated 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 on its consolidated statements of comprehensive income.No significant interest or penalties were recognized during the periods presented.

The Company operates in several taxing jurisdictions, including U.S. federal, multiple U.S. states and the Netherlands. The statute of limitations has expired for all tax years prior to 2016 for federal and prior to 2015 to 2016 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.

The Company determined the income tax provision for interim periods using an estimate of the Company's annual effective tax rate, adjusted for discrete items arising in that quarter. In each quarter, the Company updates its estimated annual effective tax rate, and if the estimated annual effective tax rate changes, a cumulative adjustment is recorded in that quarter. The Company's quarterly income tax provision and quarterly estimate of the annual effective tax rate are subject to volatility due to several factors, including our ability to accurately predict the proportion of our income before provision for income taxes in multiple jurisdictions, the tax effects of our stock-based compensation, and the effects of its foreign entity.

On March 27, 2020, the CARES Act was enacted and signed into U.S. law to provide economic relief to individuals and businesses facing economic hardship as a result of the COVID-19 PHE. The CARES Act includes, among other things, provisions relating to payroll tax credits and deferrals, net operating loss carryback periods, alternative minimum tax credits refunds, modifications to the net interest deduction limitations, and technical corrections to tax depreciation methods for qualified improvement property. The CARES Act did not have a material tax impact on the Company's consolidated financial statement presentation or results as of and for the three and six months ended June 30, 2020. The Company is continuing to assess the future implications of these provisions within the CARES Act.

9. Stockholders' equity

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 June 30, 2020, options to purchase 333 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 has a 2012 Equity Incentive Plan (2012 Plan) under which the Company granted options to purchase shares of its common stock. As of June 30, 2020, options to purchase 138,736 shares of common stock remained outstanding under the 2012 Plan. The 2012 Plan was terminated in connection with the Company's initial public offering in February 2014, 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 2014 Equity Incentive Plan (2014 Plan) that 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, restricted stock awards, stock appreciation rights, performance units and performance shares to its employees, directors and consultants and its parent and subsidiary corporations' employees and consultants.

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

As of June 30, 2020, awards with respect to 1,212,795 shares of the Company's common stock were outstanding, and 1,620,935 shares of common stock remained available for issuance under the 2014 Plan. 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 by an amount 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 2020, no additional shares were added to the 2014 Plan share reserve pursuant to the provision described above.

Stock options

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, as determined by the board of directors, at the deemed fair market value of the shares underlying the options at the date of grant.

The activity for stock options under the Company's stock plans for the six months ended June 30, 2020 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, 2019	980,884	$0.75-$83.30	$ 35.24	2.84	$ 34.07
Granted	—	—	—		
Exercised	(9,324)	1.17-44.19	20.00		
Forfeited	(3,784)	44.19-56.72	51.44		
Expired	—	—	—		
Outstanding as of June 30, 2020	967,776	0.75-83.30	35.33	2.34	7.62
Vested and exercisable as of June 30, 2020	967,776	0.75-83.30	35.33	2.34	7.62
Vested and expected to vest as of June 30, 2020	967,776	$0.75-$83.30	$ 35.33	2.34	$ 7.62

The total intrinsic value of options exercised during the six months ended June 30, 2020 and June 30, 2019 was $269 and $6,870, respectively. As of June 30, 2020, all stock-based compensation expense for options granted under the Plans was recognized.

Stock incentive awards

The Company grants restricted stock units (RSUs) and restricted stock awards (RSAs) under the 2014 Plan (Stock Awards). The Stock Awards vest either based solely on the satisfaction of time-based service conditions or on the satisfaction of time-based service conditions combined with performance criteria. Stock Awards are subject to forfeiture if the holder's services to the Company terminate before vesting.

Stock Awards granted with only time-based service vesting conditions generally vest over a four-year service period, as defined in the terms of each award. Stock Awards that vest based on the satisfaction of time-based service conditions combined with performance criteria generally vest over a three-year service and performance period, based on performance criteria established at the time of the award. The portion of the Stock Award that is earned may equal or be less than the targeted number of shares subject to the Stock Award depending on whether the performance criteria are met.

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

Stock Awards activity for the six months ended June 30, 2020 is summarized below:

Restricted stock units	**Time-based**	**Performance and time-based**	**Total**	**Weighted-average grant date fair value per share**
Unvested restricted stock units as of December 31, 2019	108,976	3,134	112,110	$ 83.48
Granted	181,313	88,458	269,771	44.88
Vested	(30,484)	—	(30,484)	88.71
Forfeited/canceled	(13,519)	(3,134)	(16,653)	81.50
Unvested restricted stock units as of June 30, 2020 (1)	246,286	88,458	334,744	$ 52.68
Unvested and expected to vest restricted stock units outstanding as of June 30, 2020			247,317	$ 53.74

Restricted stock awards	**Time-based**	**Performance and time-based**	**Total**	**Weighted-average grant date fair value per share**
Unvested restricted stock awards outstanding as of December 31, 2019	71,070	62,628	133,698	$ 95.74
Granted	—	—	—	—
Vested	(14,480)	—	(14,480)	98.42
Forfeited/canceled	—	(29,273)	(29,273)	110.27
Unvested restricted stock awards outstanding as of June 30, 2020 (1)	56,590	33,355	89,945	$ 91.45
Unvested and expected to vest restricted stock awards outstanding as of June 30, 2020			58,037	$ 84.75

(1) Outstanding restricted stock units and restricted stock awards are based on the maximum payout of the targeted number of shares.

As of June 30, 2020, the unrecognized compensation cost related to unvested employee restricted stock units and restricted stock awards was $6,438, excluding estimated forfeitures. This amount is expected to be recognized over a weighted-average period of 2.7 years.

Employee stock purchase plan

The Company's 2014 Employee Stock Purchase Plan (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 June 30, 2020, a total of670,678 shares of common stock were available for sale pursuant to the ESPP.

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

The number of shares available for sale under the ESPP is increased annually on the first day of each fiscal year by an amount 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 2020, no additional shares were added to the ESPP share reserve pursuant to the provision described above.

Stock-based compensation

Stock-based compensation expense recognized for the three and six months ended June 30, 2020 and June 30, 2019, was as follows:

	Three months ended June 30,		Six months ended June 30,	
	2020	**2019**	**2020**	**2019**
Stock-based compensation expense by type of award:				
Stock option plan awards	$ 184	$ 776	$ 709	$ 1,923
Restricted stock units and restricted stock awards	892	791	2,975	3,048
Employee stock purchase plan	201	212	377	394
Total stock-based compensation expense	$ 1,277	$ 1,779	$ 4,061	$ 5,365

Employee stock-based compensation expense was calculated based on awards of stock options, restricted stock units and restricted stock awards ultimately expected to vest based on the Company's historical award cancellations. The employee stock-based compensation expense recognized for the six months ended June 30, 2020 and June 30, 2019 has been reduced for estimated forfeitures of stock option plan awards at a rate of 7.3% and 7.3%, respectively. ASC 718 – *Compensation-Stock Compensation* requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

For the three and six months ended June 30, 2020 and June 30, 2019, respectively, stock-based compensation expense recognized under ASC 718, included in cost of revenue, research and development expense, sales and marketing expense, and general and administrative expense was as follows:

	Three months ended June 30,		Six months ended June 30,	
	2020	**2019**	**2020**	**2019**
Cost of revenue	$ 97	$ 199	$ 326	$ 484
Research and development	173	227	493	604
Sales and marketing	459	336	1,071	1,026
General and administrative	548	1,017	2,171	3,251
Total stock-based compensation expense	$ 1,277	$ 1,779	$ 4,061	$ 5,365

401(k) retirement savings plan

The Company maintains a 401(k) retirement savings plan for the benefit of eligible employees. Under the terms of this plan, eligible employees are able to make contributions to the plan on a tax-deferred basis. The Company matched employees' contributions from January 1, 2017 through June 30, 2020. The Company suspended its 401(k) match, effective July 1, 2020. The Company contributed $459 and $505, net of forfeitures, to the 401(k) plan for the six months ended June 30, 2020 and June 30, 2019, respectively.

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

10. Commitments and contingencies

Non-cancelable contractual obligations

The Company enters into non-cancelable contractual obligations for software licenses and maintenance agreements. As of June 30, 2020, the minimum aggregate payments due under specified non-cancelable contractual obligations are summarized as follows:

	Non-cancelable contractual obligations
Remaining 6 months of 2020	$ 289
2021	457
2022	—
2023	—
2024	—
Thereafter	—
	$ 746

Purchase obligations

The Company had approximately $68,200 of outstanding purchase orders with its outside vendors and suppliers as of June 30, 2020.

Warranty obligations

The following table identifies the changes in the Company's aggregate product warranty liabilities for the six and twelve-month periods ended June 30, 2020 and December 31, 2019, respectively:

	June 30, 2020	December 31, 2019
Product warranty liability at beginning of period	$ 12,571	$ 9,530
Accruals for warranties issued	4,914	8,131
Adjustments related to preexisting warranties (including changes in estimates)	(304)	1,433
Settlements made (in cash or in kind)	(3,373)	(6,523)
Product warranty liability at end of period	$ 13,808	$ 12,571

Contract liabilities

Contract liabilities primarily consist of deferred revenue related to lifetime warranties on direct-to-consumer sales revenue when payments are received in advance of services performed under the contract. The contract with the customer states the final terms of the sale, including the description, quantity, and price of each product or service purchase. The increase in deferred revenue related to lifetime warranties for the six months ended June 30, 2020 was primarily driven by $2,845 of payments received in advance of satisfying performance obligations, partially offset by $2,594 of revenue recognized that were included in the deferred revenue balances as of December 31, 2019. Deferred revenue related to lifetime warranties was $17,979 and $17,728 as of June 30, 2020 and December 31, 2019, respectively, and is classified within deferred revenue – current and deferred revenue – noncurrent in the consolidated balance sheet.

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 exclusion from government healthcare programs together with the imposition of significant fines and penalties, as well as significant repayments for patient services previously billed.

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 Health Insurance Portability and Accountability Act of 1996 (HIPAA) was enacted to ensure health insurance portability, reduce healthcare fraud and abuse, guarantee security and privacy of health information, and enforce standards for health information. The Health Information Technology for Economic and Clinical Health Act (HITECH Act), in part, imposes notification requirements of certain security breaches relating to protected health information.The Company believes that it complies in all material respects with the provisions of those regulations that are applicable to the Company's business.

Legal proceedings

Intellectual property lawsuit

On November 21, 2019, Breathe Technologies, Inc. (Breathe), a subsidiary of Hill-Rom Holdings, filed a lawsuit against Inogen, Inc., New Aera, Inc., Silverbow Development, LLC, and Todd W. Allum in the United States District Court for the Northern District of California (N.D. Cal. Lawsuit). Breathe alleged: willful infringement of the '250 patent assigned to Breathe; that inventorship was incorrectly assigned and that Breathe owns rights to certain patents filed by New Aera, Inc. and Silverbow Development LLC; breach of contract; inducing breach of contract; interference with contract; and violation of California Business and Professional Code Section 17200. The complaint seeks to correct inventorship of certain patents now owned by the Company, injunctive relief, compensatory and punitory damages in an unspecified amount including trebling of all damages awarded with respect to infringement of the '250 patent, costs and expenses, including attorneys' fees and expert fees, prejudgment and post-judgment interest and such other relief as the court deems proper. On March 31, 2020, Breathe filed a First Amended Complaint in which it dropped the patent infringement claims in the N.D. Cal. Lawsuit and added another claim for violation of California Business and Professional Code Section 17200. On the same day, Breathe re-filed the '250 patent infringement claims in the United States District Court for the Central District of California (C.D. Cal. Lawsuit). The Company intends to vigorously defend itself against the allegations in both lawsuits. The Company recorded a contingent liability of $6,000 during the three months ended June 30, 2020. The related payable was recorded in accounts payable and accrued expenses and receivable from the New Aera acquisition escrow account in prepaid expenses and other current assets as of June 30, 2020.

Securities class action and derivative lawsuits

On March 6, 2019, plaintiff William Fabbri filed a lawsuit against Inogen, Scott Wilkinson, and Alison Bauerlein, 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. On March 21, 2019, plaintiff Steven Friedland filed a substantially similar lawsuit against the same defendants in the same court. On May 20, 2019, the court issued an order consolidating the two lawsuits under the name *In re Inogen, Inc. Sec. Litig.,* No. 2:19-cv-01643-FMO-AGR, appointing Dr. John Vasil and Paragon Fund Management as lead plaintiffs, and appointing Robbins Geller Rudman & Dowd LLP and Glancy Prongay & Murray LLP as lead plaintiffs' counsel. On July 10, 2019, the lead plaintiffs filed a consolidated amended complaint on behalf of a purported class of purchasers of the Company's common stock between November 8, 2017 and May 7, 2019. The complaint generally alleges that the defendants failed to disclose that: (i) Inogen had overstated the true size of the total addressable market for its portable oxygen concentrators and had misstated the basis for its calculation of the total addressable market; (ii) Inogen had falsely attributed its sales growth to the strong sales acumen of its salesforce, rather than to deceptive sales practices; (iii) the growth in Inogen's domestic business-to-business sales to home medical equipment providers was inflated, unsustainable and was eroding direct-to-consumer sales; and (iv) Inogen's decision to focus on sales over rentals of portable oxygen concentrators harmed its ability to serve the Medicare market, in violation of sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended. The complaint seeks 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 deems proper. On January 2, 2020, the court dismissed the consolidated amended complaint with leave to amend. On January 9, 2020, the plaintiffs filed a second amended complaint generally alleging substantially similar claims as those in the previous complaint. On January 23, 2020, the defendants filed a motion to dismiss the second amended complaint. The Company intends to vigorously defend itself against these allegations.

On June 26, 2019, plaintiff Twana Brown filed a shareholder derivative lawsuit against Inogen, Scott Wilkinson, Alison Bauerlein, Benjamin Anderson-Ray, Scott Beardsley, R. Scott Greer, Raymond Huggenberger, Heath Lukatch, Loren McFarland, and Heather Rider in the United States District Court for the Central District of California. The complaint purports to bring claims on behalf of Inogen against the individual defendants for breaches of their fiduciary duties as directors and/or officers of Inogen, unjust enrichment, waste of corporate assets and violations of section 14(a) of the Securities Exchange Act of 1934, as amended. The complaint generally alleges similar claims to the securities class action. The complaint seeks compensatory damages and restitution in an unspecified amount, changes to the Company's corporate governance and internal procedures, costs and expenses, including attorneys' fees and expert fees, and such other relief as the court deems proper. On August 5, 2019, the court issued an order staying the derivative action pending the resolution of the motion to dismiss stage in *In re Inogen, Inc. Sec. Litig.* Between October 7, 2019 and October 31, 2019, three additional shareholder derivative complaints were filed in the United States District Court for the Central District of California based on similar factual allegations. These lawsuits purport to bring claims on behalf of Inogen for breach of fiduciary duty, unjust enrichment, waste of corporate assets, insider trading and misappropriation of information, and violations of section 14(a) of the Securities Exchange Act of 1934, as amended. On January 13, 2020, the court consolidated the four derivative lawsuits before it under the name *In re Inogen, Inc. S'holder Deriv. Litig.*, Lead Case No. 2:19-cv-5568-FMO-AGR and ordered that the consolidated action be stayed pending the resolution of the motion to dismiss stage in *In re Inogen, Inc., Sec. Litig.*

On September 13, 2019, plaintiff Dustin Weller filed a shareholder derivative lawsuit against Inogen, Scott Wilkinson, Alison Bauerlein, Benjamin Anderson-Ray, Scott Beardsley, R. Scott Greer, Raymond Huggenberger, Heath Lukatch, Loren McFarland, and Heather Rider in the United States District Court for the District of Delaware captioned *Weller v. Wilkinson, et al.*, No. 1:19-cv-01723-MN. On October 17, 2019, plaintiff Sharokh Soltanipour filed a shareholder derivative lawsuit against the same defendants in the same court, captioned *Soltanipour v. Wilkinson, et al.*, No. 1:19-cv-1968-MN. The complaints generally allege similar claims to those in *In re Inogen, Inc., S'holder Deriv. Litig.* The complaints purport to bring claims on behalf of Inogen for breach of fiduciary duty, unjust enrichment, waste of corporate assets, abuse of control, gross mismanagement, insider selling and misappropriation of information, violations of section 14(a) of the Securities Exchange Act of 1934, as amended, and for contribution from certain of the individual defendants. The complaints seek compensatory damages in unspecified amounts, changes to the Company's corporate governance and internal procedures, return of compensation, disgorgement of profits from sale of stock, costs and expenses, including attorneys' fees and expert fees, and such other relief as the court deems proper. On May 15, 2020, the court consolidated the two derivative lawsuits before it under the name *In re Inogen, Inc. S'holder Deriv. Litig.*, Lead Case No. 1:19-cv-01723-MN-JLH. On July 8, 2020, the court ordered that the consolidated action be stayed pending the resolution of the motion to dismiss in the securities class action, *In re Inogen, Inc., Sec. Litig*.

Other litigation

In addition to the lawsuits discussed above, 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 arising in the normal course of business 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.

11. Foreign currency exchange contracts and hedging

As of June 30, 2020 and June 30, 2019, the Company's total non-designated and designated derivative contracts had notional amounts totaling approximately $3,152 and $12,278, respectively, and $2,388 and $8,926, respectively. These contracts were comprised of offsetting contracts with the same counterparty, each expires within one to six months. During the six months ended June 30, 2020 and June 30, 2019, these contracts had, net of tax, an unrealized gain of $90 and an unrealized loss of $76, respectively.

The nonperformance risk of the Company and the counterparty did not have a material impact on the fair value of the derivatives. During the six months ended June 30, 2020 and June 30, 2019, there were no ineffective portions relating to these hedges and the hedges remained effective through their respective settlement dates. As of June 30, 2020, the Company had five designated hedges and one non-designated hedge. As of June 30, 2019, the Company had thirteen designated hedges and three non-designated hedges.

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 consolidated 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 flows, revenue, sources of revenue and results of operations, operating and other expenses;
- our assessment and expectations regarding the impact of the COVID-19 public health emergency (PHE) on our business;
- our assessment and expectations regarding reimbursement rates, future rounds of competitive bidding, Centers for Medicare and Medicaid Services (CMS) changes associated with the COVID-19 PHE impacting respiratory care, and future changes in rental revenue;
- our expectations regarding regulatory approvals and government and third-party payor coverage and reimbursement;
- our ability to develop new products, improve our existing products and increase the value of our products, including the integration of non-invasive ventilation (NIV) technology into our existing business;
- our expectations of the impact of the COVID-19 PHE on sales, productivity, hiring, media expenditures, physician-based sales team and physician referrals, and worldwide demand for oxygen and NIV therapies;
- our expectations regarding the timing of new products and product improvement launches, as well as product features and specifications;
- market share expectations, unit sales, business strategies, financing plans, expansion of our business, competitive position, industry environment, and potential growth opportunities;
- our expectations regarding the market size, market growth and the growth potential for our business;
- our ability to grow our business and enter new markets;
- our expectations regarding the average selling prices and manufacturing costs of our products, including our expectations to continue to reduce average unit costs for our systems;
- our expectations regarding our sales and marketing strategy channels;
- our expectations with respect to our European and U.S. facilities and our expectations with respect to our contract manufacturer in Europe;
- our expectations regarding tariffs being imposed by the U.S. on certain imported materials and products;
- our ability to successfully acquire and integrate companies and assets, including our recent acquisition of New Aera, Inc. (New Aera);
- our expectations regarding the impact and implementation of trade regulations on our supply chain;
- our expectations regarding excess tax benefits or deficiencies from stock-based compensation;
- our expectations of future accounting pronouncements or changes in our accounting policies;
- our assessments and estimates of our effective tax rate;
- our internal control environment;
- the effects of seasonal trends on our results of operations and estimated hiring plans;
- our expectation that our existing capital resources 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 twelve months; and
- the effects of competition.

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

Forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements. We discuss these risks in greater detail in 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. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for us to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the future events and trends discussed in this Quarterly Report on Form 10-Q may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

The forward-looking statements made in this Quarterly Report on Form 10-Q relate only to events as of the date on which the statements are made. 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.

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,” “G5,” “Live Life in Moments, not Minutes,” “Never Run Out of Oxygen,” “Oxygen Therapy on Your Terms,” “Oxygen.Anytime.Anywhere,” “Reclaim Your Independence,” “Intelligent Delivery Technology,” “Inogen At Home,” the Inogen design, “TIDAL ASSIST,” “TAV,” and “SIDEKICK” are registered trademarks with the United States Patent and Trademark Office of Inogen, Inc. We own pending applications for “Inogen,” “MOMENTUM TRANSFER” and “SONIC BLADE” with the United States Patent and Trademark Office. We own trademark registrations for the mark “Inogen” in Argentina, Australia, Canada, China, Columbia, Ecuador, South Korea, Mexico, Europe (European Union Registration), Iceland, India, Israel, Japan, Kuwait, New Zealand, Norway, Peru, Turkey, Singapore, and Switzerland. We own pending applications for the mark “Inogen” in Australia, Brazil, Chile, China, Europe (European Union application), India, Malaysia, Paraguay, South Africa and Uruguay. We own a trademark registration for the mark “イノジェン” in Japan. We own trademark registrations for the marks “印诺真” and “艾诺根” in China. We own trademark registrations for the mark “Inogen One” in Australia, Canada, China, South Korea, Mexico, and Europe (European Union Registration). We own a trademark registration for the mark “Satellite Conserver” in Canada. We own a trademark registration for the mark “Inogen At Home” in Europe (European Union Registration). We own trademark registrations for the mark “G4” in Europe (European Union Registration) and the United Kingdom. We own trademark registrations for the mark “G5” in Europe (European Union Registration) and the United Kingdom. We own trademark applications for the Inogen design in Bolivia and China. We own a trademark application for the mark “إنوجن” in Saudi Arabia. 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. and its subsidiaries.

The following discussion of our financial condition and results of operations should be read together with our consolidated 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 are based upon our consolidated financial statements which have been prepared in accordance with generally accepted accounting principles in the United States of America, 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 consolidated financial statements during the three and six months ended June 30, 2020 compared to those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2019, as filed with the SEC on February 25, 2020.

COVID-19 PHE

The novel coronavirus outbreak of COVID-19 has had and likely will continue to have significant adverse effects on businesses and healthcare institutions around the world. While it is not possible at this time to estimate the overall impact that the COVID-19 PHE could have on our business, the continued rapid spread of COVID-19, both across the United States and throughout much of the world, and the measures taken by the governments of countries and local authorities affected has adversely impacted and will likely continue to adversely impact our business operations, demand for our products, the manufacture or shipment of our products, and our financial condition and operating results.

Our priorities during the COVID-19 PHE include protecting the health and safety of our employees and supporting our patients and customers. Given the COVID-19 impact to the respiratory system, oxygen therapy is prescribed by healthcare professionals for treatment and recovery for certain patients with COVID-19. We also believe stationary oxygen concentrators, and, secondarily, portable oxygen concentrators (POCs) could provide relief to global hospital systems by allowing appropriate patients to be treated in the home, such as patients early in the disease progression or those in recovery post hospital discharge, thus making room for more severe patients who need treatment in the hospital.

However, the COVID-19 PHE adversely impacted our consolidated operating results in the three months ended June 30, 2020. We experienced lower direct-to-consumer sales starting toward the end of the first quarter of 2020 and continuing throughout the second quarter of 2020. We believe the social distancing, self-quarantine and related mandates and behaviors emanating from the COVID-19 PHE, including shelter-in-place orders, reduced travel, and lower consumer confidence reduced direct-to-consumer sales. While there was an initial surge in demand for oxygen concentrators by our home medical equipment (HME) providers early in the COVID-19 PHE, business-to-business demand declined in the second quarter of 2020 due to physician offices limiting patient interactions for chronic obstructive pulmonary disease (COPD) patient referrals, lower retail sales, HME providers minimizing patient interactions in response to the COVID-19 PHE, which includes replacing existing oxygen patient setups with POCs, and HME providers turning their purchasing focus to stationary oxygen concentrators to treat COVID-19 patients. Also, sales in Europe declined associated with the temporary closure of certain respiratory assessment centers and continued tender delays in certain markets due to the COVID-19 pandemic.

