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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2022

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.)**
301 Coromar 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 April 29, 2022, the registrant had22,835,794 shares of common stock, par value $0.001, outstanding.

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Item 1. Financial Statements

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

	March 31, 2022	December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	$ 213,399	$ 235,524
Marketable securities	9,989	9,989
Accounts receivable, net	33,983	24,452
Inventories, net	34,078	31,873
Income tax receivable	1,435	1,343
Prepaid expenses and other current assets	25,238	26,005
Total current assets	318,122	329,186
Property and equipment		
Rental equipment, net	59,387	59,073
Manufacturing equipment and tooling	10,968	12,050
Computer equipment and software	8,320	8,585
Furniture and equipment	3,135	3,167
Leasehold improvements	6,045	5,956
Land and building	125	125
Construction in process	2,705	1,639
Total property and equipment	90,685	90,595
Less accumulated depreciation	(51,356)	(51,669)
Property and equipment, net	39,329	38,926
Goodwill	32,934	32,979
Intangible assets, net	58,000	60,147
Operating lease right-of-use asset	24,080	24,912
Other assets	2,151	3,363
Total assets	$ 474,616	$ 489,513

See accompanying condensed notes to the consolidated financial statements.

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

	March 31, 2022	December 31, 2021
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable and accrued expenses	$ 32,375	$ 25,689
Accrued payroll	8,839	17,307
Warranty reserve - current	6,519	6,480
Operating lease liability - current	3,401	3,393
Deferred revenue - current	8,689	8,568
Income tax payable	—	75
Total current liabilities	59,823	61,512
Long-term liabilities		
Warranty reserve - noncurrent	6,574	7,246
Operating lease liability - noncurrent	22,409	23,281
Earnout liability - noncurrent	16,016	15,386
Deferred revenue - noncurrent	11,509	11,861
Total liabilities	116,331	119,286
Commitments and contingencies (Note 9)		
Stockholders' equity		
Common stock, $0.001 par value per share; 200,000,000 authorized; 22,836,472 and 22,731,586 shares issued and outstanding as of March 31, 2022 and December 31, 2021, respectively	23	23
Additional paid-in capital	302,020	299,463
Retained earnings	55,058	69,272
Accumulated other comprehensive income	1,184	1,469
Total stockholders' equity	358,285	370,227
Total liabilities and stockholders' equity	$ 474,616	$ 489,513

See accompanying condensed notes to the consolidated financial statements.

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

	Three months ended March 31,	
	2022	**2021**
Revenue		
Sales revenue	$ 67,402	$ 77,081
Rental revenue	12,983	9,851
Total revenue	80,385	86,932
Cost of revenue		
Cost of sales revenue	39,500	42,635
Cost of rental revenue, including depreciation of $2,638 and $1,888, respectively	5,879	4,424
Total cost of revenue	45,379	47,059
Gross profit		
Gross profit-sales revenue	27,902	34,446
Gross profit-rental revenue	7,104	5,427
Total gross profit	35,006	39,873
Operating expense		
Research and development	5,364	4,015
Sales and marketing	28,039	25,491
General and administrative	15,189	12,499
Total operating expense	48,592	42,005
Loss from operations	(13,586)	(2,132)
Other income (expense)		
Interest income	29	57
Other income (expense)	(433)	(310)
Total other expense, net	(404)	(253)
Loss before provision (benefit) for income taxes	(13,990)	(2,385)
Provision (benefit) for income taxes	224	(1,653)
Net loss	(14,214)	(732)
Other comprehensive income (loss), net of tax		
Change in foreign currency translation adjustment	(203)	(457)
Change in net unrealized gains (losses) on foreign currency hedging	(528)	1,144
Less: reclassification adjustment for net (gains) losses included in net income	454	(241)
Total net change in unrealized gains (losses) on foreign currency hedging	(74)	903
Change in net unrealized gains (losses) on marketable securities	(8)	4
Total other comprehensive income (loss), net of tax	(285)	450
Comprehensive loss	$ (14,499)	$ (282)
Basic net loss per share attributable to common stockholders (Note 6)	$ (0.62)	$ (0.03)
Diluted net loss per share attributable to common stockholders (Note 6)	$ (0.62)	$ (0.03)
Weighted average number of shares used in calculating net loss per share attributable to common stockholders:		
Basic common shares	22,754,421	22,181,394
Diluted common shares	22,754,421	22,181,394

See accompanying condensed notes to the consolidated financial statements.

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

	Three months ended March 31, 2022 and March 31, 2021					
	Common stock		Additional paid-in capital	Retained earnings	Accumulated other comprehensive income	Total stockholders' equity
	Shares	Amount				
Balance, December 31, 2020	22,131,447	$ 22	$ 273,521	$ 75,605	$ 475	$ 349,623
Stock-based compensation	—	—	2,516	—	—	2,516
Employee stock purchases	37,699	—	927	—	—	927
Restricted stock awards issued, net of forfeitures	(21,509)	—	—	—	—	—
Vesting of restricted stock units	34,117	—	(275)	—	—	(275)
Shares withheld related to net restricted stock settlement	(1,713)	—	(91)	—	—	(91)
Stock options exercised	205,753	—	3,866	—	—	3,866
Net loss	—	—	—	(732)	—	(732)
Other comprehensive income	—	—	—	—	450	450
Balance, March 31, 2021	22,385,794	$ 22	$ 280,464	$ 74,873	$ 925	$ 356,284
Balance, December 31, 2021	22,731,586	$ 23	$ 299,463	$ 69,272	$ 1,469	$ 370,227
Stock-based compensation	—	—	2,665	—	—	2,665
Employee stock purchases	30,558	—	915	—	—	915
Vesting of restricted stock units	73,495	—	(958)	—	—	(958)
Shares withheld related to net restricted stock settlement	(2,666)	—	(94)	—	—	(94)
Stock options exercised	3,499	—	29	—	—	29
Net loss	—	—	—	(14,214)	—	(14,214)
Other comprehensive loss	—	—	—	—	(285)	(285)
Balance, March 31, 2022	22,836,472	$ 23	$ 302,020	$ 55,058	$ 1,184	$ 358,285

See accompanying condensed notes to the consolidated financial statements.

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

	Three months ended March 31,	
	2022	**2021**
Cash flows from operating activities		
Net loss	$ (14,214)	$ (732)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	5,760	5,098
Loss on rental units and other fixed assets	706	158
Gain on sale of former rental assets	(52)	(24)
Provision for sales revenue returns and doubtful accounts	2,953	2,471
Provision for rental revenue adjustments	—	1,041
Provision for inventory losses	934	518
Stock-based compensation expense	2,665	2,516
Deferred income taxes	—	(1,527)
Change in fair value of earnout liability	630	265
Changes in operating assets and liabilities:		
Accounts receivable	(12,802)	(12,418)
Inventories	(2,515)	(2,686)
Income tax receivable	(92)	64
Prepaid expenses and other current assets	764	8,171
Operating lease right-of-use asset	832	(8,696)
Other noncurrent assets	66	41
Accounts payable and accrued expenses	6,539	(3,526)
Accrued payroll	(8,465)	2,105
Warranty reserve	(633)	520
Deferred revenue	(231)	518
Income tax payable	(79)	80
Operating lease liability	(864)	8,903
Net cash provided by (used in) operating activities	(18,098)	2,860
Cash flows from investing activities		
Maturities of marketable securities	—	6,125
Investment in intangible assets	—	(26)
Investment in property and equipment	(1,366)	(1,516)
Production and purchase of rental equipment	(2,777)	(3,643)
Proceeds from sale of former assets	91	46
Net cash provided by (used in) investing activities	(4,052)	986

(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)

	Three months ended March 31,	
	2022	**2021**
Cash flows from financing activities		
Proceeds from stock options exercised	29	3,866
Proceeds from employee stock purchases	915	927
Payment of employment taxes related to release of restricted stock	(1,052)	(366)
Net cash provided by (used in) financing activities	(108)	4,427
Effect of exchange rates on cash	133	(221)
Net increase (decrease) in cash and cash equivalents	(22,125)	8,052
Cash and cash equivalents, beginning of period	235,524	211,962
Cash and cash equivalents, end of period	$ 213,399	$ 220,014
Supplemental disclosures of cash flow information		
Cash paid during the period for income taxes, net of refunds received	$ 372	$ 17
Supplemental disclosure of non-cash transactions		
Property and equipment in accounts payable and accrued liabilities	91	77

See accompanying condensed notes to the consolidated financial statements.

Inogen, Inc.
Condensed Notes to the Consolidated Financial Statements
(unaudited)
(amounts in thousands, except share and per share amounts)

1. Business overview

Inogen, Inc. (Company or Inogen) was incorporated in Delaware on November 27, 2001. The Company is a medical technology company that primarily develops, manufactures and markets innovative portable oxygen concentrators (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.

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 ended March 31, 2022 shown in this report are not necessarily indicative of results to be expected for the full year ending December 31, 2022. 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 24, 2022. 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 24, 2022.

Basis of consolidation

The consolidated financial statements include the accounts of Inogen, Inc. and its wholly owned subsidiary. 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, warranty reserves and expense, determining the stand-alone selling price (SSP) and service period of performance obligations, rental asset valuations and write-downs, accounts receivable allowances for bad debts, returns and adjustments, impairment of long-lived assets, stock-based compensation expense, income taxes, fair value of acquired intangible assets and goodwill and fair value of earnout liabilities. Actual results could differ from these estimates.