The COVID-19 PHE has also and could continue to lead to volatility in consumer access to our products due to government actions impacting our ability to produce and ship products or impacting consumers' movements and access to our products. The COVID-19 PHE has caused and may continue to cause reduced demand for our products across all channels due to the global economic environment and reduced regular physician interactions and testing which could lead to a lower rate of diagnosis for long-term oxygen therapy. Additionally, while we initially planned for sales and marketing expansion in 2020, we believe this would have been negatively impacted due to the COVID-19 PHE, which may reduce the close rates on patients who contact us resulting in less efficient marketing spend, reduce the number of oxygen therapy patients who respond to our marketing campaigns, reduce the number of sales representatives hired, or impact the results or timing of a pricing trial. Given these uncertainties, we have implemented cost savings by decreasing personnel hires, suspending our 401(k) match effective July 1, 2020, and reducing advertising spend, while also increasing rental setups to improve lead utilization.

The health and safety of our people and their families continues to be our primary focus.Our ability to continue to operate without any significant negative operational impacts will in part depend on our ability to protect our employees and our supply chain. As the COVID-19 PHE has developed, we have taken numerous steps to help ensure the health and safety of our employees and their families. We follow recommended actions of government and health authorities to protect our employees, with particular measures in place for those working in our manufacturing facilities. Employees whose tasks can be done offsite have been instructed to work from home and most of our total personnel continue to work from home. We have also worked closely with local and national officials to keep our manufacturing facilities open due to the essential nature of our products. For the six months ended June 30, 2020, we were able to broadly maintain our operations. We intend to continue to work with government authorities and implement our employee safety measures to help ensure that we are able to continue manufacturing and shipping our products during the COVID-19 PHE. However, the COVID-19 PHE could result in an unforeseen disruption to our supply chain that could impact our operations.

For additional information on risk factors that could impact our results, please refer to “Risk Factors” in Part II, Item 1A of this Quarterly Report on Form 10-Q.

Overview

We are a medical technology company that primarily develops, manufactures and markets innovative POCs used to deliver supplemental long-term oxygen therapy to patients suffering from chronic respiratory conditions. Long-term oxygen therapy is defined as the provision of oxygen therapy for use at home in patients who have chronic low blood oxygen levels (hypoxemia). 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 as little as approximately 2.8 pounds with a single battery. Our Inogen One systems range from 2.6 to 6.5 hours of battery life 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. We believe 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.

We believe that we were the first oxygen therapy manufacturer to employ a direct-to-consumer marketing strategy, meaning we advertise directly to patients, process their physician paperwork, and provide clinical support as needed, which we believe has contributed to our market leadership position in the POC market. While other manufacturers have also begun direct-to-consumer marketing campaigns to drive patient sales, we believe we are the only POC manufacturer that employs a direct-to-consumer rental strategy in the United States, meaning we bill Medicare or insurance on the consumer’s behalf.

We derive the majority of our revenue from the sale and rental of our Inogen One systems and related accessories to patients, insurance carriers, home healthcare providers, resellers, charitable organizations, and distributors, including our private label partner. We sell multiple configurations of our Inogen One and Inogen At Home 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 long-term 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 long-term oxygen therapy is delivered.

To accomplish this goal and to grow our revenue, we intend to:

- *Expand our domestic direct-to-consumer sales and physician-based sales teams and increase productivity.* During the year ended December 31, 2019, the number of inside sales representatives decreased to 329 from 446 as of December 31, 2018; however, overall sales representative productivity improved during the period. In the second half of 2019, we restarted our sales capacity expansion efforts with a more measured approach, selectively hiring new sales representatives across all three of our facilities. Going forward, except as otherwise limited by the impact of the COVID-19 PHE, our long-term plan is to continue to hire to expand sales capacity while focusing on increased productivity, improved sales personnel and lead distribution systems, improved training, and more emphasis on the availability of the Inogen One G5®, which has higher patient preference. We also plan to expand our physician referral team to drive increased physician referrals for rental patients and direct-to-consumer sales. This specialized sales team consisted of 20 employees as of December 31, 2019. However, our sales expansion and productivity improvements planned in 2020 have been negatively impacted due to the COVID-19 PHE. As a result of the COVID-19 PHE, we slowed down sales representative additions in the second quarter of 2020 and plan to primarily focus on replacement of attrition for the remainder of 2020. We believe this has reduced and may continue to reduce the number of oxygen therapy patients who purchase our products through our direct-to-consumer sales channel. We have seen and believe we could continue to see a decline in sales in our direct-to-consumer channel until patient mobility and consumer confidence increases. As this is a dynamic situation, we plan to continue to monitor the COVID-19 PHE in the United States and may adjust our sales plans accordingly.
- *Expand our domestic direct-to-consumer marketing, drive better lead utilization, and optimize pricing.* We expended $40.3 million in media and advertising costs in 2019 compared to $30.8 million in 2018, to drive greater patient awareness of our products and increase patient inquiries about their ability to switch from their current oxygen products to our technology. Media and advertising costs declined to $7.2 million in the second quarter of 2020 compared to $11.6 million in the second quarter of 2019, primarily associated with reductions due to the COVID-19 PHE and increased focus on new rental setups. We initially planned to continue to increase marketing spend to drive consumer and physician awareness of our products in 2020. We also initially planned to perform a pricing trial in 2020 to optimize pricing in our direct-to-consumer sales channel as well as look for opportunities to improve the close rate of leads through product offerings, pricing, and partnerships with HME providers. However, due to the COVID-19 PHE, we revised these plans as discussed in our Quarterly Report on Form 10-Q for the period ended March 31, 2020, and we are continuing to reduce marketing spend during the COVID-19 PHE due to the lower return on those investments and to conserve cash. As this is a dynamic situation, we plan to continue to monitor the progression of the COVID-19 PHE in the United States and may adjust our marketing plan accordingly.

- *Expand our domestic HME provider and reseller sales in the face of reimbursement uncertainty.* We are also focused on building our domestic business-to-business partnerships, including relationships with distributors, key accounts, resellers, our private label partner, traditional HME providers, and charitable organizations. We offer patient-preferred, low service cost products and financing programs to help providers convert their businesses to a non-delivery POC business model.

  While HME providers have been adopting our products in prior quarters, growth has been challenged due to difficulties in their ongoing efforts to restructure from the delivery business model to the non-delivery portable model, lack of access to available credit, provider capital expenditure constraints, and pending competitive bidding Round 2021 and the lack of visibility to who will win contracts and any change in reimbursement rates. However, supplemental oxygen is a treatment prescribed by healthcare professionals for some patients with COVID-19. While there was an initial surge in demand for oxygen concentrators by our HME providers early in the COVID-19 PHE, business-to-business demand declined in the second quarter of 2020 due to physician offices limiting patient interactions for COPD patient referrals, lower retail sales, HME providers minimizing patient interactions in response to the COVID-19 PHE which includes replacing existing oxygen patient setups with POCs, and HME providers turning their purchasing focus to stationary oxygen concentrators to treat COVID-19 patients.

- *Expand our rental revenues through a dedicated rental intake team.* During the year ended December 31, 2019, we added a rental intake team to focus exclusively on new rental additions to drive overall sales productivity and simplify training. We ended 2019 with 25 patient intake representatives and administrative personnel and have scaled and plan to continue to scale the rental intake team in 2020, which we believe will lead to increased patients on service and growth in rental revenue in future periods. Due to the COVID-19 PHE, we have also seen Medicare and commercial payors reduce the administrative burden for oxygen therapy, which we believe will increase rental setups during the COVID-19 PHE, and we have also seen increased reimbursement rates in some areas for Medicare beneficiaries, which should also increase rental revenue during the COVID-19 PHE.

- *Increase international business-to-business adoption.* Although our main growth opportunity remains POC adoption in the United States given what we still believe is a relatively low penetration rate, we believe there is a large international market opportunity. In order to take advantage of these international markets, we have built out an infrastructure over the past few years, which includes sales in 46 international countries and a contract manufacturing partner, Foxconn, located in the Czech Republic to support European sales volumes. As in the United States, while there was an initial surge in demand for oxygen concentrators by our international HME customers early in the COVID-19 pandemic, international demand declined in the second quarter of 2020 due to the temporary closure of certain European respiratory assessment centers due to the COVID-19 pandemic and continued tender delays in certain European markets. In addition, as in the United States, providers turned their focus to supplying stationary oxygen concentrators with higher flow characteristics in response to the COVID-19 pandemic. To grow our international sales markets, we are also in the process of developing regulatory and sales pathways to capture opportunities in new and emerging markets. We expect to begin sales in the Chinese market as early as the end of 2021 although this could be delayed due to regulatory clearance delays, other impacts of the COVID-19 pandemic or government actions, by the United States or China that impose barriers or restrictions that would impact our ability to access the Chinese market. Over time, as the U.S. and European markets mature, our growth will depend on our ability to drive POC adoption in emerging markets, where limited oxygen therapy treatment exists today. However, growth may also be limited by currency fluctuations, capital expenditure constraints, ongoing restructuring challenges, and tender uncertainty.

- *Invest in our oxygen product offerings to develop innovative products* We incurred $3.3 million and $1.5 million for the three months ended June 30, 2020 and June 30, 2019, respectively, and $6.9 million and $3.1 million for the six months ended June 30, 2020 and June 30, 2019, respectively, in research and development expenses, and we intend to continue to make such investments in the foreseeable future. We launched our fifth-generation POC, the Inogen One G5, in our direct-to-consumer channel during the second quarter of 2019, in our domestic business-to-business channel during the third quarter of 2019, and in certain markets in our international business-to-business channel in the fourth quarter of 2019. Some international markets require additional regulatory or reimbursement clearances to release the product, and we are in the process of obtaining additional clearances to access additional markets. The Inogen One G5 weighs 4.7 pounds and produces 1,260 ml per minute of oxygen output, with very quiet operation at 38 dBA and our longest battery life at 6.5 hours for a single battery and up to 13 hours for a double battery. We estimate that the Inogen One G5 is suitable for over 90% of ambulatory long-term oxygen therapy patients based on our analysis of the patients who have contacted us and their clinical needs. We expect the Inogen One G5 to obsolete the Inogen One G3® over the intermediate term. We expect manufacturing cost for our Inogen One G5 to be at parity with our Inogen One G3 in the third quarter of 2020, and we still expect the Inogen One G5 to be our lowest cost to manufacture over time. The Inogen One G5 represented more than 66% of total domestic POC units sold in the six months ended June 30, 2020, showing the strong demand for this product from both patients and providers.

Inogen Connect, our connectivity platform on our Inogen One G4® and Inogen One G5 products in the United States and Canada is compatible with Apple and Android platforms and includes patient features such as purity status, battery life, product support functions, notification alerts, and remote software updates. We believe home oxygen providers will also find features such as remote troubleshooting, equipment health checks, and location tracking to help drive operational efficiencies when transitioning away from the oxygen tank delivery model.

- *Expand our product offerings.* In August 2019, we acquired New Aera. New Aera's patented and FDA-cleared Tidal Assist® Ventilator (TAV®) system is designed to deliver increased air flow and pressure from an approximately 4-ounce pocket-size unit, features a state-of-the-art nasal pillow interface, and is compatible with certain oxygen concentrators, oxygen cylinders, wall gas, and certain medical air sources. TAV therapy with oxygen has been clinically demonstrated during periods of exercise to reduce breathlessness, increase exercise endurance, and improve oxygen saturation for patients suffering from certain chronic lung disease compared to oxygen therapy alone. We began a limited launch of the TAV product in December 2019 in our domestic direct-to-consumer channel and in our domestic business-to-business channel. We plan to only sell this product across our domestic direct-to-consumer channel and in our domestic business-to-business channel in the remainder of 2020, although we expect limited contributions to revenue in 2020. The COVID-19 PHE also had an impact on sales of this product in the second quarter of 2020, primarily due to lower retail demand. We plan to incorporate the TAV technology directly into our Inogen One POCs and make the TAV product compatible with our Inogen At Home stationary concentrators to continue to advance patient preference and maintain our technology leadership position in the long-term oxygen therapy market.

  In addition, we plan to use this technology as a platform to expand our total addressable market into the high-growth NIV market, where we believe there is a significant worldwide untreated market opportunity. We believe this market could undergo disruption similar to oxygen given the immobile nature of legacy NIV product offerings. The monthly Medicare reimbursement rate is significantly higher for NIV products than oxygen therapy at a minimum of $934 a month. Also, effective January 1, 2019, a new Medicare Healthcare Common Procedure Coding System (HCPCS) code has been added to allow billing for a multi-function ventilator that includes both ventilation and oxygen.

  It is uncertain if the TAV product acquired from New Aera will be reimbursable in its current configuration under HCPCS code E0466. We requested confirmation on the assigned HCPCS codes for the TAV system from the Pricing, Data Analysis, and Coding (PDAC) Contractor in August 2019 following the closing of the New Aera transaction. In August 2019, we received positive confirmation that this product was assigned HCPCS code E0466. However, in September 2019, we received a revised communication that the product was assigned HCPCS code E1390 and E1352, which was then revoked at our request in December 2019. In September 2019, we appealed to the CMS, and in January 2020 our appeal was denied. We are currently pursuing additional appeal opportunities. If we do not receive revised coding, it could limit this product's adoption by HME providers and also our direct rentals until revisions are made to the product to meet the coding requirements. In addition, the Medicare Coverage Advisory Committee (MEDCAC) recently had a meeting on July 22, 2020 to discuss home use of non-invasive positive pressure ventilation in patients with chronic respiratory failure consequent to COPD. CMS is seeking MEDCAC's recommendations regarding the characteristics that define those patient selection and usage criteria. This request could signal forthcoming changes in Medicare coverage of these items, and possibly changes in HCPCS codes, which could impact our NIV business and growth initiatives. For a discussion of certain significant risks relating to the TAV reimbursement, see the risk factor entitled "*The competitive bidding process under Medicare could negatively affect our business and financial condition*."

We have been developing and refining the manufacturing of our Inogen One systems since 2004. While nearly all of our manufacturing and assembly processes were originally outsourced, assembly of the compressors, sieve beds, concentrators and certain manifolds were brought in-house in order to improve quality control and reduce cost. In support of our European sales, we use a contract manufacturer located in the Czech Republic to manufacture high volume products and perform product repairs to improve delivery to our European accounts. We expect to maintain our assembly operations for our products at our facilities in Richardson, Texas and Goleta, California. In 2020, we are focused on reducing the cost of our Inogen One G5 product, expanding manufacturing of the TAV product and our oxygen concentrator products, and increasing the robustness of our supply chain to reduce potential component constraints as we grow our business.

We also use lean manufacturing practices to maximize manufacturing efficiency. We rely on third-party manufacturers to supply several components of our products. We typically enter into master service 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, TAV-compatible stationary concentrators, columns, and some molded plastic components. We believe that maintaining a single source of supply allows us to control production costs and inventory levels and to manage component quality. In order to mitigate against the risks related to a single source of supply, for certain components we qualify alternative suppliers and develop contingency plans for responding to disruptions. However, any reduction or halt in supply from one of these single-source suppliers could limit our ability to manufacture our products or devices until a replacement supplier is found and qualified. For additional discussion of potential risks related to our manufacturing and raw materials, please see the risk factor entitled "*We obtain some of the components, subassemblies and completed products included in our products from a single source or a limited group of manufacturers or suppliers, and the partial or complete loss of one or more of these manufacturers or suppliers could cause significant production delays, an inability to meet customer demand, substantial loss in revenue, and an adverse effect on our financial condition and results of operations.*"

Historically, we have generated a majority of our revenue from sales and rentals to customers in the United States. In the three months ended June 30, 2020 and June 30, 2019, approximately 19.3% and 22.3%, respectively, and 21.2% and 22.2% for the six months ended June 30, 2020 and June 30, 2019, respectively, of our total revenue was from sales to customers outside the United States, primarily in Europe. Approximately 77.2% and 71.8% of the non-U.S. revenue for the three months ended June 30, 2020 and June 30, 2019, respectively, and 72.2% and 71.6% for the six months ended June 30, 2020 and June 30, 2019, respectively, was invoiced in Euros with the remainder invoiced in United States dollars. We sell our products in 46 countries outside the United States through our wholly-owned subsidiary, distributors or directly to large "house" accounts, which include gas companies, HME 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.

Our total revenue was $71.7 million and $101.1 million for the three months ended June 30, 2020 and June 30, 2019, respectively, and $160.2 million and $191.3 million for the six months ended June 30, 2020 and June 30, 2019, respectively. The decrease in total revenue in the three months ended June 30, 2020 compared to the three months ended June 30, 2019 was primarily due to a decline in direct-to-consumer sales and domestic and international business-to-business sales, primarily associated with the COVID-19 PHE. Similarly, the decrease in total revenue in the six months ended June 30, 2020 compared to the six months ended June 30, 2019, was primarily due to a decline in direct-to-consumer sales and domestic and international business-to-business sales, primarily associated with the COVID-19 PHE. We generated net income of $2.6 million and $10.2 million for the three months ended June 30, 2020 and June 30, 2019, respectively, and $1.0 million and $15.5 million for the six months ended June 30, 2020 and June 30, 2019, respectively. We generated Adjusted EBITDA of $10.0 million and $16.8 million in the three months ended June 30, 2020 and June 30, 2019, respectively, and $14.1 million and $27.9 million for the six months ended June 30, 2020 and June 30, 2019, respectively, (see "Non-GAAP financial measures" for reconciliations between U.S. GAAP and non-GAAP results). As of June 30, 2020, our retained earnings were $82.4 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, our Inogen At Home stationary oxygen concentrators and our TAV products. We plan to grow our system sales in the coming years through multiple strategies including: hiring additional sales representatives, productivity improvements, investing in consumer awareness through increased marketing efforts, 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, although, as mentioned above, these plans have been and may continue to be impacted by the COVID-19 PHE. While we believe most HME providers are still in the process of converting their business model to a non-delivery model and purchase POCs, growth has been challenged and we expect it could continue to be challenged due to the COVID-19 PHE, their ongoing restructuring efforts, lack of access to available credit, provider capital expenditure constraints, and pending competitive bidding Round 2021 with the lack of visibility to who will win contracts and any change in reimbursement rates. 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, their physician and the physician's staff, and includes an in-depth analysis and review of our product, the patient's diagnosis and prescribed oxygen or NIV therapy, including procuring an oxygen prescription, although, as discussed above, this process has been disrupted due to the COVID-19 PHE and we expect that such disruption will continue for the duration of the COVID-19 PHE. 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 a full system is deployed, the patient has 30 calendar days to return the product, subject to the payment of a minimal processing and handling fee. Approximately 6-10% 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 distributors, HME oxygen and NIV providers, our private label partner, resellers, and charitable organizations 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 products 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, business restructuring activities toward a non-delivery model, capital constraints, and overall changes in the net oxygen and NIV therapy patient populations, and is presently being impacted by the COVID-19 PHE. Products are shipped freight on board (FOB) Inogen dock domestically, and based on financial history and profile, businesses may either prepay or receive extended payment terms. Products are shipped both FOB Inogen dock and Delivery Duty Paid (DDP) for certain international shipments depending on the shipper used. DDP shipments are Inogen's property until title has transferred which is upon duty being paid and delivered to the customer. As a result of these factors, product purchases can be subject to changes in demand by customers.

We sold approximately 42,500 systems in the three months ended June 30, 2020 and 56,500 systems for the same period in 2019. We sold approximately 95,900 systems in the six months ended June 30, 2020 compared to 106,900 systems for the same period in 2019. 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, their 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 or NIV therapy, and their medical history to confirm the appropriateness of our product for the patient's oxygen therapy or NIV 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 for oxygen. Once the product is deployed, the patient receives instruction on product use and may receive 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 period of time from initial contact with a patient to billing can vary significantly and be up to one month or longer. However, due to the COVID-19 PHE, CMS has reduced the paperwork requirements for Medicare oxygen therapy patients, as discussed in more detail in the Reimbursement section below, effective in early March 2020.

Rental revenue increased in the three months ended June 30, 2020 as compared to the three months ended June 30, 2019, primarily due to a greater number of patients on service and higher Medicare reimbursement rates. Medicare reimbursement rates for oxygen therapy increased 1.5% to 3.5%, effective January 1, 2020. In addition, as part of the CARES Act (discussed in more detail in the Reimbursement section below), the 2% Medicare sequestration reduction was temporarily eliminated, and Medicare reimbursement rates for non-rural, non-competitive bid areas through the duration of the COVID-19 PHE were increased to a 75/25 blended rate retroactive to March 6, 2020. The 50/50 blended rate for HME providers in rural and non-contiguous, non-competitive bid areas was also extended for the duration of the COVID-19 PHE, which could increase the rates in 2021 if the COVID-19 PHE continues. We plan to add new rental patients on service in future periods through multiple strategies, including expanding our rental intake team and physician-based sales teams, expanding our direct-to-consumer marketing efforts, investing in patient and physician awareness, and securing additional insurance contracts.

A portion of rentals include a capped rental period during which no additional reimbursement is allowed unless additional criteria are met. In this scenario, the ratio of billable patients to total 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 of eligible reimbursement and enter the capped rental period. 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 had approximately 26,400 and 25,900 oxygen rental patients as of June 30, 2020 and June 30, 2019, respectively. Management focuses on patients on service as 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 location, the number of capped patients, write-offs for uncollectable balances, and rental revenue adjustments.

Reimbursement

Medicare and private insurance rentals represented 8.5% and 5.1% of our total revenue in the three months ended June 30, 2020 and June 30, 2019, respectively, and 7.1% and 5.5% in the six months ended June 30, 2020 and June 30, 2019, respectively. In cases where we rent our long-term oxygen therapy solutions directly to patients, we bill third-party payors, such as Medicare or private insurance, for monthly rentals on behalf of our patients. We process and coordinate all physician paperwork necessary for reimbursement of our solutions. A common medical criterion for long-term oxygen therapy reimbursement is insufficient blood oxygen saturation level. Our team in sales and rental intake are trained on how to verify benefits, review medical records and process physician paperwork. Additionally, an independent internal review is performed, and our products are not deployed until after physician paperwork is processed and reimbursement eligibility is verified and communicated to the patient.

We rely significantly on reimbursement from Medicare and private payors, including Medicare Advantage plans, Medicaid and patients for our rental revenue. For the three and six months ended June 30, 2020, approximately 80.0% and 79.2%, respectively, of our rental revenue was derived from Medicare's traditional fee-for-service reimbursement programs. The U.S. list price for our stationary oxygen rentals (HCPCS E1390) is $260 per month and the U.S. list price for our oxygen generating portable equipment (OGPE) rentals (HCPCS E1392) is $70 per month. The average Medicare reimbursement rates in competitive bidding areas (CBAs) in 2018 were $77.03 a month for E1390 and $36.06 a month for E1392. These are the two primary codes that we bill to Medicare and other payors for our oxygen product rentals.

There have been significant U.S. reimbursement and policy changes associated with the COVID-19 PHE that impact oxygen therapy. The CARES Act allows the U.S. Department of Health and Human Services (HHS) to waive certain Medicare telehealth payment requirements during the COVID-19 PHE declared by the HHS on January 31, 2020 to allow beneficiaries in all areas to receive telehealth services, including at their home, starting March 6, 2020. H.R. 6074 also granted authority to waive certain requirements. Under this authority, CMS clarified that HHS would not conduct audits to determine whether there was a prior physician-patient relationship for telehealth claims submitted during the COVID-19 PHE. The CARES Act included the extension of the 50/50 blended rate for HME in rural and non-contiguous, non-competitively bid areas and established a new 75/25 blended rate for all other non-competitively bid areas through the duration of the COVID-19 PHE. The 75/25 blended rate is retroactive to March 6, 2020. While the duration of the current emergency is impossible to predict, the Zika virus PHE lasted approximately 360 days, and the H1N1 flu PHE lasted approximately 450 days. The CARES Act also included a temporary elimination of the 2% percent Medicare sequestration reduction that went into effect in 2013. This relief is effective May 1, 2020 through December 31, 2020, and extends the end date of the sequester by one year, through 2030, in order to offset the 2020 suspension.

On April 6, 2020, an Interim Final Rule (IFR) was published in the Federal Register for policy and regulatory revisions in response to the COVID-19 PHE. There was a comment period until June 1, 2020. This IFR included that for the duration of the COVID-19 PHE, the face-to-face requirements and clinical indications of coverage for home oxygen, among other respiratory products, will be waived. In addition, the administration has issued a number of regulatory waivers to increase the flexibility in DMEPOS suppliers' ability to service patients quickly and without the normal requirements. For example, the patient's signature for proof of delivery has been waived when signatures cannot be collected during the COVID-19 PHE. In addition, CMS increased Medicare contractors' ability to waive replacement product requirements, paused the national prior authorization program for certain DMEPOS, automatically extended expiring accreditations, granted contractors the flexibility to grant appeals extensions, and medical review suspension. Both the IFR and temporary regulatory changes show significant flexibility from CMS to improve access for oxygen and other DMEPOS items during this COVID-19 PHE. These changes were retroactive to early March 2020. However, in July 2020, CMS released a COVID-19 Product Burden Relief FAQs that included updates to this IFR, including that the pausing of the national prior authorization program for certain DMEPOS and medical review suspension will likely end, effective August 3, 2020.

Effective January 1, 2019, Medicare beneficiaries may receive durable medical equipment from any Medicare-enrolled supplier until new contracts are in effect under competitive bidding Round 2021, which is expected to begin on January 1, 2021. Reimbursement rates between January 1, 2019 and December 31, 2020 are set at the current pricing level throughout the United States for all Medicare patients, subject to Consumer Price Index (CPI) and budget neutrality adjustments. Pricing in CBAs is subject to annual CPI adjustments beginning in 2019 until Round 2021 begins. However, CMS also changed the calculation on budget neutrality to apply the offset to all oxygen and oxygen equipment classes beginning January 1, 2019 instead of previously only applying these adjustments to stationary oxygen equipment and oxygen contents. Based on these CPI and budget neutrality adjustments, effective January 1, 2019 the average Medicare reimbursement rates in former CBAs decreased to $72.92 a month for E1390 and $35.72 a month for E1392. Medicare also established new payment classes for liquid oxygen equipment and high flow portable liquid oxygen contents effective January 1, 2019. Effective January 1, 2020, the average Medicare reimbursement rates were increased by 1.5% to $73.98 a month for E1390 and $36.25 a month for E1392 in these regions that were previously subject to competitive bidding. In addition, the average Medicare reimbursement rates in non-rural, non-former CBAs increased by 3.5% to $74.84 a month for E1390 and $36.87 a month for E1392.

In Round 2021 of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) competitive bidding program, there have been some revisions to the bidding methodology including bid surety bond requirements, lead item pricing, and setting reimbursement rates at the maximum winning bid rate instead of the median winning bid rate. In the prior round of competitive bidding, our products were categorized in the product category of respiratory equipment and related supplies and accessories, which included oxygen equipment, continuous positive airway pressure (CPAP) devices and respiratory assist devices (RADs) and related supplies and accessories. In Round 2021 of the competitive bidding program, oxygen and oxygen equipment is its own product category and the lead item has been established as E1390. However, due to the lead item pricing methodology based on the 2015 standard Medicare fee schedule, E1392 reimbursement rates could be reduced significantly (we estimate approximately 42%) even if E1390 reimbursement rates do not change. This would lead to combined E1390 plus E1392 reimbursement rates to decrease by approximately 15%. The bidding window closed on September 18, 2019, and we bid in 129 of the 130 total CBAs. It is unclear how pricing will be impacted due to these new bids. We expect contracts and pricing to be announced in 2020.

In addition to regional pricing, CMS imposed different pricing on "frontier states" and rural areas. 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. Effective June 1, 2018 through December 31, 2020, for frontier and rural states, frontier and rural zip codes in non-frontier/rural states and non-contiguous United States areas, the single payment amount will be 50/50 blended reimbursement rates based on an average of the pre-competitive bidding reimbursement rates and the current average reimbursement rates to account for higher servicing costs in these areas. In 2019, this rate was $134.71 a month for E1390 and $44.32 a month for E1392, and this rate increased by 1.5% effective January 1, 2020 to $136.71 a month for E1390 and $44.93 a month for E1392. We estimate that approximately 15% of our patients are eligible to receive the higher reimbursement rates based on the geographic locations of our current patient population.

Cumulatively in previous rounds of competitive bidding, we were offered contracts for a substantial majority of the CBAs and product categories for which we submitted bids. As of January 1, 2017, we believe we had access to over 90% of the Medicare oxygen therapy market based on our analysis of the 103 CBAs that we won out of the 130 total CBAs. These 130 CBAs represented approximately 36% of the Medicare market with the remaining approximately 64% of the market not subject to competitive bidding per Medicare's data on 2018 traditional Medicare fee-for-service beneficiaries in CBAs as compared to the total Medicare fee-for-service beneficiaries. As of January 1, 2019, we can choose to accept Medicare oxygen patients throughout the United States. As of July 2018, we are operating in all 50 states in the U.S.

We cannot guarantee that we will be offered contracts in subsequent rounds of competitive bidding. In all five rounds of competitive bidding in which we have participated, we have gained access to certain CBAs and been excluded from other CBAs.

Medicare revenue, including patient co-insurance and deductible obligations, represented 6.8% and 5.6% of our total revenue in the three and six months ended June 30, 2020, respectively.

Medicare reimbursement for oxygen rental equipment is limited to a maximum of 36 months within a 60-month service period, and the equipment remains the property of the home oxygen supplier. The supplier that billed Medicare for the 36th month of service continues to be responsible for the patient's oxygen therapy needs for months 37 through 60, and there is generally no additional reimbursement for OGPE for these later months. Medicare does not separately reimburse suppliers for oxygen tubing, cannulas and supplies that may be required for the patient. The supplier is required to keep the equipment provided in working order and in some cases, Medicare will reimburse for repair costs. At the end of the five-year useful life of the equipment, 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 supplier 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 and six months ended June 30, 2020 and June 30, 2019, respectively. Our capped patients as a percentage of total patients on service was approximately 17.2% as of June 30, 2020 and 20.2% as of June 30, 2019. 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.

Our obligations to service Medicare patients over the rental period include supplying working equipment that meets each patient's oxygen needs pursuant to his/her 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, as long as that equipment 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 continued oxygen therapy one year after the patient first receives oxygen therapy and one year after each new 36-month reimbursement period begins. The patient can choose to receive oxygen supplies and services from another supplier at any time, but the supplier may only transition the patient to another supplier in certain circumstances.

Average Medicare reimbursement rates for NIV HCPCS code E0466 were a monthly, non-capped rental with rates of $1,042.26 a month in 2019, and increased 0.9% effective January 1, 2020 to $1,051.64 a month, excluding Puerto Rico where the monthly Medicare reimbursement rate for E0466 was $1,827.24 per month in 2019 and increased to $1,843.69 a month effective January 1, 2020.

It is uncertain if the current TAV product acquired from New Aera, will be reimbursable in its current configuration under HCPCS code E0466. We requested confirmation on the assigned HCPCS codes for the TAV system from the PDAC Contractor in August 2019 following the closing of the New Aera transaction. In August 2019, we received positive confirmation that this product was assigned HCPCS code E0466. However, in September 2019, we received a revised communication that the product was assigned HCPCS code E1390 and E1352, which was then revoked at our request in December 2019. In September 2019, we appealed to CMS, and in January 2020 our appeal was denied. We are currently pursuing additional appeal opportunities. If we do not receive revised coding, it could limit this product's adoption by HME providers and also our direct rentals. In addition, the MEDCAC recently had a meeting on July 22, 2020 to discuss home use of non-invasive positive pressure ventilation in patients with chronic respiratory failure consequent to COPD. CMS is seeking MEDCAC's recommendations regarding the characteristics that define patient selection and usage criteria for these items. This request could signal forthcoming changes in Medicare coverage of these items, and possibly changes in HCPCS codes, which could impact our NIV business and growth initiatives. For a discussion of certain significant risks relating to the TAV reimbursement and the upcoming round of competitive bidding, see the risk factor entitled "*The competitive bidding process under Medicare could negatively affect our business and financial condition.*"

As of June 30, 2020, we had 90 contracts with Medicaid, Medicare Advantage, government 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 suppliers. Based on our patient population, we believe at least 44% of all oxygen therapy patients are covered by Medicare Advantage, government, and other private payors. Private payors typically provide reimbursement at a rate similar to Medicare allowables for in-network plans. We anticipate that private payor reimbursement levels will generally be reset in accordance with Medicare payment amounts.

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. As a result of design changes, supplier negotiations, bringing manufacturing and assembly largely in-house and our commitment to driving efficient manufacturing processes, we have reduced our overall POC system cost by approximately 59% from 2009 to 2019. We intend to continue to seek ways to reduce our cost of revenue through manufacturing and design improvements.

For additional discussion of the impact of the recent Medicare reimbursement proposals, see "Risk Factors" herein.

Basis of presentation

The following describes the line items set forth in our consolidated statements of comprehensive income (loss).

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 rental revenue from period-to-period. Product selling prices and gross margins 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 G4 system is higher than our Inogen One G3 system due to lower manufacturing costs and similar average selling prices. Thus, to the extent our sales of our Inogen One G4 systems are higher than sales of our Inogen One G3 systems, our overall gross margins should improve and, conversely, to the extent our sales of our Inogen One G3 systems are higher than sales of our Inogen One G4 systems, our overall gross margins should decline. Quarter-over-quarter results may vary due to seasonality in both the international and domestic markets. We believe our sales may be impacted by seasonal factors. For example, we typically experience higher total sales in the second and third quarters as a result of consumers traveling and vacationing during warmer weather in the spring and summer months, but this may vary year-over-year. Particularly, due to the mandates and behaviors emanating from the COVID-19 PHE, including shelter-in-place orders, reduced travel, and lower consumer confidence, we did not see the typical seasonal increases in direct-to-consumer sales in the second quarter of 2020 that we have seen in prior years. As more HME providers adopt POCs in their businesses, we expect our historical seasonality in the domestic business-to-business channel could change as well, which was previously influenced mainly by consumer buying patterns. Direct-to-consumer sales seasonality may also be impacted by the number of our sales representatives and the amount of marketing spend in each quarter.

Sales revenue

Our sales revenue is primarily derived from the sale of our Inogen One systems, Inogen At Home systems, TAV systems, and related accessories to individual consumers, our private label partner, HME providers, distributors, resellers, and charitable organizations worldwide. Sales revenue is classified into two areas: business-to-business sales and direct-to-consumer sales. Generally, our direct-to-consumer sales have higher gross margins than our business-to-business sales.

Rental revenue

Our rental revenue is primarily derived from the rental of our Inogen One 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. Rental revenue increased in the three and six months ended June 30, 2020, primarily due to higher patients on service and higher Medicare reimbursement rates. We expect our rental revenue to increase in future periods as we scale the rental intake team, increase new rental setups, and benefit from the higher Medicare reimbursement rates for oxygen therapy. We also expect that our rental revenue will be impacted by the number of our sales and rental intake representatives, reimbursement rate changes including the impact of COVID-19 PHE changes, Round 2021 competitive bidding, the level of and response from potential customers to direct-to-consumer marketing spend, product launches, and other uncontrollable factors such as changes in the market and competition.

Cost of revenue

Cost of sales revenue

Cost of sales revenue consists primarily of costs incurred in the production process, including 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, manufacturing engineering, and quality assurance employees and temporary labor. Cost of sales revenue also includes manufacturing freight in, depreciation expense, facilities costs and materials. We provide a 3-year, 5-year or lifetime warranty on Inogen One systems sold and a 3-year and lifetime warranty on Inogen At Home systems sold. The TAV system has a 1-year and a 3-year warranty. We establish a reserve for the cost of future warranty repairs based on historical warranty repair costs incurred as well as historical failure rates. Provisions for warranty obligations, which are included in cost of sales revenue, are provided for at the time of revenue recognition.

We continue to make progress towards reducing the average unit costs of our products as a result of our ongoing efforts to develop lower-cost systems, negotiate with our suppliers, improve our manufacturing processes, and increase production volume and yields.

At the same time, recent United States policies related to global trade and tariffs may also increase our average unit cost. The current economic environment has introduced greater uncertainty with respect to potential trade regulations, including changes to United States policies related to global trade and tariffs. We continue to monitor the Section 301 tariffs being imposed by the United States on certain imported Chinese materials and products in addition to potential retaliatory responses from other nations. In 2019 and the six months ended June 30, 2020, the impact of the Chinese tariffs on our financial results was minimal as we have received some exemptions, negotiated cost sharing and price reductions with suppliers, and re-allocated purchases. Assuming the Chinese tariffs stay at the current levels, we currently expect the overall financial impact to our business to be minimal to the average unit cost for 2020.

We expect the TAV system to have a higher sales gross margin than our existing oxygen therapy products.

For these reasons, we expect sales gross margin percentage to fluctuate over time based on the sales channel mix, product mix, and changes in average selling prices and cost per unit.

Cost of rental revenue

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

We expect rental gross margin percentage to increase over time, primarily associated with higher rental revenue per patient and lower costs. We expect the average cost of rental revenue per patient to decline in future periods as a result of our ongoing efforts to reduce average unit cost of our systems as well as reductions in depreciation, service costs, and logistics costs.

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, facility costs, laboratory supplies, product development materials, consulting fees and related costs, and testing costs for new product launches as well as enhancements to existing products. 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. Beginning in the third quarter of 2019, research and development expense also includes intangible amortization costs associated with the New Aera acquisition, which is expected to substantially increase our research and development expense in 2020 through 2028 by approximately $7.8 million per year and $4.9 million in 2029.

We plan to continue to invest in research and development activities to stay at the forefront of patient preference in oxygen therapy and NIV devices. 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 improvements. We expect increased research and development costs associated with the New Aera acquisition to incorporate the TAV technology into our oxygen concentrator and new non-invasive ventilator product portfolios as well as intangible amortization costs.

Sales and marketing

Our sales and marketing expense primarily supports our direct-to-consumer sales and rental strategy and consists mainly of personnel-related expenses, including wages, bonuses, commissions, benefits, and stock-based compensation for sales, marketing, customer service, rental intake, and clinical service employees. It also includes expenses for media and advertising, printing, informational kits, dues and fees, credit card fees, recruiting, training, sales promotional activities, travel and entertainment expenses as well as allocated facilities costs. Sales and marketing expense decreased in the three months ended June 30, 2020 as compared to June 30, 2019, primarily due to reduced advertising spend. Our average sales representative headcount in the second quarter of 2020 was relatively flat compared to the second quarter of 2019, and our plan was to hire additional sales representatives at a more controlled pace across all of our facilities to expand sales capacity for the remainder of 2020. However, due to the COVID-19 PHE, we have reduced and expect to continue to reduce marketing spend and reduce sales representative headcount additions and primarily focus on replacement of attrition of existing sales representatives for the remainder of 2020. However, we still expect a further increase in sales and marketing expense 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 rising patient support costs as our patient and customer base increases. We also expect increased sales and marketing costs in 2020 associated with the expanded launch of the TAV product following the limited launch in December 2019.

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, order intake, human resources, and information technology (IT) departments as well as facilities costs, sales 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 expense 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 expect general and administrative expense to increase in absolute dollars as we continue to invest in corporate infrastructure to support our growth including personnel-related expenses, professional services fees and compliance costs associated with operating as a public company. Those costs include increases in our accounting, human resources, and IT personnel, as well as increases in additional consulting, legal and accounting fees, facilities costs, insurance costs, and board of directors' compensation.

Other income (expense), net

Our other income (expense), net consists primarily of interest income earned on cash equivalents and marketable securities as well as foreign currency gains and (losses).

Income taxes

We account 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 our consolidated 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.

We account 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 accounting for stock-based compensation will increase or decrease our effective tax rate based upon the difference between our stock-based compensation expense and the deductions taken on our U.S. tax return, which depends upon the stock price at the time of employee option exercise or award vesting. We recognize excess tax benefits or deficiencies on a discrete basis, and we anticipate our effective tax rate will vary from quarter-to-quarter depending on our stock price in each period.

Results of operations

Comparison of three months ended June 30, 2020 and June 30, 2019

Revenue

	Three months ended June 30,		Change 2020 vs. 2019		% of Revenue	
(amounts in thousands)	**2020**	**2019**	**$**	**%**	**2020**	**2019**
Sales revenue	$ 65,612	$ 95,863	$ (30,251)	-31.6%	91.5%	94.9%
Rental revenue	6,079	5,200	879	16.9%	8.5%	5.1%
Total revenue	$ 71,691	$ 101,063	$ (29,372)	-29.1%	100.0%	100.0%

Sales revenue decreased $30.3 million for the three months ended June 30, 2020 from the three months ended June 30, 2019, or a decrease of 31.6% from the comparable period. The decrease was primarily attributable to reduced direct-to-consumer sales and reduced domestic and international business-to-business sales, primarily associated with the impacts of the COVID-19 PHE. We sold approximately 42,500 oxygen systems during the three months ended June 30, 2020 compared to approximately 56,500 oxygen systems sold during the three months ended June 30, 2019, or a decrease of 24.8%. The decrease in the number of systems sold resulted mainly from a decrease in sales across all channels, primarily due to the COVID-19 PHE.

Rental revenue increased $0.9 million for the three months ended June 30, 2020 compared to the three months ended June 30, 2019, or an increase of 16.9% from the comparable period. The increase in rental revenue was primarily related to a 1.9% increase in rental patients on service, higher Medicare reimbursement rates, and increased billable patients from the comparative period.

(amounts in thousands)	Three months ended June 30,		Change 2020 vs. 2019		% of Revenue	
Revenue by region and category	**2020**	**2019**	**$**	**%**	**2020**	**2019**
Business-to-business domestic sales	$ 21,564	$ 29,653	$ (8,089)	-27.3%	30.1%	29.4%
Business-to-business international sales	13,874	22,564	(8,690)	-38.5%	19.3%	22.3%
Direct-to-consumer domestic sales	30,174	43,646	(13,472)	-30.9%	42.1%	43.2%
Direct-to-consumer domestic rentals	6,079	5,200	879	16.9%	8.5%	5.1%
Total revenue	$ 71,691	$ 101,063	$ (29,372)	-29.1%	100.0%	100.0%

Domestic business-to-business sales decreased 27.3% for the three months ended June 30, 2020 compared to the three months ended June 30, 2019. The decrease was primarily the result of decreased demand from our HME partners for oxygen concentrators in response to the COVID-19 PHE due to physician offices limiting patient interactions that traditionally have led to new oxygen patient referrals, lower retail sales, HME providers minimizing patient interactions in response to the COVID-19 PHE which includes replacing existing oxygen patient setups with POCs, and HME providers turning their purchasing focus to stationary oxygen concentrators to treat COVID-19 patients.

International business-to-business sales decreased 38.5% for the three months ended June 30, 2020 compared to the three months ended June 30, 2019, mostly due to decreased demand from our HME partners for oxygen concentratorsdue to the temporary closure of certain European respiratory assessment centers due to the COVID-19 pandemic and continued tender delays in certain European markets. In addition, like in the United States, HME providers turned their purchasing focus to stationary oxygen concentrators to treat COVID-19 patients. In the three months ended June 30, 2020, sales in Europe as a percentage of total international sales revenue decreased to87.2% versus 88.2% in the comparative period in 2019, primarily because of the reduced sales in Europe.

Domestic direct-to-consumer sales decreased 30.9% for the three months ended June 30, 2020 compared to the three months ended June 30, 2019, primarily due to the impact of the COVID-19 PHE with government mandated shelter-in-place initiatives, reduced consumer travel, and lower consumer confidence, which decreased demand and associated close rates in the second quarter of 2020 compared to the same period in the prior year. Average sales representative headcount was relatively flat in the comparative periods.

Cost of revenue and gross profit

	Three months ended June 30,		Change 2020 vs. 2019		% of Revenue	
(amounts in thousands)	**2020**	**2019**	**$**	**%**	**2020**	**2019**
Cost of sales revenue	$ 36,082	$ 47,230	$ (11,148)	-23.6%	50.3%	46.7%
Cost of rental revenue	2,860	3,618	(758)	-21.0%	4.0%	3.6%
Total cost of revenue	$ 38,942	$ 50,848	$ (11,906)	-23.4%	54.3%	50.3%
Gross profit - sales revenue	$ 29,530	$ 48,633	$ (19,103)	-39.3%	41.2%	48.1%
Gross profit - rental revenue	3,219	1,582	1,637	103.5%	4.5%	1.6%
Total gross profit	$ 32,749	$ 50,215	$ (17,466)	-34.8%	45.7%	49.7%
Gross margin percentage - sales revenue	45.0%	50.7%				
Gross margin percentage- rental revenue	53.0%	30.4%				
Total gross margin percentage	45.7%	49.7%				

Cost of sales revenue decreased $11.1 million for the three months ended June 30, 2020 from the three months ended June 30, 2019, or a decrease of 23.6% from the comparable period. The decrease in cost of sales revenue was primarily attributable to lower sales and related bill of material costs and lower total labor and overhead expense, partially offset by higher cost per unit associated with the Inogen One G5 during the period.

Cost of rental revenue decreased $0.8 million for the three months ended June 30, 2020 from the three months ended June 30, 2019, or a decrease of 21.0% from the comparable period. The decrease in cost of rental revenue was primarily attributable to reduced rental asset depreciation expense and servicing costs. Cost of rental revenue included $1.2 million of rental asset depreciation for the three months ended June 30, 2020 compared to $1.6 million for the three months ended June 30, 2019.

Sales revenue gross margin percentage decreased to 45.0% for the three months ended June 30, 2020 from 50.7% for the three months ended June 30, 2019. The decrease was primarily related to increased mix toward domestic business-to-business sales, which have a lower gross margin than our international business-to-business and direct-to-consumer sales, lower mix of accessory sales, and increased overhead costs per unit due to lower sales volumes. In addition, average selling prices were down in the second quarter of 2020 versus the same period in the prior year across all sales channels. Domestic business-to-business sales revenue accounted for 32.9% of total sales revenue in the three months ended June 30, 2020 versus 30.9% in the three months ended June 30, 2019.

Rental revenue gross margin percentage increased to 53.0% for the three months ended June 30, 2020 from 30.4% for the three months ended June 30, 2019, primarily due to higher rental revenue per patient on service and lower depreciation and servicing costs per patient on service.

Research and development expense

	Three months ended June 30,		Change 2020 vs. 2019		% of Revenue	
(amounts in thousands)	**2020**	**2019**	**$**	**%**	**2020**	**2019**
Research and development expense	$ 3,290	$ 1,468	$ 1,822	124.1%	4.6%	1.5%

Research and development expense increased $1.8 million for the three months ended June 30, 2020 from the three months ended June 30, 2019, or an increase of 124.1% over the comparable period, primarily due to $1.9 million in intangible amortization costs related to the New Aera acquisition.

Sales and marketing expense

	Three months ended June 30,		Change 2020 vs. 2019		% of Revenue	
(amounts in thousands)	**2020**	**2019**	**$**	**%**	**2020**	**2019**
Sales and marketing expense	$ 22,086	$ 27,758	$ (5,672)	-20.4%	30.8%	27.5%

Sales and marketing expense decreased $5.7 million for the three months ended June 30, 2020 from the three months ended June 30, 2019, or a decrease of 20.4% from the comparable period, primarily attributable to decreases of $4.4 million of lower advertising expense, $0.7 million of lower personnel-related expenses and $0.4 million in credit card processing fees. In the three months ended June 30, 2020, we spent $7.2 million in media and advertising costs versus $11.6 million in the comparative period in 2019.

General and administrative expense

	Three months ended June 30,		Change 2020 vs. 2019		% of Revenue	
(amounts in thousands)	**2020**	**2019**	**$**	**%**	**2020**	**2019**
General and administrative expense	$ 9,724	$ 8,844	$ 880	10.0%	13.6%	8.7%

General and administrative expense increased $0.9 million for the three months ended June 30, 2020 from the three months ended June 30, 2019, or an increase of 10.0% from the comparable period. The increase was primarily related to $1.1 million in consulting fees and $0.9 million for the change in fair value of the New Aera earnout liability, partially offset by the $0.6 million reimbursement from the CARES Act Provider Relief Fund due to the COVID-19 PHE, $0.5 million in lower legal fees, and $0.5 million in lower personnel-related expenses.