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. 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.

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.

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

The following table summarizes fair value measurements by level for the assets measured at fair value on a recurring basis for cash, cash equivalents and marketable securities:

	As of March 31, 2022				
	Adjusted cost	Gross unrealized losses	Fair value	Cash and cash equivalents	Marketable securities
Cash	$ 36,677	$ —	$ 36,677	$ 36,677	$ —
Level 1:					
Money market accounts	176,722	—	176,722	176,722	—
Level 2:					
Corporate bonds	9,996	(7)	9,989	—	9,989
Total	$ 223,395	$ (7)	$ 223,388	$ 213,399	$ 9,989

	As of December 31, 2021				
	Adjusted cost	Gross unrealized gains	Fair value	Cash and cash equivalents	Marketable securities
Cash	$ 48,817	$ —	$ 48,817	$ 48,817	$ —
Level 1:					
Money market accounts	186,707	—	186,707	186,707	—
Level 2:					
Corporate bonds	9,988	1	9,989	—	9,989
Total	$ 245,512	$ 1	$ 245,513	$ 235,524	$ 9,989

Derivative instruments and hedging activities

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 $1,637 and $1,671 as of March 31, 2022 and December 31, 2021, respectively.

Accumulated other comprehensive income

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
Balance as of December 31, 2021	$ 328	$ 1	$ 1,140	$ 1,469
Other comprehensive loss	(203)	(8)	(74)	(285)
Balance as of March 31, 2022	$ 125	$ (7)	$ 1,066	$ 1,184

Comprehensive income (loss) is the total net earnings and all other non-owner changes in equity. Except for net income (loss) and unrealized gains and losses on cash flow hedges, the Company does not have any transactions or other economic events that qualify as other 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 March 31, 2022 and December 31, 2021. Significant increases or decreases in these inputs in isolation could result in a significant impact on the fair value measurement:

Simulation input	March 31, 2022	December 31, 2021
Revenue volatility	15.00 %	15.00 %
WACC	11.50 %	10.50 %
20-year risk free rate	2.59 %	2.02 %
Market price of risk	2.30 %	2.68 %

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

	Three months ended March 31, 2022
Balance at beginning of period	$ 16,016
Change in fair value	630
Balance at end of period	$ 16,646

The Company recorded $630 and $630 of preacquisition loss recoveries that can be withheld from any earnout amounts payable as of March 31, 2022 and December 31, 2021, respectively.

4. 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.

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

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

Cash and cash equivalents	**March 31, 2022**	**December 31, 2021**
Cash	$ 36,677	$ 48,817
Money market accounts	176,722	186,707
Total cash and cash equivalents	$ 213,399	$ 235,524
Marketable securities		
Corporate bonds	$ 9,989	$ 9,989
Total marketable securities	$ 9,989	$ 9,989

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 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 primarily 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 estimate 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 and when recording allowance for sales returns, the sales returns account (contra sales revenue account) is charged.

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 accounts receivable.

Net accounts receivable (gross accounts receivable, net of allowances) balance concentrations by major category as of March 31, 2022 and December 31, 2021 were as follows:

Net accounts receivable	**As of March 31, 2022**	**As of December 31, 2021**
Rental (1)	$ 7,072	$ 6,011
Business-to-business and other receivables (2)	26,911	18,441
Total net accounts receivable	$ 33,983	$ 24,452

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

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

(2) Business-to-business receivables included one customer with an accounts receivable balance of $4,268 and $5,945 as of March 31, 2022 and December 31, 2021, respectively. The 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 $10,000 in coverage as of March 31, 2022 and December 31, 2021 for this customer with a $400 deductible and 10% retention.

The following tables sets forth the accounts receivable allowances as of March 31, 2022 and December 31, 2021:

Allowances - accounts receivable	As of March 31, 2022	As of December 31, 2021
Doubtful accounts	$ 53	$ 52
Sales returns	969	810
Total allowances - accounts receivable	$ 1,022	$ 862

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 on a credit basis. The Company also sells its products direct-to-consumers primarily on a prepayment basis. The Medicare service reimbursement programs represented more than 10% of the Company's total revenue for the three months ended March 31, 2022. Medicare represented more than 10% of the Company's total revenue for the three months ended March 31, 2022 and one single customer for the three months ended March 31, 2021.Three single customers and Medicare each represented more than 10% of the Company's net accounts receivable balance with accounts receivable balances of $5,778, $4,268, $3,673 and $3,461, respectively, as of March 31, 2022, andone single customer and Medicare of $5,945 and $2,685, respectively, as of December 31, 2021.

The Company also rents products directly to consumers for insurance reimbursement, which resulted in a customer concentration relating to Medicare's service reimbursement programs. Medicare's service reimbursement programs accounted for 79.0% and 83.9% of rental revenue in the three months ended March 31, 2022 and March 31, 2021, respectively, and based on total revenue were 12.8% and 9.5% for the three months ended March 31, 2022 and March 31, 2021, respectively. Accounts receivable balances relating to Medicare's service reimbursement programs (including held and unbilled, net of allowances) amounted to $3,461 or 10.2% of total net accounts receivable as of March 31, 2022 as compared to $2,685 or 11.0% of total net accounts receivable as of December 31, 2021.

The Company currently purchases raw materials from a limited number of vendors, which resulted in a concentration of three major vendors. The three major vendors supply the Company with raw materials used to manufacture the Company's products. For the three months ended March 31, 2022, the Company's three major vendors accounted for 25.2%, 19.9% and 8.4%, respectively, of total raw material purchases. For the three months ended March 31, 2021, the Company's three major vendors accounted for 19.9%, 10.8% and 9.6%, 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. Approximately 73.2% and 79.3% of the non-U.S. revenue for the three months ended March 31, 2022 and March 31, 2021, respectively, were invoiced in Euros. A breakdown of the Company's revenue from U.S. and non-U.S. sources for the three months ended March 31, 2022 and March 31, 2021, respectively, is as follows:

	Three months ended March 31,	
	2022	**2021**
U.S. revenue	$ 52,444	$ 71,212
Non-U.S. revenue	27,941	15,720
Total revenue	$ 80,385	$ 86,932

Inventories

Inventories are stated at the lower of cost and net realizable value, 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 $797 and $1,943 as of March 31, 2022 and December 31, 2021, 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. The Company prepaid for raw materials of $10,968 and $15,426 as of March 31, 2022 and December 31, 2021, respectively, that were classified in prepaid expenses and other current assets. During the three months ended March 31, 2022 and March 31, 2021, $533 and $607, 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 flows. Inventories that are considered current consist of the following:

	March 31, 2022	**December 31, 2021**
Raw materials and work-in-progress	$ 22,550	$ 21,909
Finished goods	13,313	12,116
Less: reserves	(1,785)	(2,152)
Inventories, net	$ 34,078	$ 31,873

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 loss. Repair and maintenance expense, which includes labor, parts and freight, for rental equipment was $1,030 and $935 for the three months ended March 31, 2022 and March 31, 2021, 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 months ended March 31, 2022 and March 31, 2021, respectively.

	Three months ended March 31,	
	2022	**2021**
Rental equipment	$ 2,638	$ 1,888
Other property and equipment	975	946
Total depreciation and amortization	$ 3,613	$ 2,834

Property and equipment and rental equipment with associated accumulated depreciation is summarized below as of March 31, 2022 and December 31, 2021, respectively.

Property and equipment	**March 31, 2022**	**December 31, 2021**
Rental equipment, net of allowances of $1,450 and $1,290, respectively	$ 59,387	$ 59,073
Other property and equipment	31,298	31,522
Property and equipment	90,685	90,595
Accumulated depreciation		
Rental equipment	33,668	33,355
Other property and equipment	17,688	18,314
Accumulated depreciation	51,356	51,669
Property and equipment, net		
Rental equipment, net of allowances of $1,450 and $1,290, respectively	25,719	25,718
Other property and equipment	13,610	13,208
Property and equipment, net	$ 39,329	$ 38,926

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. No impairments were recorded as of March 31, 2022 and March 31, 2021.

Goodwill and other identifiable intangible assets

Goodwill

The changes in the carrying amount of goodwill for the three months ended March 31, 2022 were as follows:

Balance as of December 31, 2021	$ 32,979
Translation adjustment	(45)
Balance as of March 31, 2022	$ 32,934

As of March 31, 2022, the Company had no accumulated impairment losses related to goodwill.

Intangible assets

There were no accumulated impairment losses related to the Company's intangible assets as of March 31, 2022 and December 31, 2021.