Other income (expense)

	Three months ended June 30,		Change 2020 vs. 2019		% of Revenue	
(amounts in thousands)	**2020**	**2019**	**$**	**%**	**2020**	**2019**
Interest income	$ 176	$ 1,394	$ (1,218)	-87.4%	0.2%	1.4%
Other income	5,700	145	5,555	3831.0%	8.0%	0.1%
Total other income, net	$ 5,876	$ 1,539	$ 4,337	281.8%	8.2%	1.5%

Total other income, net increased $4.3 million for the three months ended June 30, 2020 from the three months ended June 30, 2019, or an increase of 281.8% from the comparable period. The increase was primarily attributable to $5.6 million in other income from the CARES Act Provider Relief Fund due to lost revenues from the COVID-19 PHE, partially offset by a decrease of $1.2 million in interest income on marketable securities due to the lower interest rate environment.

Income tax expense

	Three months ended June 30,		Change 2020 vs. 2019		% of Revenue	
(amounts in thousands)	**2020**	**2019**	**$**	**%**	**2020**	**2019**
Income tax expense	$ 945	$ 3,524	$ (2,579)	-73.2%	1.3%	3.4%
Effective income tax rate	*26.8%*	*25.8%*				

Income tax expense decreased $2.6 million for the three months ended June 30, 2020 from the three months ended June 30, 2019, primarily attributable to a 74.2% decrease in income before income tax expense.

Our effective tax rate in the three months ended June 30, 2020 increased compared to the three months ended June 30, 2019, primarily due to changes in income before income tax expense. In the three months ended June 30, 2020, excess tax deficiencies recognized from stock-based compensation increased our income tax expense by $0.3 million and our effective tax rate by 7.3%, as compared to the tax rate without such deficiencies. For comparison, in the three months ended June 30, 2019, excess tax deficiencies recognized from stock-based compensation increased our income tax expense by $0.2 million and our effective tax rate by 1.4%, as compared to the tax rate without such deficiencies.

Net income

	Three months ended June 30,		Change 2020 vs. 2019		% of Revenue	
(amounts in thousands)	2020	2019	$	%	2020	2019
Net income	$ 2,580	$ 10,160	$ (7,580)	-74.6%	3.6%	10.1%

Net income decreased $7.6 million for the three months ended June 30, 2020 from the three months ended June 30, 2019, or a decrease of 74.6% from the comparable period. The decrease in net income was primarily related to lower sales revenue and gross margin as well as a higher effective tax rate, partially offset by lower operating expenses.

Comparison of six months ended June 30, 2020 and June 30, 2019

Revenue

	Six months ended June 30,		Change 2020 vs. 2019		% of Revenue	
(amounts in thousands)	2020	2019	$	%	2020	2019
Sales revenue	$ 148,752	$ 180,681	$ (31,929)	-17.7%	92.9%	94.5%
Rental revenue	11,428	10,584	844	8.0%	7.1%	5.5%
Total revenue	$ 160,180	$ 191,265	$ (31,085)	-16.3%	100.0%	100.0%

Sales revenue decreased $31.9 million for the six months ended June 30, 2020 from the six months ended June 30, 2019, or a decrease of 17.7% from the comparable period. The decrease was primarily attributable to reduced direct-to-consumer sales and reduced domestic and international business-to-business sales, primarily due to the impact of the COVID-19 PHE and Inogen One G5 supply constraints in the first quarter of 2020. We sold approximately 95,900 oxygen systems during the six months ended June 30, 2020 compared to approximately 106,900 oxygen systems sold during the six months ended June 30, 2019, or a decrease of 10.3%. The decrease in the number of systems sold resulted mainly from a decrease in sales across all channels primarily due to the COVID-19 PHE and the Inogen One G5 supply constraints in the first quarter of 2020.

Rental revenue increased $0.8 million for the six months ended June 30, 2020 compared to the six months ended June 30, 2019, or an increase of 8.0% from the comparable period. The increase in rental revenue was primarily related to higher Medicare reimbursement rates, higher billable patients, and a 1.9% increase in rental patients on service from the comparative period in the prior year.

(amounts in thousands)	Six months ended June 30,		Change 2020 vs. 2019		% of Revenue	
Revenue by region and category	2020	2019	$	%	2020	2019
Business-to-business domestic sales	$ 49,118	$ 55,714	$ (6,596)	-11.8%	30.7%	29.1%
Business-to-business international sales	33,957	42,367	(8,410)	-19.9%	21.2%	22.2%
Direct-to-consumer domestic sales	65,677	82,600	(16,923)	-20.5%	41.0%	43.2%
Direct-to-consumer domestic rentals	11,428	10,584	844	8.0%	7.1%	5.5%
Total revenue	$ 160,180	$ 191,265	$ (31,085)	-16.3%	100.0%	100.0%

Domestic business-to-business sales decreased 11.8% for the six months ended June 30, 2020 compared to the six months ended June 30, 2019. The decrease was primarily due to decreased demand from our HME partners for oxygen concentrators in response to the COVID-19 PHE due to physician offices limiting patient interactions that traditionally have led to new oxygen patient referrals, lower retail sales, HME providers minimizing patient interactions in response to the COVID-19 PHE which includes replacing existing oxygen patient setups with POCs, and HME providers turning their purchasing focus to stationary oxygen concentrators to treat COVID-19 patients. In addition, lower Inogen One G5 availability early in the period and uncertainty around competitive bidding Round 2021 contributed to lower sales in the period.

International business-to-business sales decreased 19.9% for the six months ended June 30, 2020 compared to the six months ended June 30, 2019, mostly driven by the temporary closure of certain European respiratory assessment centers due to the COVID-19 pandemic and continued tender delays in certain European markets. In addition, like in the United States, HME providers turned their focus to supplying stationary oxygen concentrators with higher flow characteristics in responses to the COVID-19 pandemic. In the six months ended June 30, 2020, sales in Europe as a percentage of total international sales revenue decreased to 85.6% versus 87.4% in the comparative period in 2019, primarily because of reduced sales in Europe.

Domestic direct-to-consumer sales decreased 20.5% for the six months ended June 30, 2020 compared to the six months ended June 30, 2019, primarily due to the impact of the COVID-19 PHE with government mandated shelter-in-place initiatives, reduced consumer travel, and lower consumer confidence, which decreased demand and associated close rates in the period compared to the same period in the prior year. In addition, sales declined associated with a decline in average sales representative headcount.

Cost of revenue and gross profit

	Six months ended June 30,		Change 2020 vs. 2019		% of Revenue	
(amounts in thousands)	2020	2019	$	%	2020	2019
Cost of sales revenue	$ 83,200	$ 89,297	$ (6,097)	-6.8%	52.0%	46.7%
Cost of rental revenue	5,865	7,344	(1,479)	-20.1%	3.6%	3.8%
Total cost of revenue	$ 89,065	$ 96,641	$ (7,576)	-7.8%	55.6%	50.5%
Gross profit - sales revenue	$ 65,552	$ 91,384	$ (25,832)	-28.3%	40.9%	47.8%
Gross profit - rental revenue	5,563	3,240	2,323	71.7%	3.5%	1.7%
Total gross profit	$ 71,115	$ 94,624	$ (23,509)	-24.8%	44.4%	49.5%
Gross margin percentage - sales revenue	44.1%	50.6%				
Gross margin percentage- rental revenue	48.7%	30.6%				
Total gross margin percentage	44.4%	49.5%				

Cost of sales revenue decreased $6.1 million for the six months ended June 30, 2020 from the six months ended June 30, 2019, or a decrease of 6.8% from the comparable period. The decrease in cost of sales revenue was primarily attributable to lower sales and related bill of material costs and lower total labor and overhead expense, partially offset by higher cost per unit associated with the Inogen One G5 during the period.

Cost of rental revenue decreased $1.5 million for the six months ended June 30, 2020 from the six months ended June 30, 2019, or a decrease of 20.1% from the comparable period. The decrease in cost of rental revenue was primarily attributable to reduced rental asset depreciation expense and servicing costs. Cost of rental revenue included $2.5 million of rental asset depreciation for the six months ended June 30, 2020 compared to $3.3 million for the six months ended June 30, 2019.

Sales revenue gross margin percentage decreased to 44.1% for the six months ended June 30, 2020 from 50.6% for the six months ended June 30, 2019. The decrease was primarily related to increased domestic business-to-business sales mix which has a lower gross margin, higher cost of goods sold associated with certain manufacturing inefficiencies in the period that contributed to higher labor and overhead costs per unit, and lower average selling prices. Total domestic business-to-business sales revenue accounted for 33.0% of total sales revenue in the six months ended June 30, 2020 versus 30.8% in the six months ended June 30, 2019.

Rental revenue gross margin percentage increased to 48.7% for the six months ended June 30, 2020 from 30.6% for the six months ended June 30, 2019, primarily due to higher rental revenue per patient on service and lower depreciation and servicing costs per patient on service.

Research and development expense

	Six months ended June 30,		Change 2020 vs. 2019		% of Revenue	
(amounts in thousands)	2020	2019	$	%	2020	2019
Research and development expense	$ 6,895	$ 3,137	$ 3,758	119.8%	4.3%	1.6%

Research and development expense increased $3.8 million for the six months ended June 30, 2020 from the six months ended June 30, 2019, or an increase of 119.8% over the comparable period, primarily due to $3.9 million in intangible amortization costs related to the New Aera acquisition.

Sales and marketing expense

	Six months ended June 30,		Change 2020 vs. 2019		% of Revenue	
(amounts in thousands)	2020	2019	$	%	2020	2019
Sales and marketing expense	$ 49,249	$ 55,959	$ (6,710)	-12.0%	30.7%	29.3%

Sales and marketing expense decreased $6.7 million for the six months ended June 30, 2020 from the six months ended June 30, 2019, or a decrease of 12.0% from the comparable period, primarily attributable to decreases of $4.6 million of advertising costs, $2.1 million of personnel-related expenses partially associated with the decline in average sales representative headcount, and $0.5 million in credit card processing fees, partially offset by an increase of $0.6 million in dues, fees and license costs. In the six months ended June 30, 2020, we spent $17.2 million in media and advertising costs versus $21.8 million in the comparative period in 2019.

General and administrative expense

	Six months ended June 30,		Change 2020 vs. 2019		% of Revenue	
(amounts in thousands)	2020	2019	$	%	2020	2019
General and administrative expense	$ 19,501	$ 18,525	$ 976	5.3%	12.2%	9.7%

General and administrative expense increased $1.0 million for the six months ended June 30, 2020 from the six months ended June 30, 2019, or an increase of 5.3% from the comparable period. The increase was primarily attributable to $1.8 million in professional and consulting fees as well as $0.3 million in facilities costs, partially offset by $0.6 million in lower personnel-related costs, $0.6 million reimbursement from the CARES Act Provider Relief Fund due to the COVID-19 PHE, and $0.3 million in lower legal fees.

Other income (expense)

	Six months ended June 30,		Change 2020 vs. 2019		% of Revenue	
(amounts in thousands)	2020	2019	$	%	2020	2019
Interest income	$ 728	$ 2,728	$ (2,000)	-73.3%	0.4%	1.4%
Other income	5,640	25	5,615	22460.0%	3.5%	0.0%
Total other income, net	$ 6,368	$ 2,753	$ 3,615	131.3%	3.9%	1.4%

Total other income, net increased $3.6 million for the six months ended June 30, 2020 from the six months ended June 30, 2019, or an increase of 131.3% from the comparable period. The increase was primarily attributable to $5.6 million in other income from the CARES Act Provider Relief Fund due to lost revenues from the COVID-19 PHE, partially offset by a decrease of $2.0 million in interest income on marketable securities due to the lower interest rate environment.

Income tax expense

	Six months ended June 30,		Change 2020 vs. 2019		% of Revenue	
(amounts in thousands)	2020	2019	$	%	2020	2019
Income tax expense	$ 847	$ 4,294	$ (3,447)	80.3%	0.5%	2.2%
Effective income tax rate	*46.1%*	*21.7%*				

Income tax expense decreased $3.4 million for the six months ended June 30, 2020 from the six months ended June 30, 2019, primarily attributable to a 90.7% decrease in income before income tax expense for the year.

Our effective tax rate in the six months ended June 30, 2020 increased compared to the six months ended June 30, 2019, primarily due to the decrease in excess tax benefits recognized from stock-based compensation, partially offset by the changes in income before income tax expense, increase in favorable permanent differences and research and development credits. In the six months ended June 30, 2020, excess tax deficiencies recognized from stock-based compensation increased our income tax expense by $0.5 million and our effective tax rate by 26.9%, as compared to the tax rate without such deficiencies. For comparison, in the six months ended June 30, 2019, excess tax benefits recognized from stock-based compensation decreased our income tax expense by $0.4 million and our effective tax rate by 2.3%, as compared to the tax rate without such benefits.

Net income

	Six months ended June 30,		Change 2020 vs. 2019		% of Revenue	
(amounts in thousands)	**2020**	**2019**	**$**	**%**	**2020**	**2019**
Net income	$ 991	$ 15,462	$ (14,471)	-93.6%	0.6%	8.1%

Net income decreased $14.5 million for the six months ended June 30, 2020 from the six months ended June 30, 2019, or a decrease of 93.6% from the comparable period. The decrease in net income was primarily related to lower sales revenue and gross margin as well as a higher effective tax rate, partially offset by lower operating expenses.

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 June 30, 2020, we had purchase obligations with outside vendors and suppliers of approximately $68.2 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 February 25, 2020.

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 June 30, 2020, we had cash and cash equivalents of $214.1 million, which consisted of highly-liquid investments with a maturity of three months or less. 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 $52.4 million from proceeds related to stock option exercises and our employee stock purchase plan. For the six months ended June 30, 2020 and June 30, 2019, we received $1.3 million and $3.4 million, respectively, in proceeds related to these stock programs.

Our principal uses of cash for liquidity and capital resources in the six months ended June 30, 2020 consisted of capital expenditures of $5.6 million including additional rental equipment and other property, plant and equipment.

The COVID-19 PHE did not yet materially impact our liquidity position to date, and we believe our current cash and cash equivalents provide us with a certain degree of stability and liquidity during this time of uncertainty. We believe that our current cash, cash equivalents 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 twelve 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 funding requirements will depend on many factors, including market acceptance of our products; the cost of our research and development activities; payments from customers; the cost, timing, and outcome of litigation or disputes involving intellectual property rights, our products, employee relations, cyber security incidents, or otherwise; the cost and timing of acquisitions; the cost and timing of regulatory clearances or approvals; the cost and timing of establishing additional sales, marketing, and distribution capabilities; and the effect of competing technological and market developments. In the future, we may acquire businesses or technologies from third parties, and we may decide to raise additional capital through debt or equity financing to the extent we believe this is necessary to successfully complete these acquisitions. Our future capital requirements will also depend on many additional 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.

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

(amounts in thousands)	Six months ended June 30,		Change 2020 vs. 2019	
Summary of consolidated cash flows	**2020**	**2019**	**$**	**%**
Cash provided by operating activities	$ 14,070	$ 16,603	$ (2,533)	-15.3%
Cash provided by (used in) investing activities	851	(1,832)	2,683	146.5%
Cash provided by financing activities	1,036	2,618	(1,582)	-60.4%
Effect of exchange rates on cash	92	(76)	168	221.1%
Net increase in cash and cash equivalents	$ 16,049	$ 17,313	$ (1,264)	-7.3%

(amounts in thousands) **Working capital**	**June 30, 2020**	**December 31, 2019**
Cash and cash equivalents	$ 214,086	$ 198,037
Marketable securities	4,549	11,057
Accounts receivable, net	28,422	34,325
Inventories, net	36,180	35,664
Income tax receivable	2,984	2,976
Prepaid expenses and other current assets	16,544	10,160
Total current assets	302,765	292,219
Accounts payable and accrued expenses	29,363	30,730
Accrued payroll	6,405	6,215
Warranty reserve - current	5,769	4,923
Operating lease liability - current	1,823	2,014
Deferred revenue - current	6,266	5,478
Income tax payable	988	821
Total current liabilities	50,614	50,181
Net working capital	$ 252,151	$ 242,038

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 cash provided by operating activities for the six months ended June 30, 2020 consisted primarily of our net income of $1.0 million as well as non-cash expense items such as depreciation of equipment and leasehold improvements and amortization of our intangibles of $8.9 million, provision for sales returns and doubtful accounts of $5.7 million, stock-based compensation expense of $4.1 million, provision for rental revenue adjustments of $1.5 million, decrease in deferred tax assets of $0.7 million, and provision for inventory obsolescence and other inventory losses of $0.6 million. The net changes in operating assets and liabilitiesresulted in a net use of cashof $8.7 million.

Net cash provided by operating activities for the six months ended June 30, 2019 consisted primarily of our net income of $15.5 million as well as non-cash expense items such as provision for sales returns and doubtful accounts of $8.9 million, depreciation of equipment and leasehold improvements and amortization of our intangibles of $5.6 million, stock-based compensation expense of $5.4 million, a decrease in deferred tax assets of $4.1 million, provision for rental revenue adjustments of $1.2 million, and provision for inventory obsolescence and other inventory losses of $0.4 million. The net changes in operating assets and liabilities resulted in a net use of cash of $24.6 million.

Investing activities

Net cash provided by (used in) investing activities for each of the periods presented included cash used for acquisitions and in the production and purchase of rental assets, manufacturing tooling, and computer equipment and software to support our expanding business as well as net (purchases) maturities of marketable securities.

For the six months ended June 30, 2020, we received $11.1 million in maturities of marketable securities, partially offset by $4.6 million in purchases of marketable securities. In addition, we invested $5.8 million in the production and purchase of rental assets and other property, equipment, and intangible assets.

For the six months ended June 30, 2019, we invested $38.6 million in corporate bonds and U.S. Treasury securities with maturities greater than three months that were classified as marketable securities, partially offset by $40.2 million in maturities of marketable securities. In addition, we invested $3.4 million in the production and purchase of rental assets and other property, equipment, and leasehold improvements.

We expect to continue investing in property, equipment and leasehold improvements 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 equipment to our patients. Investments will continue to be required in order to grow our sales and rental revenue and continue to supply and replace rental equipment to our rental patients on service.

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 six months ended June 30, 2020, net cash provided by financing activities consisted of $1.3 million from purchases under our employee stock purchase program and the proceeds received from stock options that were exercised, partially offset by the payment of employment taxes related to the vesting of restricted stock awards and restricted stock units of $0.2 million.

For the six months ended June 30, 2019, net cash provided by financing activities consisted of $3.4 million from the proceeds received from stock options that were exercised and purchases under our employee stock purchase program, partially offset by the payment of employment taxes related to the vesting of restricted stock awards and restricted stock units of $0.8 million.

Sources of funds

Our cash provided by operating activities in the six months ended June 30, 2020 was $14.1 million compared to $16.6 million in the six months ended June 30, 2019. As of June 30, 2020, we had cash and cash equivalents of $214.1 million.

Use of funds

Our principal uses of cash are funding our new rental asset deployments and other capital purchases, operations, and other working capital requirements and, from time-to-time, the acquisition of businesses. Over the past several years, our revenue has increased from year-to-year and, as a result, our cash flows from customer collections have increased as have our profits. Our annual cash provided by operating activities has generally increased over time and has been a significant source of capital to the business, which we expect to continue in the future.

We may need to raise additional funds to support our investing operations, and such funding may not be available to us on acceptable terms, or at all. If we are unable to raise additional funds when needed, our operations and ability to execute our business strategy could be adversely affected. We may seek to raise additional funds through equity, equity-linked or debt financings. If we raise additional funds through the incurrence of indebtedness, such indebtedness would have rights that are senior to holders of our equity securities and could contain covenants that restrict our operations. Any additional equity financing may be dilutive to our stockholders.

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 stock-based compensation and change in fair value of earnout liability. 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 and intangible assets, the impact of stock-based compensation expense and the impact of the change in fair value of the earnout liability. 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 should not be considered in isolation or as a substitute for analysis of our results as reported under U.S. GAAP. Some of these limitations are:

- EBITDA and Adjusted EBITDA do not reflect our cash expenditures for capital equipment or other contractual commitments;
- although depreciation and amortization are non-cash charges, the assets being depreciated and amortized may have to be replaced in the future, and EBITDA and Adjusted EBITDA do not reflect capital expenditure requirements for such replacements;
- EBITDA and Adjusted EBITDA do not reflect changes in, or cash requirements for, our working capital needs;
- Adjusted EBITDA does not include changes in fair value of earnout liability related to our acquisitions; and
- other companies, including companies in our industry, may calculate EBITDA and Adjusted EBITDA measures differently, which reduces their usefulness as a comparative measure.

In evaluating EBITDA and Adjusted EBITDA, we anticipate that in the future we will incur expenses within these categories similar to 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, EBITDA and Adjusted EBITDA should be considered alongside other financial performance measures, including 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:

(amounts in thousands)	Three months ended June 30,		Six months ended June 30,	
Non-GAAP EBITDA and Adjusted EBITDA	**2020**	**2019**	**2020**	**2019**
Net income	$ 2,580	$ 10,160	$ 991	$ 15,462
Non-GAAP adjustments:				
Interest income	(176)	(1,394)	(728)	(2,728)
Provision for income taxes	945	3,524	847	4,294
Depreciation and amortization	4,480	2,760	8,942	5,554
EBITDA (non-GAAP)	7,829	15,050	10,052	22,582
Stock-based compensation	1,277	1,779	4,061	5,365
Change in fair value of earnout liability	932	—	(20)	—
Adjusted EBITDA (non-GAAP)	$ 10,038	$ 16,829	$ 14,093	$ 27,947

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to various market risks, including fluctuation in foreign currency exchange rate and interest 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.

Foreign currency exchange risk

The principal market risk we face is foreign currency exchange risk. The majority of our revenue is denominated in U.S. dollars while the majority of our European sales are denominated in Euros. Our results of operations, certain balance sheet balances and cash flows are, therefore, subject to fluctuations due to changes in foreign currency exchange rates. The volatility of exchange rates depends on many factors that we cannot forecast with reliable accuracy. We have experienced and will continue to experience fluctuations in our net income or loss as a result of transaction gains or losses related to revaluing certain current asset and current liability balances that are denominated in currencies other than the functional currency in which they are recorded. The effect of a 10% adverse change in exchange rates on foreign denominated cash, receivables and payables as of June 30, 2020 would not have had a material effect on our financial position, results of operations or cash flows. 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 enter into foreign exchange forward contracts to protect our forecasted U.S. dollar-equivalent earnings from adverse changes in foreign currency exchange rates. These hedging contracts reduce, but will not entirely eliminate, the impact of adverse currency exchange rate movements on revenue. We performed a sensitivity analysis assuming a hypothetical 10% adverse movement in foreign exchange rates to the hedging contracts and the underlying exposures described above. As of June 30, 2020, the analysis indicated that these hypothetical market movements would not have a material effect on our financial position, results of operations or cash flows. We estimate prior to any hedging activity that a 10% adverse change in exchange rates on our foreign denominated sales would have resulted in a $2.5 million decline in revenue for the six months ended June 30, 2020. 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 (loss) and subsequently reclassified into revenue to offset the hedged exposures as they occur.

Interest rate fluctuation risk

We had cash and cash equivalents of $214.1 million as of June 30, 2020, which consisted of highly-liquid investments with a maturity of three months or less. 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 interest income. We considered the historical volatility of short-term interest rates and determined that it was reasonably possible that an adverse change of 100 basis points could be experienced in the near term. A hypothetical 1.00% (100 basis points) increase in interest rates would not have materially impacted the fair value of our marketable securities as of June 30, 2020 and June 30, 2019. If overall interest rates had increased or decreased by 1.00% (100 basis points), neither our interest expense nor our interest income would have been materially affected during the three or six months ended June 30, 2020 or June 30, 2019.

Item 4. Controls and Procedures

Evaluation of disclosure controls and procedures

The Company maintains a system of disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), which are designed to provide reasonable assurance that information required to be disclosed in the reports that the Company files or submits under the Exchange Act, is recorded, processed, summarized and reported accurately and completely within the time periods specified in the SEC’s rules and forms. These disclosure controls and procedures include, among other processes, controls and procedures designed to ensure that information required to be disclosed in the reports that the Company files or submits under the Exchange Act is accumulated and communicated to management, including the Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Due to inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Further, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions over time, or that the degree of compliance with the policies and procedures may deteriorate. Accordingly, even effective disclosure controls and procedures can only provide reasonable assurance of achieving their control objectives. 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 June 30, 2020. Based upon the evaluation described above, our Chief Executive Officer and Chief Financial Officer concluded that, as of June 30, 2020, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in internal control over financial reporting

There has been no change in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Rule 13a-15 or 15d-15 that occurred during our most recent fiscal quarter 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. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Because of the inherent limitations in any control system, misstatements due to error or fraud may occur and not be detected.

Part II. OTHER INFORMATION

Item 1. Legal Proceedings

Intellectual property lawsuit

On November 21, 2019, Breathe Technologies, Inc. (Breathe), a subsidiary of Hill-Rom Holdings, filed a lawsuit against Inogen, Inc., New Aera, Inc., Silverbow Development, LLC, and Todd W. Allum in the United States District Court for the Northern District of California (N.D. Cal. Lawsuit). Breathe alleged: willful infringement of the ‘250 patent assigned to Breathe; that inventorship was incorrectly assigned and that Breathe owns rights to certain patents filed by New Aera, Inc. and Silverbow Development LLC; breach of contract; inducing breach of contract; interference with contract; and violation of California Business and Professional Code Section 17200. The complaint seeks to correct inventorship of certain patents now owned by the Company, injunctive relief, compensatory and punitory damages in an unspecified amount including trebling of all damages awarded with respect to infringement of the ‘250 patent, costs and expenses, including attorneys’ fees and expert fees, prejudgment and post-judgment interest and such other relief as the court deems proper. On March 31, 2020, Breathe filed a First Amended Complaint in which it dropped the patent infringement claims in the N.D. Cal. Lawsuit and added another claim for violation of California Business and Professional Code Section 17200. On the same day, Breathe re-filed the ‘250 patent infringement claims in the United States District Court for the Central District of California (C.D. Cal. Lawsuit). The Company intends to vigorously defend itself against the allegations in both lawsuits. The Company recorded a contingent liability for $6.0 million during the three months ended June 30, 2020. The related payable was recorded in accounts payable and accrued expenses and receivable from the New Aera acquisition escrow account in prepaid expenses and other current assets as of June 30, 2020.

Securities class action and derivative lawsuits

On March 6, 2019, plaintiff William Fabbri filed a lawsuit against Inogen, Scott Wilkinson, and Alison Bauerlein, 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. On March 21, 2019, plaintiff Steven Friedland filed a substantially similar lawsuit against the same defendants in the same court. On May 20, 2019, the court issued an order consolidating the two lawsuits under the name *In re Inogen, Inc. Sec. Litig.,* No. 2:19-cv-01643-FMO-AGR, appointing Dr. John Vasil and Paragon Fund Management as lead plaintiffs, and appointing Robbins Geller Rudman & Dowd LLP and Glancy Prongay & Murray LLP as lead plaintiffs’ counsel. On July 10, 2019, the lead plaintiffs filed a consolidated amended complaint on behalf of a purported class of purchasers of the Company’s common stock between November 8, 2017 and May 7, 2019. The complaint generally alleges that the defendants failed to disclose that: (i) Inogen had overstated the true size of the total addressable market for its portable oxygen concentrators and had misstated the basis for its calculation of the total addressable market; (ii) Inogen had falsely attributed its sales growth to the strong sales acumen of its salesforce, rather than to deceptive sales practices; (iii) the growth in Inogen’s domestic business-to-business sales to home medical equipment providers was inflated, unsustainable and was eroding direct-to-consumer sales; and (iv) Inogen’s decision to focus on sales over rentals of portable oxygen concentrators harmed its ability to serve the Medicare market, in violation of sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended. The complaint seeks 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 deems proper. On January 2, 2020, the court dismissed the consolidated amended complaint with leave to amend. On January 9, 2020, the plaintiffs filed a second amended complaint generally alleging substantially similar claims as those in the previous complaint. On January 23, 2020, the defendants filed a motion to dismiss the second amended complaint. The Company intends to vigorously defend itself against these allegations.

On June 26, 2019, plaintiff Twana Brown filed a shareholder derivative lawsuit against Inogen, Scott Wilkinson, Alison Bauerlein, Benjamin Anderson-Ray, Scott Beardsley, R. Scott Greer, Raymond Huggenberger, Heath Lukatch, Loren McFarland, and Heather Rider in the United States District Court for the Central District of California. The complaint purports to bring claims on behalf of Inogen against the individual defendants for breaches of their fiduciary duties as directors and/or officers of Inogen, unjust enrichment, waste of corporate assets and violations of section 14(a) of the Securities Exchange Act of 1934, as amended. The complaint generally alleges similar claims to the securities class action. The complaint seeks compensatory damages and restitution in an unspecified amount, changes to the Company’s corporate governance and internal procedures, costs and expenses, including attorneys’ fees and expert fees, and such other relief as the court deems proper. On August 5, 2019, the court issued an order staying the derivative action pending the resolution of the motion to dismiss stage in *In re Inogen, Inc. Sec. Litig.* Between October 7, 2019 and October 31, 2019, three additional shareholder derivative complaints were filed in the United States District Court for the Central District of California based on similar factual allegations. These lawsuits purport to bring claims on behalf of Inogen for breach of fiduciary duty, unjust enrichment, waste of corporate assets, insider trading and misappropriation of information, and violations of section 14(a) of the Securities Exchange Act of 1934, as amended. On January 13, 2020, the court consolidated the four derivative lawsuits before it under the name *In re Inogen, Inc. S’holder Deriv. Litig.*, Lead Case No. 2:19-cv-5568-FMO-AGR and ordered that the consolidated action be stayed pending the resolution of the motion to dismiss stage in *In re Inogen, Inc., Sec. Litig.*

On September 13, 2019, plaintiff Dustin Weller filed a shareholder derivative lawsuit against Inogen, Scott Wilkinson, Alison Bauerlein, Benjamin Anderson-Ray, Scott Beardsley, R. Scott Greer, Raymond Huggenberger, Heath Lukatch, Loren McFarland, and Heather Rider in the United States District Court for the District of Delaware captioned *Weller v. Wilkinson, et al*., No. 1:19-cv-01723-MN. On October 17, 2019, plaintiff Sharokh Soltanipour filed a shareholder derivative lawsuit against the same defendants in the same court, captioned *Soltanipour v. Wilkinson, et al*., No. 1:19-cv-1968-MN. The complaints generally allege similar claims to those in *In re Inogen, Inc., S'holder Deriv. Litig.* The complaints purport to bring claims on behalf of Inogen for breach of fiduciary duty, unjust enrichment, waste of corporate assets, abuse of control, gross mismanagement, insider selling and misappropriation of information, violations of section 14(a) of the Securities Exchange Act of 1934, as amended, and for contribution from certain of the individual defendants. The complaints seek compensatory damages in unspecified amounts, changes to the Company's corporate governance and internal procedures, return of compensation, disgorgement of profits from sale of stock, costs and expenses, including attorneys' fees and expert fees, and such other relief as the court deems proper. On May 15, 2020, the court consolidated the two derivative lawsuits before it under the name *In re Inogen, Inc. S'holder Deriv. Litig., Lead Case No. 1:19-cv-01723-MN-JLH.* On July 8, 2020, the court ordered that the consolidated action be stayed pending the resolution of the motion to dismiss in the securities class action, *In re Inogen, Inc., Sec. Litig.*

Other litigation

In the normal course of business, we are from time to time involved in various legal proceedings or potential legal proceedings, including matters involving employment, product liability and intellectual property. We carry insurance, subject to specified deductibles under our policies, to protect against losses from certain liabilities and costs. At this time, we do not anticipate that any of these proceedings arising in the normal course of business 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. The risks and uncertainties described below may not be the only ones we face. 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

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 long-term oxygen therapy market and the non-invasive ventilator market are highly competitive industries. We compete with a number of manufacturers and distributors of portable oxygen concentrators (POCs), as well as providers of other long-term oxygen therapy solutions such as home delivery of oxygen tanks or cylinders, stationary concentrators, transfilling concentrators, and liquid oxygen. In the non-invasive ventilator market, we compete with manufacturers and distributors of other portable non-invasive ventilators, as well as home medical equipment (HME) providers that supply these products.

Our significant manufacturing competitors are Respironics (a subsidiary of Koninklijke Philips N.V.), Invacare Corporation, Caire Medical (subsidiary of NGK Spark Plug), DeVilbiss Healthcare (a subsidiary of Drive Medical), O2 Concepts, Precision Medical, Resmed, Gas Control Equipment (subsidiary of Colfax), Breathe Technologies, Inc. (recently announced to be acquired by Hill-Rom Holdings, Inc.), Breas Medical, Ventec Life Systems, Covidien, and Nidek Medical. Additional competitors have also pre-announced upcoming product launches of POCs including 3B Medical, SysMed, and Bellascura. Given the relatively straightforward regulatory path in the oxygen therapy and non-invasive ventilator device manufacturing market, we expect that the industry will become increasingly competitive in the future. For example, some major competitors have implemented direct-to-consumer sales models, which may increase their competitiveness and sales to patients, and we have recently seen the cost per generated lead trend higher than historical averages that may in part be due to increased competition. However, the strategies of these major competitors are currently limited to direct-to-consumer sales and do not include direct-to-consumer rentals where they would be responsible to meet national accreditation and state-by-state licensing requirements and secure Medicare billing privileges. Manufacturing companies compete for sales to providers primarily on the basis of price, quality/reliability, financing, bundling, product features, and service.

For many years, Lincare, Inc. (a subsidiary of the Linde Group), Apria Healthcare, Inc., AdaptHealth Corp., Aerocare Holdings, Inc. and Rotech Healthcare, Inc. have been among the market leaders in providing respiratory therapy products, while the remaining market is serviced by local providers. Because of reimbursement reductions, we expect more industry consolidation and volatility in ordering patterns based on how providers are restructuring their businesses and their access to capital. Respiratory 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, lower pricing, longer warranties, financing or extended terms, other incentives to gain a competitive advantage;
- greater history in conducting research and development, manufacturing, marketing and obtaining regulatory approval for respiratory device products; and
- greater financial and human resources for product development, sales and marketing, and patent litigation.

As a result, our competitors may be able to respond more quickly and effectively than we can due to new or changing opportunities, technologies, standard regulatory and reimbursement development and customer requirements or changing or uncertain business conditions or macroeconomic trends. 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, including those who have adopted or may in the future adopt direct-to-consumer sales models, 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.

We depend on a limited number of customers for a significant portion of our sales revenue and the loss of, or a significant shortfall in demand from, these customers could have a material adverse effect on our financial condition and operating results.

We receive a significant amount of our sales revenue from a limited number of customers, including distributors, HME providers, our private label partner, resellers, and charitable organizations. For the three months ended June 30, 2020 and June 30, 2019, sales revenue to our top 10 customers accounted for approximately 28.5% and 34.3%, respectively, of our total revenue. One single customer represented more than 10% of our total revenue for the three months ended June 30, 2020, and no single customer represented more than 10% of our total revenue for the three months ended June 30, 2019. For the six months ended June 30, 2020 and June 30, 2019, sales revenue to our top 10 customers accounted for approximately 30.1% and 34.5%, respectively, or our total revenue. One single customer represented more than 10% of our total revenue for the six months ended June 30, 2020 and no single customer represented more than 10% of our total revenue for the six months ended June 30, 2019. We expect that sales to relatively few customers will continue to account for a significant percentage of our total revenue in future periods. Our future success will significantly depend upon the timing and volume of business from our largest customers and the financial and operational success of these customers. However, we can provide no assurance that any of these customers or any of our other customers will continue to purchase our products at current levels, pricing, or at all, and our revenue could fluctuate significantly due to changes in customer order levels, economic conditions, the adoption of competitive products, or the loss of, reduction of business with, or less favorable terms with any of our largest customers. For example, we have previously experienced a decline in sales to one large national homecare provider who purchased through our private label partner. We have also experienced a decline in sales from other home medical equipment providers and these providers have communicated to us that they continue to be subject to capital constraints. Moreover, in the second quarter of 2020, we experienced a decline in sales to HME providers due to the COVID-19 PHE. If we were to lose one of our key customers or have a key customer significantly reduce its volume of business with us, such as we previously experienced with the large national homecare provider, our revenue may be materially reduced and there would be an adverse effect on our business, financial condition and results of operations.

We obtain some of the components, subassemblies and completed products included in our products from a single source or a limited group of manufacturers or suppliers, and the partial or complete loss of one or more of these manufacturers or suppliers could cause significant production delays, an inability to meet customer demand, substantial loss in revenue, and an adverse effect on our financial condition and results of operations.

We utilize single-source suppliers for some of the components and subassemblies we use in our Inogen One systems, our Inogen At Home systems, and our Tidal Assist Ventilators (TAV). For example, we have elected to source certain key components from single sources of supply, including our batteries, motors, valves, TAV-compatible stationary concentrators, columns, and some molded plastic components. Our dependence on single-source suppliers of components may expose us to several risks, including, among other things:

- our suppliers may encounter financial hardships as a result of unfavorable economic and market conditions unrelated to our demand for components, which could inhibit their ability to fulfill our orders and meet our requirements;
- suppliers may fail to comply with regulatory requirements, be subject to lengthy compliance, validation or qualification periods, or make errors in manufacturing components that could negatively affect the 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, which could inhibit their ability to fulfill our orders and meet our requirements;
- 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 or changes in import tariffs, trade restrictions or barriers or other government actions that impact our ability to obtain such components;
- we may experience delays in delivery by our suppliers due to customs clearing delays, shipping delays, scarcity of raw materials or changes in demand from us or their other customers;
- our suppliers may be unable to meet demands due to the effect of exposure to infectious diseases, epidemics or other public health emergencies, including the COVID-19 public health emergency (PHE);
- we or our suppliers may lose access to critical services, tools, moldings, 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.

We have experienced supply problems with one or more of our suppliers and may again experience problems in the future. For example, we experienced issues with our suppliers sourcing certain components of our Inogen One G5 product in the fourth quarter of 2019 and the first quarter of 2020, which may recur in the future, and which led to orders not being filled in a timely manner. We were not able to obtain sufficient quantities of the required component and could not validate an alternative component in a timely manner. Therefore, we were required to delay manufacturing until additional supplies became available. In the future, we may face similar situations and we may not be able to quickly establish additional or replacement suppliers, particularly for our single source components or subassemblies, and may experience similar delays in manufacturing. Any interruption or delay in the supply of components or subassemblies, or our inability to obtain components or subassemblies from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and cause them to cancel orders or switch to competitive products.

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, 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 requirements could adversely affect the sourcing, availability, and pricing of minerals used in the manufacture of our products. In addition, we have incurred 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 fail to comply with the applicable regulations, we could be required to pay civil penalties, face criminal prosecution and, in some cases, be prohibited from distributing our products in commerce until the products or component substances are brought into compliance. If we are unable to satisfy commercial demand for our products 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 constitute a material modification or require a redesign of our products and, potentially, require additional Food and Drug Administration (FDA) clearance or approval before we could use any materially modified or redesigned product with new components or subassemblies, thereby causing further costs and delays that could adversely affect our business, financial condition and results of operations.

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

We may not be able to compete as effectively with our competitors and ultimately satisfy the needs and preferences of our customers unless we can continue to enhance existing products and develop new innovative products. Product development requires significant financial, technological and other resources. While we expended $3.3 million and $1.5 million for the three months ended June 30, 2020 and June 30, 2019, respectively, and $6.9 million and $3.1 million for the six months ended June 30, 2020 and June 30, 2019, respectively, in research and development efforts, we cannot assure that this level of investment will be sufficient to maintain a competitive advantage in product innovation, which could cause our business to suffer. In addition, we plan to sell the TAV, the newly acquired technology from New Aera, Inc. (New Aera), through our domestic direct-to-consumer sales channel and our business-to-business sales channels worldwide, pending reimbursement and regulatory clearances in each market. We also plan to incorporate the TAV technology directly into our oxygen concentrators. Product improvements and new product introductions also require significant planning, design, development, patent protection, 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 patent protection and 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 the market, be more effective with more features, obtain better market acceptance, or render our products obsolete. Any new products that we develop or acquire, including the TAV, 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. In addition, if we are unable to seek and obtain regulatory approval or adequate coverage and reimbursement for any new products that we develop or introduce, including the TAV, in a timely manner or at all, we may realize lower revenue than expected or even no revenue at all from these products. As a result, our business, financial condition and results of operations could be materially harmed.

We are subject to risks associated with public health threats and epidemics, including the COVID-19 PHE.

Public health outbreaks, epidemics, pandemics of contagious or infectious diseases, such as COVID-19, may significantly disrupt our business. Such outbreaks pose the risk that we or our employees, contractors, suppliers, or other partners may be prevented from conducting business activities for an indefinite period of time due to spread of the disease, or due to shutdowns that may be requested or mandated by federal, state and local governmental authorities. Business disruptions could include disruptions or restrictions on our ability to travel, as well as temporary closures of our facilities or the facilities of our contractors, suppliers, and other partners. For example, business-to-business demand declined in the second quarter of 2020 due to physician offices limiting patient interactions for COPD patient referrals, HME providers minimizing patient interactions in response to the COVID-19 PHE which includes replacing existing oxygen patient setups with POCs and temporary closure of certain respiratory assessment centers and continued tender delays in certain European markets due to the COVID-19 PHE. While it is not possible at this time to estimate the overall impact that the COVID-19 PHE could have on our business, the continued rapid spread of COVID-19, both across the United States and through much of the world, and the measures taken by the governments and local authorities of affected regions has adversely effected our operating results and could cause or contribute to, among other things: significant volatility or reductions in demand for our products; delays in our product development pipeline; delays in obtaining regulatory clearances or approvals to market our products in certain jurisdictions; failure of third parties on which we rely to meet their obligations to us, or significant disruptions in their ability to do so; and our inability to meet our customers' needs due to disruptions to our operations or the operations of our contractors, suppliers, other partners or customers including disruptions to production, development, manufacturing, administrative and supply operations and arrangements.

In addition, we have strived to follow recommended actions of government and health authorities to protect the health and safety of our employees and community, while working to ensure the sustainability of our business operations as this unprecedented situation continues to evolve. Employees whose tasks can be done offsite have been instructed to work from home and most of our total personnel continue to work from home. While we have worked closely with local and national officials and have thus far been able to keep our manufacturing facilities open due to the essential nature of our products, there can be no assurance that we will be able to keep such facilities open indefinitely during the COVID-19 PHE. We have thus far been able to keep our contract manufacturer capability and capacity available but there can be no assurance that we will be able to keep such facilities open indefinitely during COVID-19 pandemic. We continue to evaluate the impact COVID-19 may have on our ability to effectively conduct our business operations as planned to mitigate risk to our employees and customers while taking into account regulatory, institutional, and government guidance and policies, but there can be no assurance that we will be able to avoid part or all of any impact from the spread of COVID-19 or its consequences.

The COVID-19 PHE continues to rapidly evolve. The COVID-19 PHE has already adversely effected our financial results and the extent to which COVID-19 ultimately impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the United States and other countries, business closures or business disruptions, the effectiveness of actions taken in the United States and other countries to contain and treat the disease and to address its impact, including on financial markets or otherwise, and how quickly and to what extent normal economic and operating conditions can resume if and when the COVID-19 PHE subsides. While the extent of the impact of the COVID-19 PHE on our business and financial results is uncertain, we have already been negatively impacted and a continued and prolonged public health crisis could have a further material negative impact on our business, financial condition and results of operations. Even after the COVID-19 PHE has subsided, we may continue to experience materially adverse impacts on our financial condition and our results of operations and many of our known risks described in this Quarterly Report on Form 10-Q may be heightened.

While we have received funding from programs enacted under the CARES Act, due to the recent enactment of the CARES Act and related legislation, there is still a high degree of uncertainty surrounding their implementation, and the COVID-19 PHE continues to evolve. HHS is still issuing additional guidance to providers and suppliers regarding the terms and conditions associated with the implementation of the CARES Act Provider Relief Fund. The federal government may consider additional stimulus and relief efforts, but we are unable to predict whether additional stimulus measures will be enacted or their impact. There can be no assurance as to the total amount of financial and other types of assistance we will receive under the CARES Act or future legislation, if any, and it is difficult to predict the impact of such legislation on our operations. Further, there can be no assurance that the terms of provider relief funding or other programs will not change in ways that affect our funding or eligibility to participate. We will continue to assess the potential impact of the COVID-19 PHE and government responses to the pandemic on our business, results of operations, financial condition and cash flows.

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

As a provider of oxygen equipment rentals, we depend heavily on Medicare reimbursement as a result of the higher proportion of elderly persons suffering from chronic long-term 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 up to 56% of long-term oxygen therapy patients in the United States have primary coverage under traditional fee-for-service Medicare Part B. 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 HME 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 our 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 while we continue to incur customer service and maintenance costs. Our capped patients as a percentage of total patients on service was approximately 17.2% as of June 30, 2020 and 20.2% as of June 30, 2019. 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 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 certain 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. As of January 1, 2017, Centers for Medicare and Medicaid Services (CMS) has decreased prices for durable medical equipment in non-competitive bidding areas to match competitive bidding prices.
- There have been significant U.S. reimbursement and policy changes associated with the COVID-19 PHE that impact oxygen therapy and other durable medical equipment. The CARES Act allows HHS to waive certain Medicare telehealth payment requirements during the COVID-19 PHE declared by HHS on January 31, 2020 to allow beneficiaries in all areas to receive telehealth services, including at their home, starting March 6, 2020. H.R. 6074 also granted authority to waive certain requirements. Under this authority, CMS clarified that HHS would not conduct audits to determine whether there was a prior physician-patient relationship for telehealth claims submitted during the COVID-19 PHE. The CARES Act, passed on March 27, 2020 included the extension of the 50/50 blended rate for HME in rural and non-contiguous, non-competitively bid areas and established a new 75/25 blended rate for all other non-competitively bid areas through the duration of the COVID-19 PHE. The 75/25 blended rate is retroactive to March 6, 2020. While the duration of the current emergency is impossible to predict, the Zika virus PHE lasted approximately 360 days, and the H1N1 flu PHE lasted approximately 450 days. The CARES Act also included a temporary elimination of the 2% Medicare sequestration reduction that went into effect in 2013. This relief will be effective May 1, 2020 through December 31, 2020. In addition, the CARES Act established a provider relief fund of $100 billion, of which $30 billion was distributed on April 10, 2020, for Medicare providers and suppliers to prevent, prepare for, and respond to the COVID-19 PHE, and as a Medicare supplier we also received funds of $6.2 million in the second quarter of 2020. The Paycheck Protection Program and Heath Care Enhancement Act was also signed into law on April 24, 2020 and provides additional funding of $484 billion to programs enacted under the CARES Act. Of the $484 billion, $75 billion is additional funding for healthcare providers to reimburse healthcare related expenses and lost revenues attributable to COVID-19 PHE, which is in addition to the $100 billion approved in the CARES Act.
- On April 6, 2020, an Interim Final Rule (IFR) was published in the Federal Register for policy and regulatory revisions in response to the COVID-19 PHE. There was a comment period until June 1, 2020. This IFR included that for the duration of the COVID-19 PHE, the face-to-face requirements and clinical indications of coverage for home oxygen, among other respiratory products, will be waived.

- The administration has also issued a number of regulatory waivers to increase the flexibility in DMEPOS suppliers' ability to service patients quickly and without the normal requirements. For example, the patient signature for proof of delivery for DMEPOS is waived when signatures cannot be collected during the COVID-19 PHE. In addition, CMS increased Medicare contractors' ability to waive replacement product requirements, paused the national prior authorization program for certain DMEPOS, automatically extended expiring accreditations, granted contractors the flexibility to grant appeals extensions, and medical review suspension. Both the IFR and temporary regulatory changes show significant flexibility from CMS to improve access for oxygen and other durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) items during this COVID-19 PHE. These changes were retroactive to early March 2020. However, in July 2020, CMS released a COVID-19 Product Burden Relief FAQs that included updates to this IFR, including that the pausing of the national prior authorization program for certain DMEPOS and medical review suspension will likely end, effective August 3, 2020.

These legislative provisions as currently in effect have had and may continue to have a material and/or adverse effect on our business, financial condition and results of operations.

The 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 that 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). This was effective beginning January 1, 2018.

Due to budgetary shortfalls, many states are considering, or have enacted, cuts to their Medicaid programs. In addition, many private payors reimburse at a percentage of the Medicare rates. Medicare, Medicaid and private payor reimbursement rate 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.