(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:

March 31, 2022	Average estimated useful lives (in years)	Gross carrying amount	Accumulated amortization	Net amount
Technology	10	$ 77,700	$ 20,396	$ 57,304
Licenses	10	185	181	4
Patents and websites	5	4,519	3,927	592
Customer relationships	4	1,333	1,333	—
Commercials	2-3	348	248	100
Total		$ 84,085	$ 26,085	$ 58,000

December 31, 2021	Average estimated useful lives (in years)	Gross carrying amount	Accumulated amortization	Net amount
Technology	10	$ 77,700	$ 18,454	$ 59,246
Licenses	10	185	180	5
Patents and websites	5	4,519	3,746	773
Customer relationships	4	1,361	1,361	—
Commercials	2-3	799	676	123
Total		$ 84,564	$ 24,417	$ 60,147

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

	March 31, 2022
Remaining 9 months of 2022	$ 6,365
2023	7,854
2024	7,821
2025	7,790
2026	7,774
Thereafter	20,396
	$ 58,000

Current liabilities

Accounts payable and accrued expenses as of March 31, 2022 and December 31, 2021 consisted of the following:

	March 31, 2022	December 31, 2021
Accounts payable	$ 18,109	$ 10,258
Accrued inventory (in-transit and unvouchered receipts) and trade payables	10,340	12,488
Accrued purchasing card liability	2,508	1,488
Accrued franchise, sales and use taxes	492	486
Other accrued expenses	926	969
Accounts payable and accrued expenses	$ 32,375	$ 25,689

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

Accrued payroll as of March 31, 2022 and December 31, 2021 consisted of the following:

	March 31, 2022	December 31, 2021
Accrued bonuses	$ 1,292	$ 8,274
Accrued wages and other payroll related items	4,221	5,469
Accrued vacation	3,012	2,894
Accrued employee stock purchase plan deductions	314	670
Accrued payroll	$ 8,839	$ 17,307

5. Leases

The Company has entered into operating leases primarily for commercial buildings. These leases have terms which range from 2 years to 11 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 certain 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.

Rent expense, including short-term lease cost, was $971 and $987 for the three months ended March 31, 2022 and March 31, 2021.

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

	Three months ended March 31,	
	2022	2021
Cash paid for operating lease liabilities	$ 1,008	$ 554
Operating lease cost	975	763
Non-cash right-of-use assets obtained in exchange for new operating lease obligations	—	9,340
Weighted average remaining lease term	2.7 years	3.0 years
Weighted average discount rate	2.9 %	3.2 %

Maturities of lease liabilities due in the 12-month period ending March 31,	
2023	$ 3,945
2024	3,965
2025	3,362
2026	2,702
2027	2,716
Thereafter	11,416
	28,106
Less imputed interest	(2,296)
Total lease liabilities	$ 25,810

Operating lease liability - current	$ 3,401
Operating lease liability - noncurrent	$ 22,409
Total lease liabilities	$ 25,810

6. Earnings (loss) per share

Earnings (loss) 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 (loss) per share when their effect is dilutive.

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

Basic earnings (loss) per share is calculated using the Company's weighted average outstanding common shares. Diluted earnings (loss) 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 March 31,	
	2022	**2021**
Numerator—basic and diluted:		
Net loss	$ (14,214)	$ (732)
Denominator:		
Weighted average common shares - basic common stock (1)	22,754,421	22,181,394
Weighted average common shares - diluted common stock	22,754,421	22,181,394
Net income (loss) per share - basic common stock	$ (0.62)	$ (0.03)
Net income (loss) per share - diluted common stock (2)	$ (0.62)	$ (0.03)
Denominator calculation from basic to diluted:		
Weighted average common shares - basic common stock (1)	22,754,421	22,181,394
Stock options and other dilutive awards	88,193	341,716
Weighted average common shares - diluted common stock	22,842,614	22,523,110
Shares excluded from diluted weighted average shares:		
Stock options	380,890	64,498
Restricted stock units and restricted stock awards	577,242	308,787
Shares excluded from diluted weighted average shares	958,132	373,285

(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.
(2) Due to net losses for the three months ended March 31, 2022 and March 31, 2021, diluted loss per share is the same as basic.

7. Income taxes

The Company accounts for income taxes in accordance with ASC 740— *Income Taxes*. Under ASC 740, income taxes are recognized for the amount of taxes payable or refundable for the current period and deferred tax liabilities and assets are recognized for the future tax consequences of transactions that have been recognized in the Company's consolidated financial statements or tax returns. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. 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. As of March 31, 2022, the Company continued to record a valuation allowance against its deferred tax assets.

The Company accounts for uncertainties in income taxes 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.

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

8. Stockholders' equity

The Company has a 2012 Equity Incentive Plan (2012 Plan) under which the Company granted options to purchase shares of its common stock. As of March 31, 2022, options to purchase 67,953 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.

As of March 31, 2022, awards with respect to 1,033,824 shares of the Company's common stock were outstanding, and 1,111,771 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 2012 Plan and 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 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 2022, 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 three months ended March 31, 2022 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, 2021	459,441	$1.17-$83.30	$ 42.18	1.36	$ 4.31
Exercised	(3,499)	8.37	8.37		
Forfeited	(7,500)	38.54-44.19	42.31		
Outstanding as of March 31, 2022	448,442	1.17-83.30	42.44	1.04	3.97
Vested and exercisable as of March 31, 2022	448,442	1.17-83.30	42.44	1.04	3.97
Vested and expected to vest as of March 31, 2022	448,442	$1.17-$83.30	$ 42.44	1.04	$ 3.97

The total intrinsic value of options exercised during the three months ended March 31, 2022 and March 31, 2021 was $84 and $6,504, respectively. As of March 31, 2022, 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.

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

Stock Awards granted with only time-based service vesting conditions generally vest over afour-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.

Stock Awards activity for the three months ended March 31, 2022 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, 2021	289,166	99,112	388,278	$ 54.81
Granted	304,975	164,722	469,697	35.32
Vested	(63,388)	(37,677)	(101,065)	53.98
Forfeited/canceled	(9,042)	—	(9,042)	47.16
Unvested restricted stock units as of March 31, 2022 (1)	521,711	226,157	747,868	$ 43.27
Unvested and expected to vest restricted stock units outstanding as of March 31, 2022			568,034	$ 43.27

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, 2021	10,416	5,629	16,045	$ 87.12
Vested	(2,111)	(5,629)	(7,740)	103.09
Unvested restricted stock awards outstanding as of March 31, 2022 (1)	8,305	—	8,305	$ 76.71
Unvested and expected to vest restricted stock awards outstanding as of March 31, 2022			7,922	$ 77.34

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

As of March 31, 2022, the unrecognized compensation cost related to unvested employee restricted stock units and restricted stock awards was $2,969, 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.

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

As of March 31, 2022, a total of 539,308 shares of common stock were available for sale pursuant to the ESPP.

The number of shares available for sale under the ESPP is increased annually on the first day of each fiscal year 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 2022, 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 months ended March 31, 2022 and March 31, 2021, was as follows:

	Three months ended March 31,	
	2022	**2021**
Stock-based compensation expense by type of award:		
Restricted stock units and restricted stock awards	2,468	$ 2,330
Employee stock purchase plan	197	186
Total stock-based compensation expense	$ 2,665	$ 2,516

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. 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 months ended March 31, 2022 and March 31, 2021, 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 March 31,	
	2022	**2021**
Cost of revenue	$ 233	$ 238
Research and development	384	298
Sales and marketing	591	612
General and administrative	1,457	1,368
Total stock-based compensation expense	$ 2,665	$ 2,516

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

9. Commitments and contingencies

Purchase obligations

The Company had approximately $122,900 of outstanding purchase orders due within one year with its outside vendors and suppliers as of March 31, 2022.

Warranty obligation

The following table identifies the changes in the Company's aggregate product warranty liabilities for the three and twelve-month periods ended March 31, 2022 and December 31, 2021, respectively:

	March 31, 2022	December 31, 2021
Product warranty liability at beginning of period	$ 13,726	$ 14,394
Accruals for warranties issued	1,330	9,168
Adjustments related to preexisting warranties	873	(597)
Settlements made (in cash or in kind)	(2,836)	(9,239)
Product warranty liability at end of period	$ 13,093	$ 13,726

Contract liabilities

Contract liabilities primarily consist of deferred revenue related to lifetime warranties on direct-to-consumer sales revenue when cash 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 decrease in deferred revenue related to lifetime warranties for the three months ended March 31, 2022 was primarily driven by $1,595 of revenue recognized that was included in the deferred revenue balances as of December 31, 2021, partially offset by $1,342 of payments received in advance of satisfying performance obligations. Deferred revenue related to lifetime warranties was $17,723 and $17,976 as of March 31, 2022 and December 31, 2021, respectively, and is classified within deferred revenue – current and noncurrent deferred revenue 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

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.