On January 17, 2017, HHS published a final rule effective March 20, 2017 to address the appeals backlog that includes allowing certain decisions to be made by the Medicare Appeals Council to set precedent for lower levels of appeal, expansion of the pool of available adjudicators, and increasing decision-making consistency among the levels of appeal. In addition, it included provisions to improve the efficiency by streamlining the appeals process, allowing attorneys to handle some procedural matters at the administrative law judge level, and proposed funding increases and legislative actions outlined in the federal budget for 2017. HHS estimates this could eliminate the backlog in appeals by 2021. However, if this plan is not effective, the appeals backlog could increase, which could increase our collection times and decrease our cash flow, increase billing administrative costs, and/or increase the provision for rental revenue adjustments, which 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 HHS 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.

Effective January 1, 2019, Medicare beneficiaries may receive durable medical equipment from any Medicare-enrolled supplier until new contracts are in effect under competitive bidding Round 2021, which is expected to begin on January 1, 2021. Reimbursement rates between January 1, 2019 and December 31, 2020 will be set at the current pricing level throughout the United States for all Medicare patients, subject to Consumer Price Index (CPI) and budget neutrality adjustments. Pricing in competitive bidding areas will be subject to annual CPI adjustments beginning in 2019 until Round 2021 begins. However, CMS also changed the calculation on budget neutrality to apply the offset to all oxygen and oxygen equipment classes beginning January 1, 2019 instead of previously only applying these adjustments to stationary oxygen equipment and oxygen contents. Based on these CPI and budget neutrality adjustments, effective January 1, 2019 the average Medicare reimbursement rates in former competitive bidding areas decreased to $72.92 a month for E1390 and $35.72 a month for E1392. Effective January 1, 2020, the average Medicare reimbursement rates were increased by 1.5% to $73.98 a month for E1390 and $36.25 a month for E1392 in these regions that were previously subject to competitive bidding. In addition, the average Medicare reimbursement rates in non-rural, non-former competitive bidding areas increased by 3.5% to $74.84 a month for E1390 and $36.87 a month for E1392. In Round 2021 of DMEPOS competitive bidding program, there have been some revisions to the bidding methodology including surety bond requirements, lead item pricing, and setting reimbursement rates at the maximum winning bid rate instead of the median winning bid rate. In prior rounds of competitive bidding, our products were categorized in the product category of respiratory equipment and related supplies and accessories, which included oxygen equipment, continuous positive airway pressure (CPAP) devices and respiratory assist devices (RADs) and related supplies and accessories. In Round 2021 of bidding, oxygen and oxygen equipment is its own product category and the lead item has been established as E1390. However, due to the lead item pricing methodology based on the 2015 standard Medicare fee schedule, E1392 reimbursement rates could be reduced significantly (we estimate approximately 42%) even if E1390 reimbursement rates do not change. This would lead to combined E1390 plus E1392 reimbursement rates to decrease by approximately 15%. The bidding window closed on September 18, 2019. It is unclear how pricing will be impacted due to these new bids. We expect contracts and pricing to be announced in 2020.

In addition to regional pricing, CMS imposed different pricing on “frontier states” and rural areas. 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. Effective June 1, 2018 through December 31, 2020, for frontier and rural states, frontier and rural zip codes in non-frontier/rural states and non-contiguous United States areas, the single payment amount will be the 50/50 blended reimbursement rates based on an average of the pre-competitive reimbursement bidding rates and the current average reimbursement rates to account for higher servicing costs in these areas. In 2019, this rate was $134.71 a month for E1390 and $44.32 a month for E1392, and this rate increased by 1.5% effective January 1, 2020 to $136.71 a month for E1390 and $44.93 a month for E1392. We estimate that approximately 15% of our patients are eligible to receive the higher reimbursement rates based on the geographic locations of our current patient population.

Cumulatively in previous rounds of competitive bidding, we were offered contracts for a substantial majority of the Competitive Bidding Areas (CBAs) and product categories for which we submitted bids. Effective January 1, 2017, we believe we had access to over 90% of the Medicare oxygen therapy market based on our analysis of the 103 CBAs that we won out of the 130 total CBAs. These 130 CBAs represented approximately 36% of the Medicare market with the remaining approximately 64% of the market not subject to competitive bidding. As of January 1, 2019, and until Round 2021 of competitive bidding becomes effective, we can choose to accept Medicare oxygen patients throughout the United States. As of July 2018, we currently operate in all 50 states in the U.S. We did not sell or rent to patients in Hawaii due to the licensure requirements from inception to June 2018.

We cannot guarantee that we will be offered contracts in subsequent rounds of competitive bidding. In all five rounds of competitive bidding in which we have participated, we have gained access to certain CBAs and been excluded from other CBAs.

Medicare revenue, including patient co-insurance and deductible obligations, represented 6.8% and 4.1% of our total revenue in the three months ended June 30, 2020 and June 30, 2019, respectively, and 5.6% and 4.5% in the six months ended June 30, 2020 and June 30, 2019, respectively.

Medicare reimbursement for oxygen rental equipment is limited to a maximum of 36 months within a 60-month service period, and the equipment remains the property of the home oxygen supplier. The supplier that billed Medicare for the 36th month of service 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 supplier is required to keep the equipment provided in working order and in some cases, CMS will reimburse for repair costs. At the end of the five-year useful life of the equipment, 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 supplier 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 as of June 30, 2020 and June 30, 2019. Our capped patients as a percentage of total patients on service was approximately 17.2% and 20.2% as of June 30, 2020 and June 30, 2019, respectively. 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.

Our obligations to service Medicare patients over the rental period include supplying working equipment that meets each patient’s oxygen needs pursuant to his/her 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, as long as that equipment 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 the patient first receives oxygen therapy and one year after each new 36-month reimbursement period begins. The patient can choose to receive oxygen supplies and services from another supplier at any time, but the supplier may only transition the patient to another supplier in certain circumstances.

Average Medicare reimbursement rates for NIV Healthcare Common Procedure Coding System (HCPCS) code E0466 were a monthly, non-capped rental with rates of $1,042.26 a month in 2019, and increased 0.9% effective January 1, 2020 to $1,051.64 a month, excluding Puerto Rico where the monthly Medicare reimbursement rate for E0466 was $1,827.24 per month in 2019 and increased to $1,843.69 a month effective January 1, 2020. While NIV has been removed from competitive bidding round 2021, NIV may be included in future rounds, which could reduce the reimbursement rates for these products. In addition, the Medicare Coverage Advisory Committee (MEDCAC) recently had a meeting on July 22, 2020 to discuss home use of non-invasive positive pressure ventilation in patients with chronic respiratory failure consequent to COPD. CMS is seeking MEDCAC's recommendations regarding the characteristics that define patient selection and usage criteria for these items. This request could signal forthcoming changes in Medicare coverage of these items, and possibly changes in HCPCS codes, which could impact our NIV business and growth initiatives.

On May 15, 2019, a bi-partisan bill was introduced in the House of Representatives that would provide relief from competitive bidding in non-bid areas. As of July 1, 2020, there were 75 co-sponsors on this bill. If passed, the bill would provide retroactive relief to rural areas by making the 50/50 blended reimbursement rate in rural and noncontiguous areas to all items and services furnished with dates of service from June 1, 2018, with no end date, and by introducing a 75/25 blended reimbursement rate for areas other than rural or noncontiguous areas. The legislation also proposes to remedy a double-dip cut to oxygen payments caused by the misapplication of a 2006 budget neutrality offset balancing increased utilization for oxygen generating portable equipment with lower reimbursement for stationary equipment. There is no known timing on voting on this bill. As part of the CARES Act, portions of this bill including the 50/50 blended reimbursement rate in rural and noncontiguous areas and the 72/25 blended reimbursement rate for non-rural, non-competitive bidding areas were approved effective for claims after March 6, 2020 for the length of the COVID-19 PHE.

In February 2020, the current presidential administration sent Congress a 2021 budget proposal that included language on competitive bidding. Specifically, the proposal would eliminate the requirement under the competitive bidding program that CMS pay a single payment amount based on the median bid price, proposing instead that CMS pay winning suppliers at their own bid amounts beginning in 2024. Additionally, this proposal would expand competitive bidding to all areas of the country, including rural areas, which will be based on competition in those areas rather than on competition in urban areas. In addition to changes to competitive bidding, the 2021 budget proposal would allow on an annual basis through rulemaking for CMS to use retail price information to create DMEPOS fee schedule rates, which would not take into account associated services that Medicare DME suppliers offer. The proposal would also enable CMS not to impose the face-to-face requirement on all providers for durable medical equipment. Furthermore, the proposal seeks to address excessive billing of durable medical equipment that requires refills or serial claims. Specifically, Medicare would gain authority to test whether using a benefits manager for serial durable medical equipment claims would result in lower improper payments and reductions in inappropriate utilization. The benefits manager would be responsible for ensuring beneficiaries were receiving the correct quantity of supplies or service for the appropriate time period. Lastly, the proposal would expand prior authorization to additional items and services that are both high-cost and at high-risk for improper payments. These provisions were not included in the latest omnibus budget, so it is unclear if any of these proposals will be implemented. We believe additional cuts to reimbursement would continue to drive conversion to non-delivery technologies, including POCs; however, this could also exacerbate patient access issues for treatment.

On August 6, 2019, CMS issued a proposed rule to establish methodologies to modernize pricing of new DMEPOS items and services based on commercial pricing data. In addition, the proposed rule recommends streamlining requirements related to face-to-face encounters, written orders prior to delivery and/or prior authorizations to reduce provider confusion. Lastly, the proposed rule recommends revising the existing DMEPOS competitive bidding program regulations to recognize that changes of ownership may occur on shorter timeframes and revising the submission of a hearing request in notices of breach of contract. CMS solicited comments on this proposed rule through September 27, 2019.

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

The Medicare Fee-For-Service (FFS) sequestration reduction has and may continue to negatively affect 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 co-insurance, any applicable deductible, and any applicable Medicare secondary payment adjustments. These reductions are included in rental revenue adjustments. This sequestration reduction was scheduled to continue until further notice. However, a provision in the CARES Act temporarily eliminated the 2% Medicare sequestration reduction for claims dated from May 1, 2020 through December 31, 2020 and extends the end date of the sequester by one year, through 2030, in order to offset the 2020 suspension. Once the sequestration reduction is reinstated after December 31, 2020, this could adversely affect our financial condition 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 DMEPOS that the agency characterizes as "frequently subject to unnecessary utilization." The final rule was published on December 30, 2015 and specified an initial master list of 135 items that could potentially be subject to PA. Initially stationary oxygen rentals (code E1390) was included on the master list, but it was later removed. On April 22, 2019, stationary oxygen rentals (E1390) was again added to the list of potential codes that could be subject to PA. The master list is 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." 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 sub-regulatory guidance on these timelines in the future. On April 6, 2020, an IFR was published in the Federal Register for policy and regulatory revisions in response to the COVID-19 PHE, and there was a comment period until June 30, 2020. Pursuant to a temporary regulatory waiver implemented by the administration, CMS has paused the national prior authorization program for certain DMEPOS. However, in July 2020, CMS released a COVID-19 Product Burden Relief FAQs that included updates to this IFR, including that the pausing of the national prior authorization program for certain DMEPOS will likely end, effective August 3, 2020. 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.

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, 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 created, among other things, 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 reimbursements to providers up to 2% per fiscal year, which went into effect on April 1, 2013, and will remain in effect through 2030 unless additional Congressional action is taken. For example, a provision in the CARES Act temporarily eliminated the 2% Medicare sequestration reduction for claims dated from May 1, 2020 through December 31, 2020 and extends the end date of the sequester by one year, through 2030, in order to offset the 2020 suspension. 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. 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 in a particular state, which would adversely impact our business, financial condition and results of operations.

We face uncertainties that might result from modification or repeal of any of the provisions of the Patient Protection and Affordable Care Act, including as a result of current and future executive orders, legislative actions and judicial decisions. The impact of those changes on us and potential effect on the durable medical equipment industry as a whole is currently unknown. But, any changes to the Patient Protection and Affordable Care Act are likely to have an impact on our results of operations and may have a material adverse effect on our results of operations. We cannot predict what other healthcare programs and regulations will ultimately be implemented at the federal or state level or the effect of any future legislation or regulation in the United States may have on our business.

We depend upon reimbursement from Medicare, private payors, Medicaid and payments from 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 be adversely affected.

A significant portion of our rental 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 June 30, 2020 and June 30, 2019, approximately 8.5% and 5.1%, respectively, and for the six months ended June 30, 2020 and June 30, 2019, approximately 7.1% and 5.5%, respectively, of our total revenue was derived from Medicare, private payors, Medicaid, and individual patients who directly receive reimbursement from third-party payors and this percentage could increase as a percent of total revenue if we increase net patient additions faster than our sales revenue growth.

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 process, it would adversely affect our business, financial condition and results of operations.

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. For example, our TAV product is sold in some cases with a stationary concentrator produced by another oxygen concentrator manufacturer. Due to the COVID-19 PHE and related increased demand for stationary oxygen concentrators, we have limited supply of these stationary oxygen concentrators at this time. This will have an impact on TAV sales until supply is stabilized or we receive regulatory clearance or approval to use the TAV with another oxygen concentrator source. We may also be affected by other supply limitations during the COVID-19 PHE that could impact our ability to fulfill orders. If we inaccurately forecast demand or fail to place orders timely enough relative to fluctuating lead time requirements for components or subassemblies, our ability to manufacture and commercialize our products 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 or if our suppliers, in the near term or the long term, are not able to supply sufficient quantities of components or subassemblies needed for our products due to the COVID-19 PHE, we may be required to change suppliers which would be time consuming and disruptive and could adversely affect our business, financial condition and results of operations.

If our manufacturing facilities become unavailable or inoperable, we could be unable to continue manufacturing our products and, as a result, our business, financial condition and results of operations could be adversely affected until we are able to secure a new facility.

We assemble our products at our facilities in Richardson, Texas and Goleta, California and through our contract manufacturer in the Czech Republic. 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 products would be costly to replace and could require substantial lead time to procure, repair or replace. Our facilities may be harmed or rendered inoperable by natural or man-made disasters, including, but not limited to, the COVID-19 PHE related facility shutdowns, fire, flood, earthquakes and power outages, which may render it difficult or impossible for us to manufacture our products for some period of time. Although we and our contract manufacturer have been able to keep our manufacturing facilities open thus far during the COVID-19 PHE, we cannot assure that we will be able to continue to do so indefinitely. If any of our facilities become unavailable to us, we cannot provide assurances that we will be able to secure and equip 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 and business interruptions which may help us recover some of the costs of damage to our property, costs of recovery and lost income from the disruption of our business, insurance coverage of certain perils may be limited or unavailable at cost effective rates and may therefore 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 could not be able to manufacture, store, and ship our products in sufficient quantity or a cost effective or timely manner, which would adversely affect our business, financial condition and results of operations.

We rely upon a third-party contract manufacturer for certain manufacturing operations and our business and results of operations may be adversely affected by risks associated with their business, financial condition and the geography in which they operate.

We utilize a third-party contract manufacturer located in the Czech Republic for production of a portion of our Inogen One G3 and Inogen One G5 concentrators. In 2018, 2019 and the first half of 2020, our contract manufacturer produced the vast majority of the concentrators required to support our European demand and we expect this to continue for the remainder of 2020. There are a number of risks associated with our dependence on a contract manufacturer, including:

- reduced control over delivery schedules and planning;
- reliance on the quality assurance procedures of a third party;
- risks associated with our contract manufacturer failing to manufacture our products according to our specifications, quality regulations, including the FDA's Quality System regulations, or otherwise manufacturing products that we or regulatory authorities deem to be unsuitable for commercial use;
- risks associated with our contract manufacturer's ability to successfully undergo FDA and other regulatory authority quality inspections;
- potential uncertainty regarding manufacturing yields and costs;
- availability of manufacturing capability and capacity, particularly during periods of high demand and the COVID-19 PHE;
- risks and uncertainties associated with the location or country where our products are manufactured, including potential manufacturing disruptions caused by social, geopolitical or environmental factors;
- changes in U.S. law or policy governing foreign trade, manufacturing, development and investment in the countries where we manufacture our products, including the World Trade Organization Information Technology Agreement or other free trade agreements;
- delays in delivery by suppliers due to customs clearing delays, shipping delays, scarcity of raw materials and changes in demand from us or their other customers;
- limited warranties provided to us; and
- potential misappropriation of our intellectual property.

These and other risks could impair our ability to fulfill orders, harm our sales and impact our reputation with customers. If our contract manufacturer is unable or unwilling to manufacture our products or components of our products, or if our contract manufacturer discontinues operations, we may be required to identify and qualify alternative manufacturers, which could cause us to be unable to meet our supply requirements to our customers and result in the breach of our customer agreements. The process of qualifying a new contract manufacturer and commencing volume production is expensive and time-consuming, and if we are required to change or qualify a new contract manufacturer, we would likely lose sales revenue and damage our existing customer relationships.

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

A portion of our rental revenue is derived from private payors. Based on our patient population, we estimate approximately 44% of potential customers have non-Medicare insurance coverage (including Medicare Advantage plans). 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 results of operations. 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 reimbursement 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 maintain or obtain new private payor contracts or the unavailability of third-party coverage or inadequacy of reimbursement for our products would adversely affect our business, financial condition and results of operations.

If we are unable to manage our anticipated growth effectively, our business could be harmed.

We have previously experienced periods of rapid growth in short periods of time. These periods of rapid growth of our business have placed a significant strain on our managerial and operational resources and systems. For example, as our business has grown, we have seen the cost per generated lead trend higher than historical averages. In addition, many of the sales representatives we hired in 2018 were unable to meet sales targets and were thus transitioned out To continue to grow our business, we must attract and retain capable personnel and manage and train them effectively, particularly related to sales representatives and supporting sales personnel. We must also upgrade our internal business processes and capabilities to create the scalability that a growing business demands. Going forward, we are hiring additional sales representatives at a more controlled pace across all three facilities to expand sales capacity, but our sales representative headcount was down significantly at year-end 2019 compared to year-end 2018 and, due to the impact of the COVID-19 PHE, we expect a lower growth rate of sales representative headcount for the remainder of 2020. Our growth expectations in direct-to-consumer sales are lower given the slowdown of hiring new sales representatives and lower productivity due to the impact of the COVID-19 PHE, including lower consumer travel and consumer confidence. While we believe we are making the necessary changes to improve sales management infrastructure to support sales representative training and onboarding, it will take more time to evaluate whether these changes are effective in the long term, particularly given the impact of the COVID-19 PHE, and to the extent they are not effective it may negatively affect our financial condition and results of operations. In addition, our initially planned sales expansion and productivity improvements for 2020 have been and may continue to be negatively impacted due to the COVID-19 PHE. In connection with the COVID-19 PHE, we expect to reduce sales representative headcount additions for the remainder of 2020, and we expect the COVID-19 PHE may continue to reduce the number of oxygen therapy patients who purchase our products directly through our direct-to-consumer sales channel, and the number of sales generated from physician offices or make it more difficult to get paperwork and testing from physician offices. The reduction in nonessential travel may also continue to harm our business, particularly for our physician-based sales representatives and business-to-business partners who rely on physician office and hospital visits to drive business, and patients who rely on physicians to prescribe them oxygen therapy after in-office testing.

We also experienced increased demand for our products towards the end of the first quarter of 2020 since physicians may prescribe supplemental oxygen as a treatment for COVID-19. As a result, we initially saw increased demand for our products for applicable patients who may be treated in the home instead of an acute hospital setting. This demand is mostly being filled through our HME provider partners, who work closely with hospitals to discharge patients into a home treatment program. If this demand increase resumes and we cannot meet this demand, we may lose market share to competitors or lose customers, which may negatively affect our financial conditions and results of operations. In addition, even if we are able to meet any such increased demand, such an increase in business-to-business sales mix may negatively impact our gross margin as HME provider purchases have a significantly lower average selling price than direct-to-consumer purchases.

During 2019, we signed leases to expand our facilities located in Richardson, Texas and Goleta, California, which are expected to commence in 2021. Domestic expansion, combined with our use of a contract manufacturer in Europe to produce a portion of our Inogen One G3 and Inogen One G5 concentrators, is expected to be sufficient to meet our manufacturing needs provided that these facilities remain operational. However, construction delays due to shelter-in-place orders related to the COVID-19 PHE may delay our access to our facility in Goleta, California. In addition, our anticipated growth may place additional strain on our supply chain and manufacturing facilities, resulting in an increased need for us to carefully monitor parts inventory, capable staffing and quality assurance. Any failure by us to manage the scalability of our process or other aspects of our growth effectively could have an adverse effect on our ability to achieve our development and commercialization goals and negatively affect our financial condition and results of operations.

We may expand through acquisitions of, or investments in, other companies, each of which may divert our management's attention, result in additional dilution to our stockholders, increase expenses, disrupt our operations, and harm our results of operations.

Our business strategy may, from time to time, include acquiring or investing in complementary services, technologies or businesses, such as our acquisition of MedSupport in 2017 and our acquisition of New Aera in 2019. We do not have an extensive history of acquiring other companies and cannot assure you that we will successfully identify suitable acquisition candidates, integrate or manage disparate technologies, lines of business, personnel and corporate cultures, realize our business strategy or the expected return on our investment, or manage a geographically dispersed company. Any such acquisition or investment could materially and adversely affect our financial condition and results of operations. We may issue equity securities which could dilute current stockholders' ownership, incur debt, assume contingent or other liabilities and expend cash in acquisitions, which could negatively impact our financial condition, stockholder equity, and stock price. The acquisition and integration process is complex, expensive and time-consuming, and may cause an interruption of, or loss of momentum in, product development and sales activities and operations of both companies, and we may incur substantial cost and expense, as well as divert the attention of management.

Acquisitions and other strategic investments involve significant risks and uncertainties, including:

- the potential failure to achieve the expected benefits of the combination or acquisition;
- the potential failure to successfully develop or commercialize the acquired products or technology;
- unanticipated costs and liabilities;
- difficulties in integrating new products, businesses, operations, and technology infrastructure in an efficient and effective manner;
- difficulties in maintaining customer relations;
- the potential loss of key employees of the acquired businesses;
- the diversion of the attention of our senior management from the operation of our daily business;
- the potential adverse effect on our cash position to the extent that we use cash for the purchase price;
- the potential incurrence of interest expense and debt service requirements if we incur debt to pay for an acquisition;
- the potential issuance of securities that would dilute our stockholders' percentage ownership;
- the potential to incur large and immediate write-offs and restructuring and other related expenses;
- the potential of amortization expenses related to intangible assets;
- the potential failure to achieve anticipated reimbursement classifications for acquired products;
- the potential to become involved in intellectual property litigation related to such acquisitions or strategic investments; and
- the inability to maintain uniform standards, controls, policies, and procedures.

Any acquisition or investment could expose us to unknown liabilities. Moreover, we cannot assure you that we will realize the anticipated benefits of any acquisition or investment. In addition, our inability to successfully operate and integrate newly acquired businesses appropriately, effectively, and in a timely manner could impair our ability to take advantage of future growth opportunities and other advances in technology, as well as on our revenues, gross margins, and expenses.

As part of our ongoing efforts to advance patient preference and maintain our technology leadership position, we acquired New Aera in 2019 and have completed our integration process. We have made certain assumptions relating to the New Aera acquisition, which assumptions may be inaccurate, including the failure to realize the expected benefits of the acquisition, failure to realize expected revenue, higher than expected operating, transaction and integration costs, as well as general economic and business conditions that adversely affect the combined company following the acquisition. If our assumptions relating to the acquisition are inaccurate, we may not be able to realize anticipated synergies and opportunities as a result of the acquisition, and the business may not perform as planned as a result of many of the risks and uncertainties that apply to the acquisition and to the rest of our business. For example, additional risks and uncertainties that could cause actual results to differ materially from currently anticipated results include, but are not limited to; risks relating to our ability to successfully integrate New Aera's business and operations within our existing business and operations; our ability to commercialize the TAV; market acceptance of the TAV; our ability to obtain Medicare or commercial reimbursement for the TAV; our ability to successfully incorporate TAV into our existing products; competition; our sales, marketing and distribution capabilities; our planned sales, marketing, and research and development activities; interruptions or delays in the supply of components or materials for, or manufacturing of, our products, which in certain cases are purchased through sole and single source suppliers; seasonal variations in customer operations; unanticipated increases in costs or expenses; risks associated with international operations; intellectual property risks and the other risks identified in this Quarterly Report on Form 10-Q. We may also encounter difficulties in integrating New Aera into our existing business. If anticipated synergies and opportunities are not realized, our business, operating results and financial condition would be harmed.

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

Our products are manufactured using complex parts and processes, sophisticated equipment and strict adherence to design specifications and quality standards. Any unforeseen manufacturing problems, such as disruption related to the COVID-19 PHE, contamination of our facility, equipment malfunction or miscalibration, supply chain shortages, regulatory findings, or failure to strictly follow procedures or meet design 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. For example, in July 2019 we experienced unforeseen manufacturing challenges with respect to a battery issue on the Inogen One G3 and a motherboard issue on the Inogen One G5. The ongoing servicing costs associated with these issues, or other manufacturing issues we may experience in the future may increase our cost of goods sold, adversely affect our operating results and harm our reputation. Additionally, regulators may disagree with our handling of any such incidents and take action. Also, although we believe we are addressing these issues, we may experience additional unexpected product defects or errors that could have adverse effects. In addition to these manufacturing issues, we also have experienced issues with our supply chain, as discussed in detail in the risk factor entitled "*We obtain some of the components, subassemblies and completed products included in our products from a single source or a limited group of manufacturers or suppliers, and the partial or complete loss of one or more of these manufacturers or suppliers could cause significant production delays, an inability to meet customer demand, substantial loss in revenue, and an adverse effect on our financial condition and results of operations.*"

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 essentially 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.

We are exposed to the credit and non-payment risk of our HME providers, distributors, private label partners and resellers, especially during times of economic uncertainty and tight credit markets, which could result in material losses.

We sell our products to certain HME providers, distributors, private label partner and resellers on unsecured credit, with terms that vary depending upon the customer's credit history, solvency, cash flow, credit limits and sales history, as well as prevailing terms with similarly situated customers and whether sufficient credit insurance can be obtained. In particular, two customers each represented more than 10% of our net accounts receivable balance with accounts receivable balances of $8.9 million and $5.9 million, respectively, as of June 30, 2020, and two customers each with an accounts receivable balance of $10.7 million and $5.2 million, respectively, as of December 31, 2019. Challenging economic conditions, including those associated with the COVID-19 PHE, may impair the ability of our customers to pay for products they have purchased, and as a result, our reserve for doubtful accounts could increase and, even if increased, may turn out to be insufficient. Moreover, even in cases where we have insolvency risk insurance to protect against a customer's bankruptcy, insolvency or liquidation, this insurance typically contains a significant deductible and co-payment obligation and does not cover all instances of non-payment. Our exposure to credit risks of our business partners may increase if our business partners and their end customers are adversely affected by global or regional economic conditions, including those associated with the COVID-19 PHE. One or more of these business partners could delay payments or default on credit extended to them, either of which could adversely affect our business, financial condition and results of operations.

We generate a substantial portion of our revenue internationally and are subject to various risks relating to such international activities, which could adversely affect our operating results. In addition, any disruption or delay in the shipping of our products, whether domestically or internationally, may have an adverse effect on our financial condition and results of operations.

During the six months ended June 30, 2020 and June 30, 2019, approximately 21.2% and 22.2%, respectively, of our total revenue was generated from customers located outside of the United States. We believe that a significant percentage of our future revenue will continue to come from international sources as we expand our international operations and develop opportunities in other countries. Engaging in international business inherently involves a number of difficulties and risks, including:

- required compliance with anti-bribery laws, such as the U.S. Foreign Corrupt Practices Act and U.K. Bribery Act, data privacy regulations, such as the European Union General Data Protection Regulation (GDPR), labor laws, and anti-competition regulations;
- export or import delays and restrictions;
- obtaining and maintaining regulatory clearances, approvals and certifications;
- laws and business practices favoring local companies;
- difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
- unstable economic, political, and regulatory conditions;
- supply chain complexities;
- fluctuations in currency exchange rates;
- fluctuations in demand due to country-specific tenders and tender uncertainty and capital expenditure constraints;
- potentially adverse tax consequences, tariffs, customs charges, bureaucratic requirements, and other trade barriers;
- any other government actions, by the United States, China or other countries, that impose barriers or restrictions that would impact our ability to sell or ship products to customers; and
- difficulties protecting or procuring intellectual property rights.

If one or more of these risks occurs, it could require us to dedicate significant resources to remedy, and if we are unsuccessful in finding a solution, our financial condition and results of operations will suffer.

In addition, on June 23, 2016, the United Kingdom (U.K.) held a referendum in which voters approved an exit from the European Union, commonly referred to as "Brexit." This decision created an uncertain political and economic environment in the U.K. and other European Union countries, and the formal process for leaving the European Union has taken years to complete. The U.K. formally left the European Union on January 31, 2020 and is now in a transition period through December 31, 2020. Adverse consequences concerning Brexit or the future of the European Union could include deterioration in global economic conditions, instability in global financial markets, political uncertainty, volatility in currency exchange rates or adverse changes in the cross-border agreements currently in place, any of which could have an adverse impact on our financial results in the future.

A significant amount of our international product sales are currently denominated in U.S. dollars and fluctuations in the value of the U.S. dollar relative to foreign currencies could decrease demand for our products and adversely impact our financial performance. For example, if the value of the U.S. dollar increases relative to foreign currencies, our products could become more costly to the international consumer and therefore less competitive in international markets. Our results of operations and cash flows are, therefore, subject to fluctuations due to changes in foreign currency exchange rates. The volatility of exchange rates depends on many factors that we cannot forecast with reliable accuracy. We have experienced and will continue to experience fluctuations in our net income or loss as a result of transaction gains or losses related to revaluing certain current asset and current liability balances that are denominated in currencies other than the functional currency of the entities in which they are recorded. For example, for the six months ended June 30, 2020 and June 30, 2019, we experienced net foreign currency gains of less than $0.1 million and less than $0.1 million, respectively. Fluctuations in currency exchange rates could have an adverse impact on our financial results in the future. While we have a hedging program for Euros that attempts to manage currency exchange rate risks to an acceptable level based on management's judgment of the appropriate trade-off between risk, opportunity, and cost, this hedging program does not completely eliminate the effects of currency exchange rate fluctuations. In addition, currency hedging may result in a reduction or increase in revenue should the currency strengthen or decline during the contract period. A discussion of the hedging program is contained in Item 7A. Quantitative and Qualitative Disclosures about Market Risk in our Annual Report on Form 10-K for the year ended December 31, 2019. Additional information on our hedging arrangements is also contained in Note 4 – Fair value measurements and Item 3 – Quantitative and Qualitative Disclosures About Market Risk in the condensed notes to our consolidated financial statements in this Quarterly Report on Form 10-Q.

We rely on shipping providers to deliver products to our customers globally. Labor, tariff, or World Trade Organization-related disputes, piracy, physical damage to shipping facilities or equipment caused by severe weather or terrorist incidents, congestion at shipping facilities, inadequate equipment to load, dock, and offload our products, energy-related tie-ups, shipping delays associated with the COVID-19 PHE, or other factors could disrupt or delay shipping or offloading of our products domestically and internationally. Such disruptions or delays may have an adverse effect on our financial condition and results of operations.

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 and manufacturer 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. We provide training to all employees, including management, to ensure compliance with the FCPA. 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 have to defend ourselves and 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 results of operations 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 affect our financial condition and results of operations. 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 retain or 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 resulting in adverse results of operations.

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 results of operations.

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 or product 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 results of operations 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, patent defense 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 affect our business, financial condition and results of operations.

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

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 condition 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, accounting and compliance staff as well as our sales and marketing personnel. 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 executive management team. The loss of any member of our executive management team could harm our ability to implement our business strategy and respond to the market conditions in which we operate.

We and our vendors and service providers rely on information technology networks and systems, and if we are unable to protect against service interruptions, data corruption, cybersecurity risks, data security incidents and/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, customer, operational, compliance, 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 networks and systems may be susceptible to damage, disruptions or shutdowns, hardware or software failures, power outages, computer viruses, cybersecurity risks, data security incidents, telecommunication failures, user errors or catastrophic events. Like other companies, we have experienced data security incidents before. For example, on April 13, 2018, we announced that messages within an employee email account were accessed by unknown persons outside of our company without authorization. Some of the messages and attached files in that email account contained personal information belonging to our rental customers. We immediately took steps to secure customer information and hired a leading forensics firm to investigate the incident and to bolster our security. The unauthorized access of the potentially impacted email account appears to have occurred between January 2, 2018 and March 14, 2018. We notified approximately 30,000 current and former rental customers of this incident as well as the applicable regulatory authorities. We also provided resources, including credit monitoring and an insurance reimbursement policy, to assist all potentially affected individuals. We have incurred remedial, legal and other costs in connection with this incident. We have insurance coverage in place for certain potential liabilities and costs relating to service interruptions, data corruption, cybersecurity risks, data security incidents and/or network security breaches, but this insurance is limited in amount, subject to a deductible, and may not be adequate to cover us for all costs arising from these incidents.

If our information technology networks and systems suffer unauthorized access, severe damage, disruption or shutdown, and our business does not effectively identify or resolve the issues in a timely manner, our operations could be disrupted, we could be subject to regulatory and consumer lawsuits and our business could be negatively affected. In addition, cybersecurity risks and data security incidents could lead to potential unauthorized access to or acquisition of confidential information (including protected health information), and data loss and corruption. There is no assurance that we will not experience service interruptions, security breaches, cyber security risks and data security incidents, or other information technology failures in the future.

Due to the COVID-19 PHE, we have an increased number of employees working remotely. As a result, we may have increased cyber security and data security risks, due to increased use of home wi-fi networks and virtual private networks, as well as increased disbursement of physical machines. While we implement IT controls to reduce the risk of a cyber security and data security breach, there is no guarantee that these measures will be adequate to safeguard all systems with an increased number of employees working remotely.

The methods used to obtain unauthorized access, disable or degrade service or sabotage systems are constantly evolving and may be difficult to anticipate or to detect for long periods of time. As a result of these types of risks and attacks, we have implemented and periodically review and update systems, processes, and procedures to protect against unauthorized access to or use of data and to prevent data loss. For example, we have increased the security of our systems by requiring all email users to change their passwords following our recent data security incident and sooner than they would have otherwise been required to. We also implemented multi-factor authentication for remote email access and have taken additional steps to further limit access to our systems. However, the ever-evolving threats mean we and our third-party service providers and vendors must continually evaluate and adapt our respective systems and processes and overall security environment. There is no guarantee that these measures will be adequate to safeguard against all data security breaches, system compromises or misuses of data.

The compromise of our technology systems resulting in the loss, disclosure, misappropriation of, or access to, customers', employees' or business partners' information or failure to comply with regulatory or contractual obligations with respect to such information could result in legal claims or proceedings, liability or regulatory penalties under laws protecting the privacy of personal information, disruption to our operations and damage to our reputation, any or all of which could adversely affect our business. The costs to remediate breaches and similar system compromises that do occur could adversely affect our results of operations.

Any new laws, regulations, other legal obligations or industry standards, or any changed interpretation of existing laws, regulations or other standards may require us to incur additional costs and restrict our business operations. For example, many jurisdictions have enacted laws requiring companies to notify individuals of data security breaches involving certain types of personal data. These mandatory disclosures regarding a security breach could result in negative publicity to us, which may cause our customers to lose confidence in the effectiveness of our data security measures which could adversely affect our business, financial condition and results of operations.

Increasing data privacy regulations could impact our business and expose us to increased liability.

We must comply with increasingly complex and rigorous regulatory standards enacted to protect business and personal data in the U.S., Europe and elsewhere. For example, the European Union adopted the GDPR, which became effective on May 25, 2018. The GDPR imposes additional obligations on companies regarding the processing of personal data and provides certain individual privacy rights to natural persons whose data is stored. Compliance with existing, proposed and recently enacted laws (including implementation of the privacy and process enhancements called for under the GDPR) and regulations can be costly and any failure to comply with these regulatory standards could subject us to legal and reputational risks. In addition, we are required under the GDPR to respond to customers' Subject Access Reports (SARs) within a certain time period, which entails determining what personal data is being processed, the purpose of any such data processing, to whom such personal data has been disclosed and whether personal data is being disclosed for the purpose of making automated decisions relating to that customer. We may dedicate significant resources to responding to our customers' SARs, which could adversely affect our business, financial condition and results of operations. Misuse of or failure to secure or properly process personal information could also result in violation of data privacy laws and regulations, proceedings against the Company by governmental entities or others, damage to our reputation and credibility and could have a negative impact on revenues and profits. As the regulatory environment related to information security, data collection and use, and privacy becomes increasingly rigorous, with new and constantly changing requirements applicable to our business, compliance with those requirements could continue to result in significant costs.

Following the GDPR, a number of states in the U.S. have introduced bills, which, if passed, would impose operational requirements on U.S. companies similar to the requirements reflected in the GDPR. In 2018, California passed the California Consumer Privacy Act (CCPA), which gives consumers significant rights over the use of their personal information, including the right to object to the "sale" of their personal information. These rights may restrict our ability to use personal information in connection with our business operations. The CCPA also provides a private right of action for security breaches. Washington and Massachusetts have introduced significant privacy bills and Congress is debating federal privacy legislation, which if passed, may restrict our business operations and require us to incur additional costs for compliance.

Any new laws, regulations, other legal obligations or industry standards, or any changed interpretation of existing laws, regulations or other standards may require us to incur additional costs and restrict our business operations.

Our financial condition and results of operations 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; HME providers' ability to adopt and finance POC purchases and restructure their businesses to remove delivery expenses; 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; declines in sales personnel productivity; increased marketing cost per generated lead; unanticipated regulatory reimbursement changes that could result in positive or negative impacts to our earnings; changes or updates to generally accepted accounting principles; additional legal costs associated with pending legal matters; and fluctuations in foreign currency exchange rates. In particular, due to the COVID-19 PHE, we have seen and expect to continue to see a disruption in our normal seasonal trends, as, due to the mandates and behaviors emanating from the COVID-19 PHE, including shelter-in-place orders, reduced travel, and lower consumer confidence, we have not seen and may not see the typical seasonal increases in direct-to-consumer sales in 2020 that we have seen in prior years. As more HME providers adopt POCs in their businesses, we expect that this could change our historical seasonality in the domestic business-to-business channel as well, which was previously influenced mainly by consumer buying patterns. 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. We have experienced significant revenue growth in the past, but we may not achieve similar growth rates, profit margins and/or net income in future periods. You should not rely on our operating results for any prior quarterly or annual period as an indication of our future operating performance. If we are unable to maintain adequate revenue growth and cost control, our operating results could suffer, and our stock price could decline, primarily because a significant amount of our expenses are fixed and would take additional time to reduce. 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.

Given our levels of stock-based compensation, our tax rate may vary significantly depending on our stock price.

The tax effects of the accounting for share-based compensation may significantly impact our effective tax rate from period-to-period. In periods in which our stock price is higher than the grant price of the stock-based compensation vesting in that period, we will recognize excess tax benefits that will decrease our effective tax rate. However, in periods in which our stock price may be lower than the grant price of the stock-based compensation vesting in that period, we will recognize excess tax deficiencies that will increase our effective tax rate. For example, in the six months ended June 30, 2020, excess tax deficiencies recognized from stock-based compensation increased our provision for income taxes by $0.5 million and our effective tax rate by 26.9% as compared to the tax rate without such deficiencies. The amount and value of stock-based compensation issued relative to our earnings in a particular period will also affect the magnitude of the impact of stock-based compensation on our effective tax rate. These tax effects are dependent on our stock price and employee stock option exercises, which we do not control, and a decline in our stock price could significantly increase our effective tax rate and adversely affect our results of operations.

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 and NIV markets, both in the United States and internationally, (ii) the size and percentage of the long-term oxygen therapy market and NIV market that is subject to competitive bidding in the United States, (iii) the number of oxygen therapy and NIV patients, (iv) the number of patients requiring ambulatory and stationary oxygen, (v) the number of patients who rely on the delivery model, (vi) the percentage of the long-term oxygen therapy and NIV markets serviced by Medicare, Medicare Advantage, and other third party-payors, (vii) the size of the retail long-term oxygen therapy market and how the opportunity may change as POC penetration increases, (viii) the share of POCs as a percentage of the total oxygen therapy spend, (ix) the size of the early-stage COPD market and the interest and clinical benefit of NIV technology to this patient population are based on estimates that we believe are reliable, and (x) the impact of the COVID-19 PHE on our business and our markets generally. These estimates may prove to be incorrect, new data or studies may change the estimated incidence or prevalence of patients requiring long-term oxygen therapy or NIV therapy, or the type of long-term oxygen therapy patients. The COVID-19 pandemic may also reduce the number of oxygen therapy patients worldwide due to the higher risk of mortality of elderly patients with existing respiratory diseases if they are exposed to the virus. 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.

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

We operate in multiple taxing jurisdictions and certain revenue streams may be subject to sales and use taxAny changes, ambiguity, or uncertainty in taxing jurisdictions' administrative interpretations, decisions, policies and positions, including, the position of taxing authorities with respect to taxability of our revenue also materially impact our sales and use tax liabilities. 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 three states may be subject to sales and use tax, but in other states they should be exempt from 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 condition.

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

We prepare our consolidated financial statements in accordance with accounting principles generally accepted in the United States of America (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 (FASB) is currently working together with the International Accounting Standards Board (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 condition and results of operations.

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

Utilization of our net operating losses and tax credit carryforwards may be subject to annual limitations arising from ownership change limitations imposed by the Internal Revenue Code and similar state provisions. Such annual limitations could result in the expiration of our net operating losses and tax credit carryforwards before their utilization.

Changes in tax laws or tax rulings could materially affect our financial condition, results of operations, and cash flows.

Current economic and political conditions make tax laws and regulations, or their interpretation and application, in any jurisdiction subject to significant change. Changes in tax law or tax rulings, or changes in interpretations of existing law, could adversely affect our financial condition and results of operations. For example, changes to the U.S. tax laws enacted in December 2017 had a significant impact on our deferred tax assets, income tax provision and effective tax rate for the year ended December 31, 2017. In addition, many countries in Europe, as well as a number of other countries and organizations, have recently proposed or recommended changes to existing tax laws or have enacted new laws that could significantly increase our tax obligations in many countries where we do business or require us to change the manner in which we operate our business.

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 results of operations.

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 many states 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 audits and obtain information from healthcare providers. Violations of federal and state regulations can result in severe criminal, civil and administrative fines, 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 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 products 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 510(k) clearance from the FDA, clearance under the de novo process 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.

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 subject to pre-market approval, the FDA may demand that we obtain a pre-market approval prior to marketing certain 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), de novo application 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 uses;
- 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 Regulations.

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 such modified products.

Any modification we make to our products that could significantly affect their safety or effectiveness, or would constitute a material change in intended use, manufacture, design, materials, labeling, or technology requires the submission and clearance of a new 510(k) pre-market notification, a de novo application 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.

The FDA issued a new Final Guidance titled Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE) in March 2020. The intent of the guidance is to help address the urgent COVID-19 PHE. It may expand the availability of devices that support patients with respiratory insufficiency due to COVID-19. The guidance allows certain modifications to applicable FDA-cleared respiratory devices without requiring compliance with the pre-market requirements such as submitting a new 510(k). Manufacturers must ensure the device is safe and effective prior to placing the modified device on the market. This guidance and any future guidance or enforcement policy be the FDA may introduce new competitive products that could compete with our products with an easier regulatory pathway which could harm our business, financial condition and results of operations. If Inogen uses this guidance to introduce devices that do not have the FDA clearance, these products will have to go through FDA 510(k) clearance in the future, and may not be granted such clearance, which would mean we would have to withdraw these products from the market when the FDA terminates or revokes such guidance or enforcement policy, which could harm our business, financial condition and results of operations.

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 exiting 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 effect 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. 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. 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. 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 condition and results of operations.

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 results of operations.

If we, our contract manufacturer, 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, our contract manufacturer, 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, calibration, 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 we fail to implement timely and appropriate corrective actions that are acceptable to the FDA or if our other manufacturing facilities or those of any of our component manufacturers, contract 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 condition and results of operations.

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.

The primary regulatory body in Europe is the European Commission, which includes most of the major countries in Europe. The European Commission has adopted numerous directives and standards regulating the design, manufacture, clinical trial, labeling and adverse event reporting for medical devices. Devices that comply with the requirements of a relevant directive will be entitled to bear the CE conformity marking, indicating that the device conforms to the essential requirements of the applicable directives and, accordingly, can be commercially distributed throughout Europe. The method of assessing conformity varies depending on the class of the product, but normally involves a combination of self-assessment by the manufacturer and a third-party assessment by a "Notified Body." An assessment by a Notified Body of one country within the European Union is required in order for a manufacturer to commercially distribute the product throughout the European Union.

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

Approximately 19.3% and 22.3% of our total revenue was from sales outside of the United States for the three months ended June 30, 2020 and June 30, 2019, respectively, and 21.2% and 22.2% for the six months ended June 30, 2020 and June 30, 2019, respectively. We sell our products in 46 countries outside of the United States through our wholly owned subsidiary, 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 product testing. The time required to obtain approval abroad may be longer than the time required to obtain FDA clearance.

For example, the European Union requires that manufacturers of medical devices obtain the right to bear the "CE" conformity marking which designates compliance with existing directives and standards regulating the design, manufacture and distribution of medical devices in member countries of the European Union. In 2017, the European Union adopted the EU Medical Device Regulation (Council Regulations 2017/745) which imposes stricter requirements for the marketing and sale of medical devices, including new clinical evaluation, quality system, and post-market surveillance requirements. The regulation has a three-year implementation period, with full application of the regulation to occur in May 2020 and will replace the existing directives on medical devices in the European Union. After May 2020, medical devices marketed in the European Union will require certification according to these new requirements, except that devices with valid CE certificates, issued pursuant to the Medical Device Directive before May 2020, may be placed on the market until May 2024. Only medical devices that comply with certain conformity requirements of the Medical Device Directive are allowed to be marketed within the European Union. The company's products will be required to comply with the European Medical Device Regulation (MDR). Products that fail to be certified with the MDR may not be marketed or sold in the European Union. The European Commission delayed EU MDR implementation by one year, which would delay this requirement until May 26, 2021 due to the COVID-19 pandemic.

The foreign regulatory approval process, including with respect to MDR, 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, we may be required to discontinue sales in those countries which would negatively affect our overall market penetration, revenues, results of operations and financial condition.

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 results of operations.

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. We could experience a significant increase in pre-payment reviews of our claims by the Durable Medical Equipment Medicare Administrative Contractors, which could cause 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 CMS, 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 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 results of operations, but such impact could be material.

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 effect on our reputation and results of operations.

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 protected 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 from unauthorized disclosure. 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 are determined to be out of compliance 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 results of operations and 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 affect 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, Physician Self-Referral Law, false claims and anti-inducement laws, we could face substantial penalties and our business, results of 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 the referral of an individual to a person for the furnishing of, or in return for purchasing, leasing, ordering, or arranging for or recommending 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 financial arrangements 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 it does 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. Failure to meet all requirements of a safe harbor is not determinative of a kickback issue but could subject the practice to increased scrutiny by the government.

The Physician Self-Referral Law, commonly known as the "Stark Law," prohibits a physician from referring a patient to an entity with which the physician (or an immediate family member) has a financial relationship, for the furnishing of certain designated health services (DHS) for which payment may be made by Medicare or Medicaid, unless an exception applies. 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 federal healthcare programs. Although we believe that we have structured our provider arrangements to comply with current Stark Law requirements, regulatory authorities may determine otherwise.

The Federal False Claims Act prohibits 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 Federal False Claims Act allows 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 statute) 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 this federal law may include civil monetary penalties, exclusion from federal and state healthcare 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 the 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 majority of states also have statutes or regulations similar to the federal anti-kickback, physician self-referral, 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. Penalties under these state laws are similar to those under their federal equivalents.

The Patient Protection and Affordable Care Act also created the federal Physician Payments Sunshine Act, which requires applicable manufacturers of drugs, devices, biologicals, and medical supplies covered under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to CMS, information related to payments or other transfers of value made to physicians, as defined, and teaching hospitals, as well as ownership and investment interests in such manufacturer held by physicians and their immediate family members. Additionally, the "Substance Use-Disorder Prevention that Promoted Opioid Recovery and Treatment for Patients and Communities Act" enacted in 2018, extends the reporting and transparency requirements for physicians under the Physician Payments Sunshine Act to physician assistants, nurse practitioners and other mid-level practitioners, with reporting requirements going into effect in 2022 for payments made in 2021. Failure to submit the required information under the federal Physician Payment Sunshine Act may result in civil monetary penalties of up to an aggregate of $0.18 million per year (and up to an aggregate of $1.177 million per year for "knowing failures"), subject to an annual adjustment for inflation.