10. Foreign currency exchange contracts and hedging

As of March 31, 2022 and March 31, 2021, the Company's total non-designated and designated derivative contracts had notional amounts totaling approximately $2,445 and $15,680, respectively, and $1,704 and $20,491, respectively. These contracts were comprised of offsetting contracts with the same counterparty, each expires within one to nine months. During the three months ended March 31, 2022 and March 31, 2021, these contracts had, net of tax, an unrealized loss of $74 and an unrealized gain of $903, 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 three months ended March 31, 2022 and March 31, 2021, there were no ineffective portions relating to these hedges and the hedges remained effective through their respective settlement dates. As of March 31, 2022, the Company had eight designated hedges and one non-designated hedge. As of March 31, 2021, the Company had twenty-two designated hedges and two 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 expectations of the impact of the COVID-19 pandemic and related public health emergency (PHE) on sales, productivity, hiring, media expenditures, prescriber sales team and physician referrals, worldwide demand for oxygen therapies, and our supply chain, including supply constraints and cost inflation related to semiconductor chips used in our batteries and printed circuit boards which are components of our portable oxygen concentrators (POCs) and the possibility of a future impact on our manufacturing facilities in California and Texas;
- 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 pandemic and related PHE impacting respiratory care, CMS changes to Home Use of Oxygen national coverage determination and how those changes are implemented, and future changes in rental revenue;
- our expectations regarding regulatory approvals, including the period of time during which our sales in Europe will be suspended due to delayed European Medical Device Regulation approval, 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 potential integration of Tidal Assist® Ventilator (TAV®) technology into our existing products;
- 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 related to the impact of supply chain disruptions on our manufacturing costs and our ongoing efforts to reduce average unit costs for our systems;
- our expectations regarding our sales and marketing channels related to our prescriber sales team, including the expansion of the sales team and concierge service representatives and implementation of healthcare data, insights and tools through our partnership with Ashfield Healthcare, LLC (Ashfield) and its impact on clinician awareness and coverage, POC penetration, and sales team productivity;
- 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;
- 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 and our assessments and estimates of our effective tax rate;
- our expectations of future accounting pronouncements or changes in our accounting policies;
- 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 a pending application for “Inogen” with the United States Patent and Trademark Office. We own trademark registrations for the mark “Inogen” in Argentina, Australia, Canada, Chile, China, Columbia, Ecuador, South Korea, Mexico, Europe (European Union Registration), the United Kingdom, Iceland, India, Israel, Japan, Kuwait, New Zealand, Norway, Paraguay, Peru, Turkey, Singapore, Switzerland, and Uruguay. We own pending applications for the mark “Inogen” in Brazil, India, Malaysia, and South Africa. 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, Europe (European Union Registration), and the United Kingdom. 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) and the United Kingdom. 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 a trademark application for the Inogen design in Bolivia. We own a trademark registration for the Inogen design in China. We own a trademark registration 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 subsidiary.

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.

The purpose of Management's Discussion and Analysis (MD&A) is to provide an understanding of Inogen's financial condition, results of operations and cash flows by focusing on changes in certain key measures from year to year. The MD&A is provided as a supplement to, and should be read in conjunction with, our consolidated financial statements and accompanying condensed notes. The MD&A is organized in the following sections:

- Critical accounting policies and estimates
- COVID-19 pandemic and related PHE
- Overview
- Basis of presentation
- Results of operations
- Liquidity and capital resources
- Sources of funds
- Use of funds
- Non-GAAP financial measures

Critical accounting policies and 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.

Critical accounting policies and estimates are those that we consider the most important to the portrayal of our financial condition and results of operations because they require our most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. Our critical accounting policies and estimates include those related to:

- revenue recognition; and
- acquisitions and related acquired intangible assets and goodwill.

There have been no material changes in our critical accounting policies and estimates in the preparation of our consolidated financial statements during the three months ended March 31, 2022 compared to those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2021, as filed with the SEC on February 24, 2022.

COVID-19 pandemic and related 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 pandemic and related PHE could have on our business, the continued spread of COVID-19, both across the United States and throughout the world, and the measures taken by the governments of countries and local authorities affected has adversely impacted and could likely continue to adversely impact patient mobility, care accessibility, diagnosis rates, demand for our products, our business operations, including manufacturing, due to supply chain constraints, hiring and continued employment of our employees and contractors, shipment, cost of our products, and our financial condition and operating results.

Our priorities during the COVID-19 pandemic and related 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, we anticipate that it is possible that the demand for long-term oxygen therapy will increase due to new cases of chronic respiratory failure or exacerbation or progression of preexisting respiratory conditions will sustain or increase, although this is not based on clinical data. We also believe stationary oxygen concentrators, and, secondarily, POCs could help meet the needs of global healthcare systems by allowing appropriate patients to use oxygen therapy at home to treat respiratory symptoms.

However, the COVID-19 pandemic and related PHE adversely impacted our consolidated operating results starting in the second quarter of 2020. We experienced lower direct-to-consumer sales starting toward the end of the first quarter of 2020, which we believe was primarily associated with shelter-in-place orders, self-quarantine, reduced mobility and travel, and reduced access to clinicians for diagnosis and follow-up for chronic obstructive pulmonary disease (COPD) patients related to the mandates and behaviors emanating from the COVID-19 pandemic and PHE. In periods with lower COVID-19 spread, we saw improved consumer demand for our products, which we believe was due to increasing vaccination rates and other effective containment measures, higher consumer confidence, mobility and interest in travel, versus lower demand in periods with higher COVID-19 spread. Those impacts were in addition to our traditional seasonality in consumer buying patterns. We continue to believe that potential future shelter-in-place orders, reduced travel, lower consumer confidence, or the impacts of new variants could reduce consumer demand in future periods.

Despite the COVID-19 pandemic and related PHE adverse impacts to direct-to-consumer sales, we experienced increased rental setups in the second quarter of 2020 through the first quarter of 2022, which we believe was due to Medicare and commercial payors reducing some of the administrative burden for oxygen therapy and our focus on the rental channel of the business. We believe this change will continue to contribute to increased rental setups during the remainder of the COVID-19 pandemic and related PHE. We have also seen increased reimbursement rates in some areas for Medicare beneficiaries, which have increased rental revenue during the COVID-19 pandemic and related PHE and are expected to continue to do so for the remainder of the COVID-19 pandemic and related PHE.

In the business-to-business channel, there have been certain surges in demand for oxygen concentrators by our home medical equipment (HME) providers worldwide during the COVID-19 pandemic and related PHE in specific markets with significant COVID-19 case rates due to the tendency of hospitals to discharge COVID-19 impacted patients for treatment at home during rehabilitation due to space and labor shortages in hospitals. However, overall business-to-business demand has been lower because of the COVID-19 pandemic and related PHE due to lower patient travel, physician offices limiting patient interactions for COPD patient referrals, HME providers minimizing patient interactions in response to the COVID-19 pandemic and related 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 due to the temporary closure and reduced operating capacity of certain respiratory assessment centers and continued tender delays in certain markets due to the COVID-19 pandemic. Similar to our direct-to-consumer sales channel, business-to-business sales improved in periods with lower COVID-19 spread, higher consumer confidence, interest in travel, and availability of effective vaccines. In addition, this channel is impacted by COPD patient referral volumes in our core markets of the United States and Europe, which tends to improve in periods with lower COVID-19 spread due to a patient's willingness to see their physician. However, supply constraints, primarily due to limited semiconductor chip availability, negatively impacted sales in 2021 and the first quarter of 2022 mainly in the domestic business-to-business channel, as discussed in more detail below.

During 2020 and 2021, we were able to broadly maintain our operations, but in the first quarter of 2022 we were forced to temporarily suspend production for a period of approximately six weeks due to the semiconductor chip shortages discussed below. As seen in this temporary production halt, the COVID-19 pandemic and related PHE have caused and could continue to cause disruption to our supply chain that could impact our operations, limit our growth, and increase our cost of goods sold per unit.

For example, we have seen reduced semiconductor chip availability in 2021 and the first quarter of 2022, which has impacted our ability to produce and sell systems and batteries. We expect availability issues to continue through the remainder of 2022 and possibly into 2023 as the semiconductor chip shortage is being experienced across many industries, placing additional pressure on existing supplies. In addition, gas required for manufacturing of semiconductors and manufacturing capacity constraints as a result of the war in Ukraine as well as the COVID-19 extended lockdown in China are expected to impact our operations into the second half of 2022. We have attempted to mitigate the impact of this increased supply shortage, but it has and will likely continue to negatively impact our ability to manufacture product, and we could be forced to slowdown or temporarily halt production again. We are continuing to focus our mitigation efforts on product redesign, seeking increased commitments on supply and shipment dates from our regular suppliers, sourcing from the open semiconductor channel, and using appropriate pricing actions such as price increases, to help offset some of the increased cost.

We saw inflated costs related to the acquisition of semiconductor chips begin to negatively impact our cost of goods sold in the second half of 2021which continued through the first quarter of 2022, and we expect this to have an increased impact on our cost of goods soldfor the remainder of 2022 and into 2023. Even though we paid significant costs in the second half of 2021 and the first quarter of 2022 associated with acquiring chips on the open market, most of these costs increased our prepaid expense and inventory given that these components were not yet in finished products that were sold during the period. We believe based on our assessment and industry feedback that these supply shortages and increased costs are likely to continue through the remainder of 2022 and into 2023. In addition to the semiconductor chip limitations, we are continuing to see supply chain constraints and cost inflation for other components used in our products albeit to a lower degree. Due to semiconductor chip shortages, we temporarily suspended manufacturing operations at our Texas and California locations as well as Foxconn, our Czech Republic-based original equipment manufacturer (OEM), beginning January 3, 2022 until early February 2022 when we resumed production and restarted our manufacturing operations at all three locations. While we have been able to restart manufacturing operations at all locations, we are still seeing challenges in terms of available supply and we believe the supply shortages continue to represent an increased risk to the business in 2022, and we may have to suspend manufacturing again in the future due to these shortages. As a result, in the interim we expect to be supply constrained and unable to meet all customer demand for our products.

Additionally, we have experienced, along with most other companies across many industries, the macro-economic impact of a challenging employment environment related to hiring and retaining employees and wage inflation. We expect that these hiring, retention, and wage inflation challenges, as well as challenges related to maintaining our current workforce, will continue into 2022. These challenges may negatively affect our ability to grow our business and keep our best employees or increase our cost of operations. In response we have implemented more flexible workplace requirements depending on the role, such as increasing ability for remote work, but we still expect to be challenged by the macro-economic employment environment.

The COVID-19 pandemic and related 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 pandemic and related PHE has caused demand to fluctuate for our products across all channels due to the global economic environment and changes to physician visits, interactions, testing requirements and diagnosis. Additionally, while we planned for sales and marketing expansion in 2021, we saw lower hiring and increased attrition in our direct-to-consumer sales force, primarily due to increased competition for sales professionals in 2021 and the first quarter of 2022. The labor shortage trend for qualified sales professionals may continue in 2022, limiting our ability to grow in future periods.

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. As the COVID-19 pandemic and related 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, and those with patient, prescriber, or customer face-to-face interactions. Employees whose tasks can be done offsite have been allowed to work from home and most of our 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 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 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 as needed. 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 employ a direct-to-consumer market and rental strategy that we believe contributes to our leadership position in the POC market. Our direct-to-consumer market and rental strategy means that we (i) advertise directly to consumers, process their physician paperwork, and provide clinical support as needed and (ii) bill Medicare or insurance on the patient's behalf in the United States. We believe that we are the only POC manufacturer offering patients both a purchase and a rental option to acquire an oxygen therapy device.

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. 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 prescriber sales teams and increase productivity.* We expect minimal net new inside direct-to-consumer sales hires in the near term due to the size and quality of the candidate pool and expected attrition, but as part of our growth plans, we are increasing our focus on improving performance and productivity of our existing sales force. Going forward, except as otherwise limited by the impact of the COVID-19 pandemic and related PHE, our plan is to continue to expand sales capacity while focusing on increased productivity driven by improved sales management discipline, insights-informed tools, and optimized patient lead generation.

  During the year ended December 31, 2021, the number of inside direct-to-consumer sales representatives decreased to 292 from 300 as of December 31, 2020, and we have continued to see our inside direct-to-consumer sales representative headcount decline in the first quarter of 2022 due to attrition outpacing hiring. In 2021 and continuing into the first quarter of 2022, hiring was challenging due to the continued impacts of the COVID-19 pandemic and related PHE. We hope to offset attrition with replacement hiring through the remainder of 2022 while we opportunistically increase the total inside direct-to-consumer sales representatives if and when required while maintaining our hiring standards and being mindful of the supply constraints.

  We also plan to expand our prescriber sales team to drive increased physician referrals for patient rentals. This specialized sales team consisted of 35 sales representatives and 6 support personnel as of December 31, 2021. In addition, we are using a third-party contract sales organization, Ashfield, that will only represent Inogen in the field, to enhance our go-to-market capabilities in the U.S. As of March 31, 2022, we had approximately 54 dedicated sales representatives and 12 concierge service representatives on our prescriber sales team. Additionally, Ashfield has provided access to its best-in-class data-driven sales management disciplines, proprietary prescriber insights, and analytics to support our growth strategy and drive performance in the clinician sales channel. The combined sales organization, Inogen and Ashfield, will benefit from access to Ashfield's comprehensive offering of analytics tools, sales operations support, and personalized concierge services that will help drive productivity and efficiency.

- *Expand our domestic direct-to-consumer marketing efficiently and optimize pricing.* We maintained our marketing efforts to continue to drive patient awareness of our products and patient inquiries about their ability to switch from their current oxygen products to our technology as patient interest increased. We plan to optimize marketing spend to drive consumer and physician awareness of our products in 2022 and beyond. We raised prices as of September 1, 2021 and March 1, 2022 to partially offset rising product costs. We plan to continue to monitor the progression of the COVID-19 pandemic and related PHE in the United States and may adjust our marketing plan accordingly.

- *Expand our rental revenues.* We are evolving our operating model to focus the enhanced prescriber sales team on rental opportunities with our direct-to-consumer sales team focusing mainly on cash sales. We believe the new specialized operating model will drive higher rental setups as we expand prescriber and payor awareness of our products and services.

  Due to the COVID-19 pandemic and related PHE, Medicare and commercial payors have reduced some of the administrative burden for oxygen therapy, which also contributed to increased rental setups in the second quarter of 2020 through the first quarter of 2022. We believe this change will continue to contribute to increased rental setups during the remainder of the COVID-19 pandemic and related PHE. We have also seen increased reimbursement rates in some areas for Medicare beneficiaries, which have increased rental revenue during the COVID-19 pandemic and related PHE and are expected to continue to do so for the remainder of the COVID-19 pandemic and related PHE. CMS has finalized additional changes to the administrative requirements to dispense and bill for oxygen therapy, which is discussed in more detail in the Reimbursement section below. These changes may reduce the administrative burden and increase patient access to our products; however, we still need additional clarity on how it will be implemented.

- *Expand our domestic HME provider and reseller sales.* 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 services to help providers convert their businesses to a non-delivery POC business model.

  Supplemental oxygen is a treatment prescribed by healthcare professionals for some patients with hypoxemia, which in some cases may be caused or exacerbated by COVID-19. While there have been surges in demand for oxygen concentrators by our HME providers during the COVID-19 pandemic and related PHE in specific markets with significant COVID-19 case rates, domestic business-to-business demand in 2020 declined. In 2020, the COVID-19 pandemic and related PHE represented a period of isolation, with lower patient travel, fewer visits to physician offices (limiting patient interactions for COPD patient referrals) and HME providers minimizing patient interactions. Domestic HME provider demand increased in the year ended December 31, 2021 and in the three months ended March 31, 2022, primarily due to increased demand for POCs as hospital systems and stationary oxygen concentrator supply were strained to keep up with the increase in COVID-19 cases and increased patient ambulation and consumer confidence.

  However, in spite of the increased demand, starting in the third quarter of 2021 through the first quarter of 2022, we saw supply constraints associated with the semiconductor chip shortage that led to a significant decline in this channel, specifically in the first quarter as we were forced to temporarily halt production from early January 2022 to early February 2022 due to these supply constraints. We expect these supply constraints to continue to impact the domestic business-to-business channel in the remainder of 2022.

- *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 sizable international market opportunity, particularly in Europe where there is existing oxygen reimbursement for respiratory conditions. In order to take advantage of these international markets, we have partnered with distributors who serve those markets and key customers in them. We additionally have an Inogen base of operations for sales and customer service in the Netherlands, and use a contract manufacturer, Foxconn, located in the Czech Republic to support the majority of our European sales volumes. We have sold our products in a total of 59 international countries and overseas regions.

  Current Inogen products are commercialized in the European Union and United Kingdom under Medical Device Directive (MDD) certificates, expiring on May 18, 2022. The extension of the existing certificates under the MDD or obtaining a new certificate under the European Medical Device Regulation (MDR) is required for continued marketing in the European Union after May 18, 2022. Our EU MDR Generic Device Group submission has been filed for our POCs and are under review. In addition, United Kingdom Conformity Assessed has been filed and accepted. The Swiss Medic Submissions has been filed and awaiting final steps. Derogation requests have also been filed in Germany, France, Spain, Italy, Belgium and Netherlands. Additional requests are in the process of preparation. Due to the expected reduced availability of products in Europe in the second quarter and second half of 2022 due to the delay in MDR approval, we will place intentional focus on fulfilling European orders in our international business-to-business sales channel until May 18, 2022 when the MDR certificate expires.

  As in the United States, there have been surges in demand for oxygen concentrators by our international HME customers during the COVID-19 pandemic in specific markets with significant COVID-19 case rates. However, international demand declined in the second quarter of 2020 and continuing through the first quarter of 2021, primarily due to the temporary closures and reduced operating capacity of certain European respiratory assessment centers due to the COVID-19 pandemic, tender delays in certain European markets, and decreased sales in other markets, primarily Canada. In addition, during this period, providers turned their focus to supplying stationary oxygen concentrators with higher flow characteristics in response to the COVID-19 pandemic. We experienced increased demand for the remainder of 2021 and during the first quarter of 2022, which we believe was due to improving COVID-19 vaccination rates and increased ambulation of patients in Europe, increased operational capacity of certain European respiratory assessment centers, and increased sales in certain markets associated with spikes in COVID-19 cases in such instances. 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.

  Over time, as the U.S. and European markets mature, our growth will depend on our ability to drive POC adoption in developing or emerging markets, where limited oxygen therapy treatment and reimbursement exists today. However, growth may also be limited by regulatory and reimbursement clearances, currency fluctuations, capital expenditure constraints, ongoing restructuring challenges, and tender uncertainty.

- *Invest in our oxygen product offerings to develop innovative products and expand clinical evidence* We incurred $16.6 million and $14.1 million in 2021 and 2020, respectively, in research and development expenses, and we intend to continue to make such investments in the foreseeable future. We incurred $5.4 million and $4.0 million for the three months ended March 31, 2022 and March 31, 2021, respectively, in research and development costs.