In addition, there has been a recent trend of increased federal and state regulation of payments and other transfers of value made to applicable recipients, including physicians. Certain states mandate implementation of compliance programs and/or the tracking and annual reporting of gifts, compensation and other remuneration to physicians and other applicable recipients. 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 many violate one or more of the requirements.

The Federal Civil Monetary Penalties Law grants authority to the HHS Office of Inspector General (OIG) to seek civil monetary penalties (CMPs) against an individual or entity based on a wide variety of conduct including violations of the Anti-Kickback Statute, Stark Law, and False Claims Act. An entity that offers to or transfers remuneration to any individual eligible for benefits under Medicare or Medicaid that such entity knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any Medicare or Medicaid payable item or service may be liable for CMPs. This is commonly known as a beneficiary inducement. 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, including the safe harbor regulation for discounts, the federal government may find that our marketing activities violate the law. If we are found to be in non-compliance, we could be subject to CMPs of up to $0.18 million (subject to annual adjustment for inflation) 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 restriction of our operations or exclusion from participation in the federal healthcare programs. Any penalties, damages, fines, curtailment or restructuring or our operations could harm our ability to operate our business and our results of operations. 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. HHS makes annual inflation-related increases to the civil monetary penalties in its regulations pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015. The HHS Annual Civil Monetary Penalties Inflation Adjustment Final Rule issued on January 17, 2020, sets forth adjusted civil monetary penalty amounts that apply to penalties assessed on or after January 17, 2020, if the violation occurred on or after November 2, 2015.

We are also exposed to the risks of fraud, misconduct, or other illegal activity by our employees and third parties who act for us or on our behalf, such as our independent contractors, consultants, commercial partners, and vendors. It is not always possible to identify and deter misconduct by employees and third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with federal and state healthcare fraud and abuse laws. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

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

We sell our products in 46 countries outside the United States through our wholly owned subsidiary, 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 products versus other available 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 international, 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 of each country in which we conduct business, 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 and adversely affect our financial condition and results of operations.

Regulatory requirements under Proposition 65 could adversely affect our business.

We are subject to California’s Proposition 65, or Prop 65, which requires a specific warning on any product that contains a substance listed by the State of California as having been found to cause cancer or birth defects, unless the level of such substance in the product is below a safe harbor level. Prop 65 required that all businesses must be in compliance by August 30, 2018 with new regulations that require modifications to product warnings and for businesses to coordinate with upstream vendors or downstream customers for the 800+ regulated chemicals in consumer products and assess whether new occupational exposure warnings need to be posited in California facilities. We have taken steps to add warning labels to our products packaged in California and manufactured after August 30, 2018. Although we cannot predict the ultimate impact of these new requirements, they could reduce overall consumption of our products or leave consumers with the perception (whether or not valid) that our products do not meet their health and wellness needs, all of which could adversely affect our business, financial condition andresults of operations.

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, defending, 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, defend, 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;
- prevent our competitors from producing counterfeit products;
- prevent our competitors or other parties from suing us for alleged infringement; 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 June 30, 2020, we have thirty-four pending U.S. and international patent applications, thirty-eight issued U.S. patents, and nine issued foreign patents relating to the design and construction of our oxygen concentrators, our intelligent delivery technology and our non-invasive ventilator, including its proprietary nasal interface. We cannot specify which of these patents individually or as a group will permit us to gain or maintain a competitive advantage. Patents may be subject to reexamination, *inter partes* review, post-grant review, and derivation proceedings in the U.S. Patent and Trademark Office or comparable proceedings in other patent offices worldwide. 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, post grant review, defense, opposition and derivation 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 any competitive advantage or adequate protection from allegations of infringement, whether valid or frivolous, which may result in the incurrence of material defense costs. 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 or non-invasive ventilation 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 or appear to 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 patents and other intellectual property rights. Our competitors hold a significant number of patents relating to respiratory therapy devices and products. Third parties have in the past asserted and may in the future assert that we are employing their proprietary technology without authorization. For example, Breathe Technologies, Inc. (Breathe), a subsidiary of Hill-Rom Holdings, filed a lawsuit against us, New Aera, Inc., Silverbow Development LLC, and one of our employees on November 21, 2019 in the United States District Court for the Northern District of California. The lawsuit alleged, among other things, willful infringement of a patent assigned to Breathe, that inventorship was incorrectly assigned and that Breathe has rights to certain patents filed by New Aera, Inc. and Silverbow Development LLC, breach of contract, inducing breach of contract, interference with contract, and violation of California Business and Professional Code section 17200. If we fail in defending against lawsuits or claims brought against us in the future, we could be subject to substantial monetary damages, injunctive relief, and loss of valuable intellectual property rights, and we cannot predict the outcome of any lawsuit. An adverse determination or protracted defense costs of such lawsuits could have a material 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 previously pursued litigation against Inova Labs, Inc. (a subsidiary of ResMed Corp.) for infringement of two of our patents seeking damages, injunctive relief, costs, and attorneys' fees. While we settled our lawsuit with Inova Labs in June 2016, an adverse decision in any other legal action could limit our ability to assert our intellectual property rights, limit the value of our technology or otherwise negatively affect 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, 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 or appear to 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 whether valid or frivolous.

Determining whether a product infringes a patent involves complex legal and factual issues, defense costs and the outcome of a patent litigation action are 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 or appearing to cover 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 may vary by jurisdiction and some patent applications may not be published in the U.S., 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 or appear to 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 respiratory products and 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 patents in litigation or other proceedings, including declaratory judgment actions, patent reexaminations, post grant reviews, or *inter partes* reviews. As a result, we may become involved in unwanted protracted litigation that could be costly, result in diversion of management's attention, require us to pay damages and/or licensing royalties and force us to discontinue selling our products.

Infringement and other intellectual property claims and proceedings brought against us, whether successful or not, could result in substantial costs and harm to our reputation. Such claims and proceedings can also distract and divert management and key personnel from other tasks important to the success of the business. We cannot be certain that we will successfully defend against allegations of infringement of patents or other intellectual property rights. In the event that we become subject to a patent infringement or other intellectual property related lawsuit and if the asserted patents or other intellectual property were upheld as valid and enforceable and we were found to infringe the asserted patents or other intellectual property, 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 royalty 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 and other intellectual property. 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," "G5," "Live Life in Moments, not Minutes," "Never Run Out of Oxygen," "Oxygen Therapy on Your Terms," "Oxygen.Anytime.Anywhere," "Reclaim Your Independence," "Intelligent Delivery Technology," "Inogen At Home," the Inogen design, "TIDAL ASSIST," "TAV," and "SIDEKICK" are registered trademarks with the United States Patent and Trademark Office of Inogen, Inc. We own pending applications for "Inogen," "MOMENTUM TRANSFER" and "SONIC BLADE" with the United States Patent and Trademark Office. We own trademark registrations for the mark "Inogen" in Argentina, Australia, Canada, China, Columbia, Ecuador, South Korea, Mexico, Europe (European Union registration), Iceland, India, Israel, Japan, Kuwait, New Zealand, Norway, Peru, Turkey, Singapore, and Switzerland. We own pending applications for the mark "Inogen" in Australia, Brazil, Chile, China, Europe (European Union application), India, Malaysia, Paraguay, South Africa, and Uruguay. We own a trademark registration for the mark "イノジェン" in Japan. We own trademark registrations for the marks "印诺真" and "艾诺根" in China. We own trademark registrations for the mark "Inogen One" in Australia, Canada, China, South Korea, Mexico, and Europe (European Union registration). We own a trademark registration for the mark "Satellite Conserver" in Canada. We own a trademark registration for the mark "Inogen At Home" in Europe (European Union Registration). We own trademark registrations for the mark "G4" in Europe (European Union registration) and the United Kingdom. We own trademark registrations for the mark "G5" in Europe (European Union Registration) and the United Kingdom. We own trademark applications for the Inogen design in Bolivia and China. We own a trademark application for the mark "إنوجن" in Saudi Arabia. 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, agents or we have wrongfully used or disclosed alleged trade secrets of other companies.

Some of our employees and consultants, including employees who joined us following our acquisition of New Aera, were previously employed by or contracted with other medical device companies focused on the development of oxygen therapy and non-invasive ventilation products, including our competitors. We may be subject to claims that these employees or agents 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. For example, Breathe Technologies, Inc. (Breathe), a subsidiary of Hill-Rom Holdings, filed a lawsuit against us, New Aera, Inc., Silverbow Development, LLC, and one of our employees on November 21, 2019 in the United States District Court for the Northern District of California. The lawsuit alleged, among other things, willful infringement on certain patents, declared that inventorship was incorrectly assigned and their rights to certain patents filed by New Aera, Inc. and Silverbow Development, LLC, breach of contract, inducing breach of contract, interference with contract, and violation of California Business and Professional Code section 17200. If we fail in defending against such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights and may be enjoined from using valuable technology in our products. 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 compliance initiatives and corporate governance practices.

As a public company, especially now that we are no longer an "emerging growth company," we will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002 and rules enforced by the Public Companies Oversight Board (PCAOB) 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, external audit 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 and public accounting firms are subject to PCAOB compliance audits. 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 and document 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. Now that we are no longer an “emerging growth company,” our independent registered public accounting firm is required to undertake an assessment of our internal control over financial reporting, and the cost of our compliance with Section 404(b) is higher. 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, or Section 404, requires that we maintain internal control over financial reporting that meets applicable standards. We may err in the design, operation or documentation 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 significant changes made in our internal controls and procedures on a quarterly basis. Now that we are no longer an “emerging growth company,” our independent registered public accounting firm is also required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404. 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 or consultants, which may adversely affect our results of operations and financial condition.

Although prior material weaknesses have been remediated, 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 controls over financial reporting are 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.

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 or NIV markets;
- reimbursement or legislative changes in the oxygen therapy or NIV markets;
- 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 or due to any other reason;
- any future sales of our common stock or other securities;
- any major change to the composition of our board of directors or management;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- 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. 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.

Stockholder litigation has been filed against us in the past, and a class action securities lawsuit and related derivatives complaints against us are currently pending, as discussed in the "Legal Proceedings" section of this Quarterly Report on Form 10-Q. While we are continuing to defend such actions vigorously, the defense of such actions can be costly, divert the time and attention of our management and harm our operating results, and any judgment against us or any future stockholder litigation could result in substantial costs.

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 June 30, 2020, one holder of approximately 3.5 million shares, or approximately 16.1%, 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 June 30, 2020, 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 67.2% 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.

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 affected 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 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 and currently intend to retain our future earnings to fund the development and growth of our business. In addition, we may become subject to covenants under future debt arrangements that place restrictions on our ability to pay dividends. As a result, capital appreciation, if any, of our common stock is expected to 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 or six months ended June 30, 2020 and June 30, 2019.

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	Incorporated by Reference From Form	Incorporated by Reference From Exhibit Number	Date Filed
10.1	Third Amendment to lease, dated July 14, 2020, between Registrant and Rockbridge Investments, L.P.	Filed herewith		
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	Filed herewith		
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	Filed herewith		
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	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.			
101.SCH	Inline XBRL Taxonomy Extension Schema Document			
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document			
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document			
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document			
101.DEF	Inline XBRL Taxonomy Extension Definition Document			
104	The cover page of this Quarterly Report on Form 10-Q, formatted in inline XBRL.			

(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: August 4, 2020	By: /s/ Scott Wilkinson Scott Wilkinson Chief Executive Officer President Director *(Principal Executive Officer)*
Dated: August 4, 2020	By: /s/ Alison Bauerlein Alison Bauerlein Chief Financial Officer Executive Vice President, Finance Secretary and Treasurer *(Principal Financial and Accounting Officer)*

Exhibit 10.1

THIRD AMENDMENT TO LEASE

THIS THIRD AMENDMENT TO LEASE (this "Amendment"), dated July 14, 2020, for reference purposes only, is made and entered into by and between ROCKBRIDGE INVESTMENTS, L.P., a California limited partnership ("Landlord"), and INOGEN, INC., a Delaware corporation ("Tenant").

RECITALS

A. Landlord and Tenant entered into that certain Multi-Purpose Commercial Building Lease dated February 1, 2010 (the "Original Lease"), as amended by the First Amendment to Lease dated September 16, 2011 (the "First Amendment"), and as further amended by the Second Amendment to Lease dated January 20, 2015 (the "Second Amendment"). The Original Lease, the First Amendment and the Second Amendment are collectively referred to in this Amendment as the "Lease."

B. Pursuant to the terms of the Lease, Landlord leased to Tenant, and Tenant leased from Landlord, approximately 38,851 square feet of leasable space, located at 326 Bollay Drive, City of Goleta, County of Santa Barbara, State of California, as more particularly set forth in the Lease (the "Premises").

C. The initial term of the Lease was for five (5) years, commencing on or around November 1, 2010 and ending on October 31, 2015.

D. Pursuant to the Second Amendment, the term of the Lease was extended for five (5) years, commencing November 1, 2015 and ending on October 31, 2020.

E. Pursuant to the terms of the Lease, as amended, Tenant had the right to extend the then-current term for an additional five (5) years (the "Option"). Pursuant to the terms of the Option, Tenant was required to provide Landlord written notice of its intent to exercise the Option not more than twelve (12) months nor less than nine (9) months prior to the expiration of the then-current term. Accordingly, the last day to exercise the Option was January 31, 2020. Tenant did not exercise the Option and the current term of the Lease is scheduled to expire on October 31, 2020.

F. Tenant has requested a short term extension of the Lease and, subject to the terms and conditions set forth in this Amendment and Tenant's timely performance of each of the obligations set forth herein, Landlord is willing to extend the existing term of the Lease for two (2) months, commencing November 1, 2020 and ending on December 31, 2020.

NOW THEREFORE, in consideration of the mutual promises contained in this Amendment and of other valuable consideration, the receipt and adequacy of which both Landlord and Tenant hereto expressly acknowledge, it is agreed as follows:

AMENDMENT

1. Defined Terms. All initially capitalized terms in this Amendment, not otherwise defined herein, will have the same meanings as defined in the Lease.

2. Extended Term. The Term of the Lease is hereby extended for two (2) months, commencing November 1, 2020 and ending on December 31, 2020 (the "Extended Term").

3. Minimum Monthly Rent. During the Extended Term, the Minimum Monthly Rent will remain fixed at approximately $1.29 per square foot, per month, payable in advance on or before the fifth day of each calendar month during the Extended Term in equal monthly installments of $50,286.22, each as otherwise provided in Section 3 of the Lease.

4. Total Operating Costs. During the Extended Term, and the Option Term (defined in Section 5) as the case may be, Tenant will reimburse Landlord for Tenant's proportionate share of Landlord's estimated Total Operating Costs in the amount of approximately $0.38 per square foot, per month, payable in advance on or before the fifth day of each calendar month during the Extended Term, and the Option Term as the case may be, in equal monthly installments of $14,883.00, each as otherwise provided in Section 7.3 of the Lease.

5. Options to Extend.

(a) Landlord hereby grants to Tenant two (2) successive options to extend the Lease following the Extended Term for up to two (2) additional months (respectively, the "First Option," and the "Second Option"). The First Option, if properly exercised by Tenant in accordance with the terms of this Amendment, shall commence January 1, 2021 and end on January 31, 2021 (the "First Option Term"). The Second Option, if property exercised by Tenant in accordance with the terms of this Amendment, shall commence February 1, 2021 and end of February 28, 2021 (the "Second Option Term"). The First Option Term and the Second Option Term shall collectively be referred to in this Amendment as the "Option Term").

(b) Tenant shall exercise either of said options, if at all, by written notice given to Landlord on or prior to the dates set forth in Section 6, and Section 7, as the case may be (each, the "Option Notice"). The Option Notice, once delivered to Landlord shall be irrevocable and thereafter, Tenant shall be obligated to pay the entire First Option Term Rent (defined in Section 6) for the entire First Option Term and the Second Option Term Rent (defined in Section 7) for the entire Second Option Term, as the case may be. The Option Notice must (i) specify the extended termination date and (ii) coincide with the applicable calendar month's end.

6. First Option Term. Provided Tenant is not then in default under any terms of the Lease, as hereby amended, Tenant shall provide Landlord written notice in accordance with Section 5(b) above, of its intent to exercise the First Option Term on or before (i) September 1, 2020, or (ii) October 1, 2020:

(a) If notice properly provided by Tenant on or before September 1, 2020 The Minimum Monthly Rent payable during the First Option Term shall be an amount equal to one hundred and twenty five percent (125%) of the Minimum Monthly Rent payable immediately prior to the commencement of the First Option Term, in the amount of $62,857.78 (the "First Option Term Rent Notice by September"), plus Tenant's proportionate share of Landlord's estimated Total Operating Costs as provided in Section 4 above.

(b) If notice properly provided by Tenant after September 1, 2020 and on or before October 1, 2020 The Minimum Monthly Rent payable during the First Option Term shall be an amount equal to one hundred and thirty five percent (135%) of the Minimum Monthly Rent payable immediately prior to the commencement of the First Option Term, in the amount of $67,886.40 (the "First Option Term Rent Notice by October"), plus Tenant's proportionate share of Landlord's estimated Total Operating Costs as provided in Section 4 above. The First Option Term Rent Notice by September and the First Option Term Rent Notice by October shall be referred to in this Amendment as the "First Option Term Rent."

7. Second Option Term. Provided Tenant is not then in default under any terms of the Lease, as hereby amended, Tenant shall provide Landlord written notice in accordance with Section 5(b) above, of its intent to exercise the Second Option Term on or before (i) October 1, 2020, or (ii) November 1, 2020:

(a) If notice properly provided by Tenant on or before October 1, 2020 The Minimum Monthly Rent payable during the Second Option Term shall be an amount equal to one hundred and thirty five percent (135%) of the Minimum Monthly Rent payable immediately prior to the commencement of the First Option Term, in the amount of $67,886.40 (the "Second Option Term Rent Notice by October"), plus Tenant's proportionate share of Landlord's estimated Total Operating Costs as provided in Section 4 above.

(b) If notice properly provided by Tenant after October 1, 2020 and on or before November 1, 2020 The Minimum Monthly Rent payable during the Second Option Term shall be an amount equal to one hundred and forty five percent (145%) of the Minimum Monthly Rent payable immediately prior to the commencement of the First Option Term, in the amount of $72,915.02 (the "Second Option Term Rent Notice by November"), plus Tenant's proportionate share of Landlord's estimated Total Operating Costs as provided in Section 4 above. The Second Option Term Rent Notice by October and the Second Option Term Rent Notice by November shall be referred to in this Amendment as the "Second Option Term Rent." The First Option Term Ren and the Second Option Term Rent shall be referred to in this Amendment as the "Option Term Rent."

8. Continued Occupancy.

(a) If Tenant fails to deliver possession of the Premises in accordance with the applicable provisions of the Lease on or before expiration of the First Option Term, or the Second Option Term as the case may be, the Minimum Monthly Rent for first calendar month following the expiration of the applicable Option Term (the "First Holdover Month") shall be an amount equal to ***one hundred and fifty percent (150%)*** of the applicable Option Term Rent; ***provided, however,*** Tenant shall pay such amount on or before the last business day of the applicable Option Term, together with Tenant's proportionate share of Landlord's estimated Total Operating Costs as provided in Section 4 above, and each as otherwise provided in Sections 3 and 7.3 of the Lease;

(b) If Tenant fails to deliver possession of the Premises in accordance with the applicable provisions of the Lease on or before expiration of the First Holdover Month, the Minimum Monthly Rent for second calendar month following the expiration of the applicable Option Term (the "Second Holdover Month") shall be an amount equal to ***one hundred and seventy five percent (175%)*** of the Minimum Monthly Rent payable during the First Holdover Month; ***provided, however,*** Tenant shall pay such amount on or before the last business day of the First Holdover Month together with Tenant's proportionate share of Landlord's estimated Total Operating Costs as provided in Section 4 above, and each as otherwise provided in Sections 3 and 7.3 of the Lease; and

(c) Thereafter, if Tenant fails to deliver possession of the Premises in accordance with the applicable provisions of the Lease on or before expiration of the Second Holdover Month, the Minimum Monthly Rent for each calendar month following the Second Holdover Month (each, a "200% Holdover Month") until the Outside Expiration Date (as defined in Section 8(d), below) shall be an amount equal to ***two hundred percent (200%)*** of the Minimum Monthly Rent payable during the immediately prior calendar month; ***provided, however,*** Tenant shall pay such amount on or before the last business day of the calendar month then expiring (e.g., the Second Holdover Month and thereafter, each 200% Holdover Month) together with Tenant's proportionate share of Landlord's estimated Total Operating Costs as provided in Section 4 above, and each as otherwise provided in Sections 3 and 7.3 of the Lease.

(d) Notwithstanding the foregoing, Tenant may *not* continue to occupy the Premises beyond June 30, 2021 (the "Outside Expiration Date") unless the parties have entered into a new lease or written amendment to the existing Lease (collectively, a "New Lease") on terms and conditions acceptable to the Landlord. If Tenant has failed to deliver possession of the Premises on or before the Outside Expiration Date, other than in connection with a New Lease, Landlord will have the unilateral right to commence action to evict Tenant and such other rights and remedies it may have under the Lease, in equity or at law.

(e) All rents and Tenant's proportionate share of Landlord's estimated Total Operating Costs payable during any of the calendar month periods set forth in Section 8(a) through 8(c) shall not be prorated for any period in which Tenant only occupies the Premises for a partial calendar month and Tenant shall not be entitled to any equitable or proportionate reduction or refund.

(f) Nothing in this Amendment shall relieve Tenant from paying its full proportionate share of Landlord's actual Total Operating Costs during any period in which Tenant occupies the Premises and Tenant hereby acknowledges Landlord's right to seek the reimbursement of any such amounts pursuant to Article 7 of the Lease for up to one (1) year following the date Tenant tenders possession of the Premises to Landlord.

9. Successors and Assigns. This Amendment will inure to the benefit of and be binding upon the parties and their respective successors and assigns.

10. Counterparts and Electronic Signatures. This Amendment may be executed in two or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, California's Uniform Electronic Transaction Act [Cal. Civil Code § 1633.1, et seq.] or other applicable law) or other transmission method, and any counterpart so delivered will be deemed to have been duly and validly delivered and be valid and effective for all purposes.

AGREED this 14th day of July 2020

LANDLORD

ROCKBRIDGE INVESTMENTS, LP,
a California limited partnership

By: Michael Towbes Construction & Development, Inc.,
a California corporation

Its: General Partner

By: /s/ Michelle Konoske
Michelle Konoske, CFO

TENANT

INOGEN, INC.,
a Delaware corporation

By: /s/ Alison Bauerlein
Alison Bauerlein
CFO

By: __________
Name: __________
Its: __________

Exhibit 31.1

Certification by the Chief Executive Officer Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Scott Wilkinson, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Inogen, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: August 4, 2020

By: /s/ Scott Wilkinson
Scott Wilkinson
Chief Executive Officer, President and Director
(Principal Executive Officer)

Exhibit 31.2

Certification by the Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Alison Bauerlein, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Inogen, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: August 4, 2020

By: /s/ Alison Bauerlein
Alison Bauerlein
Chief Financial Officer
Executive Vice President, Finance
Secretary and Treasurer
(Principal Financial Officer)

Exhibit 32.1

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO 18 U.S.C. § 1350, AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002**

I, Scott Wilkinson, the chief executive officer of Inogen, Inc. (the "Company"), certify for the purposes of 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge,

(i) the Quarterly Report of the Company on Form 10-Q for the three months ended June 30, 2020 (the "Report"), fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

August 4, 2020

By: /s/ Scott Wilkinson
Scott Wilkinson
Chief Executive Officer, President and Director

Exhibit 32.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. § 1350, AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

I, Alison Bauerlein, the chief financial officer of Inogen, Inc. (the "Company"), certify for the purposes of 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge,

(i) the Quarterly Report of the Company on Form 10-Q for the three months ended June 30, 2020 (the "Report"), fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

August 4, 2020

By: /s/ Alison Bauerlein
Alison Bauerlein
Chief Financial Officer
Executive Vice President, Finance
Secretary and Treasurer