We launched our fifth-generation POC, the Inogen One G5 in 2019. 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 short-term. The Inogen One G5 represented more than75% of total domestic POC units sold in the three months ended March 31, 2022, 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.

We plan to also invest in clinical studies to evaluate expected improvements in clinical, economic and patient reported outcomes associated with the use of our products as part of our efforts to drive payor and prescriber advocacy for our products.

- *Expand our product offerings.* We are primarily focused on creating innovative, evidence-based chronic respiratory care solutions to strengthen and build preference and advocacy for our respiratory therapies and brand across patients, prescribers, and payors. We plan to do this with an expanded, high quality, connected, and innovative product portfolio that strengthens our differentiation. We are also committed to pursuing complementary acquisition opportunities to strengthen our technology, product offerings, and channel access.

  In August 2019, we acquired New Aera. New Aera's patented and Food and Drug Administration (FDA)-cleared 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 plan to only sell this product across our domestic direct-to-consumer channel and in our domestic business-to-business channel in 2022, and we expect limited contributions to revenue in its existing configuration.

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 Texas and California. In 2022, we are focused on securing supply for components to make our products in spite of the higher costs of semiconductor chips, reducing the cost of our Inogen One G5 product (excluding semiconductor chips), 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 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. In some cases, maintaining a single source of supply can allow us to control production costs and inventory levels and to manage component quality, but also may lead to supply availability risks, and means our ability to maintain production is dependent on these single source suppliers, which may put us at an increased risk of supply disruption, as we have seen from the production halt we implemented in early January 2022 through early February 2022. In order to help 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, a continued reduction or halt in supply from one of these single-source suppliers, any dual-sourced suppliers or any other limited source suppliers with similar sub-component suppliers could limit or prevent our ability to manufacture our products or devices until one or more sufficient replacement suppliers 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 in some cases those components are available in only limited supplies from limited manufacturers or suppliers, and the partial or complete loss of one or more of these manufacturers or suppliers could cause significant production delays or stoppages, 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 March 31, 2022 and March 31, 2021, approximately 34.8% and 18.1%, respectively, of our total revenue was from sales to customers outside the United States, primarily in Europe. Approximately 73.2% and 79.3% of the non-U.S. revenue for the three months endedMarch 31, 2022 and March 31, 2021, respectively, were invoiced in Euros with the remainder invoiced in United States dollars. We have sold our products in a total of 59 international countries and overseas regions 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 $80.4 million and $86.9 million for the three months ended March 31, 2022 and March 31, 2021, respectively. The decrease in total revenue was primarily due to supply chain constraints that limited production capacity and resulted in lower sales in our domestic business-to-business channel. We generated net losses of $14.2 million and $0.7 million for the three months ended March 31, 2022 and March 31, 2021, respectively. We generated Adjusted EBITDA of ($5.0) million and $5.4 million in the three months ended March 31, 2022 and March 31, 2021, respectively (see "Non-GAAP financial measures" for reconciliations between U.S. GAAP and non-GAAP results). As of March 31, 2022, our retained earnings were $55.1 million.

Sales revenue

Our future financial performance will be driven in part by the growth in sales of our Inogen One POCs, 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 directly or through our contract sales organization, improving productivity, investing in consumer and physician awareness and advocacy through increased sales and marketing efforts, expanding our clinical evidence, expanding our sales infrastructure and efforts outside of the United States, expanding our business-to-business sales through key strategic 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 pandemic and related 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 pandemic and related PHE, their ongoing restructuring efforts, lack of access to available credit, provider capital expenditure constraints, and potential changes in reimbursement rates.

Our direct-to-consumer and prescriber sales processes involve 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 therapy, including procuring an oxygen prescription, although, as discussed above, this process has been disrupted due to the COVID-19 pandemic and related PHE and we expect that such disruption will continue for the duration of the COVID-19 pandemic and related 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 secured. 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 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 or reimbursement rates, business restructuring activities toward a non-delivery model, capital constraints, and overall changes in the net oxygen therapy patient populations, and is presently being impacted by the COVID-19 pandemic and related 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 30,400 systems in the three months ended March 31, 2022 and 49,400 systems for the same period in 2021. While management focuses on system sales as an indicator of current business success, the decline in the current period was caused by supply chain constraints and associated temporary suspension of manufacturing at all three locations.

Rental revenue

Our 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 therapy, and their medical history to confirm the appropriateness of our product for the patient's oxygen therapy and compliance with Medicare and private payor billing requirements, which often necessitates additional physician evaluation and/or testing 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, during 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. CMS has also adopted additional changes to the administrative requirements to dispense and bill for oxygen therapy, which is discussed in more detail in the Reimbursement section below, which may reduce the administrative burden and increase patient access to our products.

Rental revenue increased in the three months ended March 31, 2022 compared to the three months ended March 31, 2021, primarily due to a greater number of patients on service and higher Medicare reimbursement rates. Medicare reimbursement rates for oxygen therapy have increased, as detailed in the Reimbursement section below. In addition, as part of the various stimulus bills in 2020 (also discussed in more detail in the Reimbursement section below), the 2% Medicare sequestration reduction was temporarily paused, 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, which increased the rates in 2021 and 2022 while the COVID-19 PHE continued. The 50/50 blended rate for HME providers in rural and non-contiguous, non-competitive bid areas was extended permanently as part of the final rule published in December 2021. We plan to add new rental patients on service in future periods through multiple strategies, including expanding our prescriber sales teams, expanding our direct-to-consumer marketing efforts, investing in patient and physician awareness and advocacy, expanding clinical evidence, 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. This capped period begins after month 36 and continues until month 60. 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 43,200 and 34,700 oxygen rental patients as of March 31, 2022 and March 31, 2021, 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 16.2% and 11.3% of our total revenue in the three months ended March 31, 2022 and March 31, 2021, respectively. The increased rental revenue as a percentage of total revenue was primarily due to increased rental patients on service and increased reimbursement rates. 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 months ended March 31, 2022 and March 31, 2021, approximately 79.0% and 83.9%, 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 Healthcare Common Procedure Coding System (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 former competitive bidding areas (CBAs) in the prior five years are outlined in the table below for E1390 and E1392, which are the two primary codes that we bill to Medicare and other payors for our oxygen product rentals. These rates are typically updated annually each January as they are subject tothe Consumer Price Index (CPI), sequestration and budget neutrality adjustments, but are also subject to adjustments during the year due to legislative rulings Competitive bidding contracts were scheduled to go into effect on January 1, 2021; however, on October 27, 2020, CMS announced that competitive bidding contracts would not be awarded for most product categories, including oxygen, due to the payment amounts not achieving the expected savings and the current COVID-19 pandemic and related PHE. Effective April 1, 2021, rates were adjusted to remove a percentage reduction that was put in place to meet the budget neutrality requirement previously mandated by section 1834(a)(9)(D)(ii) of the Social Security Act. See the table below for average Medicare rates in former CBAs, using a simple average of rates in each CBA.

Average Medicare reimbursement rates in former CBAs	E1390	E1392
As of January 1, 2022	$ 85.31	$ 41.81
As of April 1, 2021	$ 81.25	$ 39.82
As of January 1, 2021	$ 73.88	$ 36.20
As of January 1, 2020	$ 73.98	$ 36.25
As of January 1, 2019	$ 72.92	$ 35.72
As of January 1, 2018	$ 77.03	$ 36.06

Medicare payment rates are based upon whether the beneficiary resides in former or current CBAs, or in rural or non-rural non-CBAs, or in non-contiguous states. Non-CBA payment rates are based on regional pricing, that are derived from (former) competitive bidding payment rates. In rural areas and non-contiguous states, payment rates are higher, to account for higher servicing costs in those areas. The Medicare reimbursement rates in rural areas is outlined in the table below, and include areas that are considered non-contiguous (Alaska, Hawaii, Puerto Rico, and the Virgin Islands). We estimate that approximately 18% of our patients are eligible to receive the higher reimbursement rates based on the geographic locations of our current patient population. These rates are typically updated annually each January as they are subject to the CPI, sequestration and budget neutrality adjustments, but are also subject to adjustments during the year due to legislative rulings. Effective April 1, 2021, rates were adjusted to remove a percentage reduction that was put in place to meet the budget neutrality requirement previously mandated by section 1834(a)(9)(D)(ii) of the Social Security Act. Therefore, Medicare payment rates are no longer affected by a budget neutrality adjustment, as of April 1, 2021. See the table below for average Medicare rates in rural areas, using a simple average of rates in each state.

Average Medicare reimbursement rates in rural areas	E1390	E1392
As of January 1, 2022	$ 151.15	$ 48.39
As of April 1, 2021	$ 143.48	$ 47.13
As of January 1, 2021 (retroactively revised March 1, 2021)	$ 136.84	$ 44.99
As of January 1, 2020	$ 136.71	$ 44.93
As of January 1, 2019	$ 134.71	$ 44.32
As of January 1, 2018	$ 76.31	$ 41.91

Rates in non-former CBAs that are not defined as rural are set based on the rates in former CBAs. See the table below for average Medicare rates in these non-former CBAs, non-rural areas, using a simple average of rates in each state. These rates are typically updated annually each January as they are subject to the CPI, sequestration and budget neutrality adjustments but are also subject to adjustments during the year due to legislative rulings. Effective April 1, 2021, rates were adjusted to remove a percentage reduction that was put in place to meet the budget neutrality requirement previously mandated by section 1834(a)(9)(D)(ii) of the Social Security Act. Note that the 2022 rates listed below include Coronavirus Aid, Relief, and Economic Security (CARES Act) increased rates due to the COVID-19 PHE, which may not be in place for all of 2022. If the COVID-19 PHE is declared over, the rates in these non-former CBAs, non-rural areas are expected to adjust down to the former CBA rates listed in the table above.

Average Medicare reimbursement rates in non-former CBAs, non-rural areas	E1390	E1392
As of January 1, 2022	$ 115.14	$ 43.69
As of April 1, 2021	$ 109.39	$ 42.12
As of January 1, 2021 (retroactively revised March 1, 2021)	$ 104.07	$ 40.06
As of January 1, 2020	$ 74.84	$ 36.87
As of January 1, 2019	$ 72.32	$ 35.64
As of January 1, 2018	$ 69.31	$ 38.10

There have been significant U.S. reimbursement and policy changes that impact oxygen therapy associated with the COVID-19 PHE declared by the U.S. Department of Health and Human Services (HHS) on January 31, 2020. The CARES Act allows HHS to waive certain Medicare telehealth payment requirements during the COVID-19 PHE to allow beneficiaries in all areas to receive telehealth services, including at their home, starting March 6, 2020. The Coronavirus Preparedness and Response Supplemental Appropriations Act (H.R. 6074) also granted HHS the authority to waive certain requirements with respect to telehealth services. 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 home medical equipment (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 was 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 2% Medicare sequestration benefit that was in place since May 2020 due to the COVID-19 PHE was set to expire on December 31, 2021 but was extended by Congress through March 31, 2022. The sequestration has now resumed with a 1% reduction to rates from April 1, 2022 until June 30, 2022, with the full 2% Medicare sequestration set to resume starting July 1, 2022 and expected to continue through September 30, 2030.

On April 6, 2020, CMS published an Interim Final Rule (IFR) in the Federal Register for policy and regulatory revisions in response to the COVID-19 PHE. 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, are waived. In addition, the prior 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. In August 2020, CMS resumed medical review of claims and the prior authorization program for certain DMEPOS.

CMS also issued a final rule in December 2021 (CMS-1738-P) to establish payment amounts that will be effective after the COVID-19 PHE for DMEPOS products and services covered under Medicare. We believe that Medicare rates will not change for the length of the COVID-19 PHE, except for any net change for inflation and sequestration adjustments, as outlined above.

CMS established three different fee schedule adjustment methodologies for non-CBAs after the termination of the COVID-19 PHE: (1) for non-contiguous non-CBAs; (2) for contiguous non-CBAs defined as rural areas; and (3) for non-rural non-CBAs within the contiguous United States. The final payment methodology sets the fee schedule amounts to 100% of the Medicare (competitive bid derived) rates in all non-rural areas. This will reduce Medicare rates after the PHE is over in the current areas that are considered non-rural but not covered by a former CBA, as those areas are currently receiving a 75/25 blended payment rate. The final payment methodology establishes the fee schedule amounts to a 50/50 blended payment rate in rural areas, which is the same rate that is currently applicable in these areas.

CMS is required to propose future rounds of competitive bidding, which could change reimbursement rates, negatively impact the premium for POCs over other oxygen modalities, or limit beneficiary access to our technologies. At this point, CMS has not yet announced when a new round of competitive bidding will occur. 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 (when the last round of competitive bidding was in effect), 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 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 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 any 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.

In September 2021, CMS published a Decision Memo which revised the Home Use of Oxygen national coverage determination and removed the national coverage determination for Home Oxygen Use to Treat Cluster Headaches. This allows the Medicare Administrative Contractors to make coverage determinations regarding the use of home oxygen and oxygen equipment for cluster headaches. CMS also expanded patient access to oxygen and oxygen equipment in the home by allowing oxygen use for acute or short-term needs instead of limiting coverage to chronic hypoxemia, removed the requirement for alternative treatment measures before dispensing of oxygen therapy, and removed the limited list of conditions for which oxygen may be covered to respiratory-related diseases, to allow the physician flexibility to make that determination. In addition, CMS defined exercise more broadly to include functional performance of the patient and allow more flexibility on pulse oximetry readings to account for differences in skin pigmentation. Lastly, CMS removed from the national coverage determination the oxygen certificate of medical necessity requirement. We believe these changes will expand coverage for patients who would benefit from oxygen therapy, reduce administrative burdens, and give more decision-making authority on proper patient care to the physicians. CMS issued guidance on February 10, 2022 to the Medicare Administrative Contractors detailing that the implementation date of the revised national coverage policy will be June 14, 2022. However, we do not yet have visibility on the details of how the Medicare Administrative Contractors will change their coverage determinations or the effective date of the new national coverage determinations.

Medicare revenue, including patient co-insurance and deductible obligations, represented 12.8% and 9.5% of our total revenue in the three months ended March 31, 2022 and March 31, 2021, 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 months ended March 31, 2022 and March 31, 2021, respectively. Our capped patients as a percentage of total patients on service was approximately 8.1% as of March 31, 2022 and 9.8% as of March 31, 2021. The decrease in percentage of capped patients in the comparative periods was primarily due to the significant increase in new patients coming on service, which substantially exceeded the number of patients that entered the capped 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.

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 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, and we can deploy used assets in working order as long as the prescription requirements are met. We must also procure a renewal 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.

We have contracts with Medicaid, Medicare Advantage, government and private payors that 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. We had 95 contracts as of March 31, 2022. 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 historically reduced our overall POC system cost and 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 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, our product costs change, we have changes in purchase volumes, and as currency variations occur. For example, the higher costs for semiconductor chips has had a negative impact on our gross margin, and we expect that will continue in the remainder of 2022. Additionally, fluctuations in the channel mix could cause variability in our gross margins, as direct-to-consumer sales and rental revenue have higher margins than the business-to-business channels. Quarter-over-quarter results may vary due to seasonality in both the international and domestic markets, as discussed in Item 1. *Seasonality* and elsewhere in our Annual Report on Form 10-K for the year ended December 31, 2021, as filed with the SEC on February 24, 2022.

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 months ended March 31, 2022 compared to the three months ended March 31, 2021, 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 and sales teams and increase new rental setups. In addition, for the duration of the COVID-19 PHE, we expect to benefit from higher Medicare reimbursement rates and reduced administrative requirements for oxygen therapy enacted due to the COVID-19 PHE. 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, the level of and response from potential customers to direct-to-consumer marketing spend, product launches, the number of billable patients and denial rates, 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 expense, 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 as well as temporary labor. Cost of sales revenue also includes manufacturing freight in, depreciation expense, facilities costs and materials. Provisions for warranty obligations are included in cost of sales revenue and are provided for at the time of revenue recognition.

We continue to make progress towards reducing the average unit costs of our products (excluding the impact of the semiconductor chip cost increases) 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. However, we have experienced and expect to continue experiencing supply chain disruptions through the remainder of 2022 and into 2023, primarily associated with semiconductor chips used in our batteries and printed circuit boards which are components of our POCs, which drove up the cost of our products in 2021 and the first quarter of 2022, and which we expect will continue to drive up the cost of our products in the remainder of 2022. In addition, supply chain disruptions and increased cost of critical components are expected to continue into the second half of 2022 due to the war in Ukraine as well as the COVID-19 extended lockdown in China.

As a result, we saw these inflated costs negatively impact our cost of goods sold starting in the third quarter of 2021 through the first quarter of 2022, and we expect this to have an increased impact on our material costs in the remainder of 2022 until supply and demand get closer to equilibrium. Even though we paid significant costs in the second half of 2021 and the first quarter of 2022 associated with these chips, most of these costs increased our prepaid expense and inventory given that these components were not yet sold in finished products during the period. We believe based on our assessment and industry feedback that these supply shortages are likely to continue through the remainder of 2022 and into 2023. In addition to the semiconductor chip limitations, we are continuing to see supply chain constraints for other components used in our products. As a result of the semiconductor chip shortages, we temporarily suspended manufacturing operations at our Texas and California locations from January 3, 2022 to February 7, 2022 and Foxconn, our Czech Republic-based OEM, suspended manufacturing due to the same supply constraints from January 3, 2022 to February 9, 2022. While we were able to resume manufacturing operations at all locations, we are still seeing challenges in terms of available supply, and we believe the supply shortages continue to represent an increased risk to the business in the remainder of 2022 and into 2023, and we may be required to suspend manufacturing again in the future due to these shortages. As a result, in the interim we expect to be supply constrained and unable to meet all customer demand for our products.

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 2021 and the three months ended March 31, 2022, the impact of the China 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 2022.

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

Cost of rental revenue

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

We expect rental gross margin percentage to decrease in 2022, primarily associated with lower rental revenue per patient on service and higher costs per patient on service. We expect the average cost of rental revenue per patient on service 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 service costs as we leverage more volume through an experienced team.

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, engineering, and medical affairs employees. It also includes facility costs, laboratory supplies, product development materials, consulting fees, clinical studies 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.

We plan to continue to invest in research and development activities to stay at the forefront of patient preference in oxygen therapy, including significant investments in clinical research. We also 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 broadening our product portfolio.

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.

We continue to recruit to add new sales representatives, while maintaining our hiring standards and being mindful of the supply constraints. Headcount was down slightly as of March 31, 2022 compared to December 31, 2021. We expect minimal net new hires in the near term due to the size and quality of the candidate pool and expected attrition, but as part of our growth plans, we are increasing our focus on improving productivity of our existing sales force. Going forward, except as otherwise limited by the impact of the COVID-19 pandemic and related PHE, our plan is to continue to expand sales capacity while focusing on increased productivity, improved sales personnel and lead distribution systems, and improved training. We expect an 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 which includes our prescriber sales team, increasing our rental infrastructure, increasing media spend to drive consumer awareness, and rising patient support costs as our patient and customer base increases.

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, regulatory, legal, human resources, and information technology (IT) departments as well as facilities costs, 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. General and administrative expense also includes changes in the fair value of the New Aera earnout liability.

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. General and administrative expense will 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.

Other income (expense), net

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

Income taxes

We account for income taxes in accordance with Accounting Standards Codification (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 year-to-year depending on our stock price in each period.

Results of operations

Comparison of three months ended March 31, 2022 and March 31, 2021

Revenue

	Three months ended March 31,		Change 2022 vs. 2021		% of Revenue	
(amounts in thousands)	**2022**	**2021**	**$**	**%**	**2022**	**2021**
Sales revenue	$ 67,402	$ 77,081	$ (9,679)	-12.6%	83.8%	88.7%
Rental revenue	12,983	9,851	3,132	31.8%	16.2%	11.3%
Total revenue	$ 80,385	$ 86,932	$ (6,547)	-7.5%	100.0%	100.0%

Sales revenue decreased $9.7 million for the three months ended March 31, 2022 from the three months ended March 31, 2021, a decrease of 12.6% from the comparable period. The decrease was primarily attributable to supply chain constraints that mostly limited sales in our domestic business-to-business channel, partially offset by improved average selling prices and sustained demand. We sold approximately 30,400 oxygen systems during the three months ended March 31, 2022 compared to approximately 49,400 oxygen systems sold during the three months ended March 31, 2021, a decrease of 38.5%. The decrease in the number of systems sold resulted from a decrease in sales in the domestic business-to-business channel, primarily due to supply chain constraints.

Rental revenue increased $3.1 million for the three months ended March 31, 2022 from the three months ended March 31, 2021, an increase of 31.8% from the comparable period. The increase in rental revenue was primarily related to higher rental patients on service and higher Medicare reimbursement rates.

	Three months ended March 31,		Change 2022 vs. 2021		% of Revenue	
(amounts in thousands)						
Revenue by region and category	**2022**	**2021**	**$**	**%**	**2022**	**2021**
Business-to-business domestic sales	$ 5,101	$ 30,743	$ (25,642)	-83.4%	6.3%	35.4%
Business-to-business international sales	27,941	15,720	12,221	77.7%	34.8%	18.1%
Direct-to-consumer domestic sales	34,360	30,618	3,742	12.2%	42.7%	35.2%
Direct-to-consumer domestic rentals	12,983	9,851	3,132	31.8%	16.2%	11.3%
Total revenue	$ 80,385	$ 86,932	$ (6,547)	-7.5%	100.0%	100.0%

Domestic business-to-business sales decreased 83.4% for the three months ended March 31, 2022 compared to the three months ended March 31, 2021. The decrease was primarily due to the supply chain constraints that limited our ability to meet all customer demand and strategic sales channel optimization decisions, partially offset by improved average selling prices and sustained demand.

International business-to-business sales increased 77.7% for the three months ended March 31, 2022 compared to the three months ended March 31, 2021, mostly driven by increased average selling prices and improved demand primarily in Europe as we placed intentional focus on fulfilling European orders in our international business-to-business sales channel prior to the EU MDR certificate expiration. In the three months ended March 31, 2022, sales in Europe as a percentage of total international sales revenue increased to 98.2% versus 86.5% in the comparative period in 2021.

Domestic direct-to-consumer sales increased 12.2% for the three months ended March 31, 2022 compared to the three months ended March 31, 2021, primarily due to increased average selling prices versus the comparative period in the prior year. Inside sales representative productivity increased in the quarter despite lower average inside sales representative headcount, which was down approximately 6.9% from the comparative period in 2021.

Domestic direct-to-consumer rentals increased 31.8% for the three months ended March 31, 2022 compared to the three months ended March 31, 2021, primarily due to an increase in patients on service and increased Medicare reimbursement rates due to the removal of the budget neutrality provision effective April 1, 2021 and inflation adjustment effective January 1, 2022.

Cost of revenue and gross profit

	Three months ended March 31,		Change 2022 vs. 2021		% of Revenue	
(amounts in thousands)	**2022**	**2021**	**$**	**%**	**2022**	**2021**
Cost of sales revenue	$ 39,500	$ 42,635	$ (3,135)	-7.4%	49.1%	49.0%
Cost of rental revenue	5,879	4,424	1,455	32.9%	7.4%	5.1%
Total cost of revenue	$ 45,379	$ 47,059	$ (1,680)	-3.6%	56.5%	54.1%
Gross profit - sales revenue	$ 27,902	$ 34,446	$ (6,544)	-19.0%	34.7%	39.7%
Gross profit - rental revenue	7,104	5,427	1,677	30.9%	8.8%	6.2%
Total gross profit	$ 35,006	$ 39,873	$ (4,867)	-12.2%	43.5%	45.9%
Gross margin percentage - sales revenue	41.4%	44.7%				
Gross margin percentage- rental revenue	54.7%	55.1%				
Total gross margin percentage	43.5%	45.9%				

Cost of sales revenue decreased $3.1 million for the three months ended March 31, 2022 from the three months ended March 31, 2021, a decrease of 7.4% from the comparable period. The decrease in cost of sales revenue was primarily attributable to lower sales volumes, partially offset by higher material cost per unit and labor and overhead per unit. The first quarter of 2022 included $3.7 million of higher material costs associated with open-market purchases of semiconductor chips used in its batteries and POCs.

Cost of rental revenue increased $1.5 million for the three months ended March 31, 2022 from the three months ended March 31, 2021, an increase of 32.9% from the comparable period. The increase in cost of rental revenue was primarily attributable to an increase in total patients on service, which led to increased rental asset depreciation expense and servicing costs. Cost of rental revenue included $2.6 million of rental asset depreciation for the three months ended March 31, 2022 compared to $1.9 million for the three months ended March 31, 2021.

Gross margin on sales decreased to 41.4% for the three months ended March 31, 2022 from 44.7% for the three months ended March 31, 2021. The decrease was primarily due to higher cost of goods sold per unit in the quarter, related to increased material and labor and overhead costs caused by lower labor and overhead absorption due to the temporary manufacturing shutdown in early 2022. The decrease was partially offset by higher average selling prices and decreased mix of domestic business-to-business sales, which have a lower gross margin than direct-to-consumer and international business-to-business sales. Total worldwide business-to-business sales revenue accounted for 49.0% of total sales revenue in the three months ended March 31, 2022 versus 60.3% in the three months ended March 31, 2021.

Rental revenue gross margin decreased to 54.7% for the three months ended March 31, 2022 from 55.1% for the three months ended March 31, 2021, primarily due to higher servicing costs and depreciation expense per patient on service, partially offset by higher Medicare reimbursement rates.

Research and development expense

	Three months ended March 31,		Change 2022 vs. 2021		% of Revenue	
(amounts in thousands)	**2022**	**2021**	**$**	**%**	**2022**	**2021**
Research and development expense	$ 5,364	$ 4,015	$ 1,349	33.6%	6.6%	4.6%

Research and development expense increased $1.3 million for the three months ended March 31, 2022 from the three months ended March 31, 2021, an increase of 33.6% over the comparable period, primarily due to a $0.8 million increase in product development expenses and a $0.5 million increase in personnel-related expenses.

Sales and marketing expense

	Three months ended March 31,		Change 2022 vs. 2021		% of Revenue	
(amounts in thousands)	2022	2021	$	%	2022	2021
Sales and marketing expense	$ 28,039	$ 25,491	$ 2,548	10.0%	34.9%	29.3%

Sales and marketing expense increased $2.5 million for the three months ended March 31, 2022 from the three months ended March 31, 2021, an increase of 10.0% from the comparable period, primarily attributable to an increase of $2.2 million of consulting fees, primarily for the development of the physician sales team. In the three months ended March 31, 2022, we spent $7.9 million in media and advertising costs versus $7.6 million in the comparative period in 2021.

General and administrative expense

	Three months ended March 31,		Change 2022 vs. 2021		% of Revenue	
(amounts in thousands)	2022	2021	$	%	2022	2021
General and administrative expense	$ 15,189	$ 12,499	$ 2,690	21.5%	18.9%	14.4%

General and administrative expense increased $2.7 million for the three months ended March 31, 2022 from the three months ended March 31, 2021, an increase of 21.5% from the comparable period. The increase was primarily attributable to an increase of $1.6 million in personnel-related expenses, including recruiting and severance costs, and a $0.4 million increase in the change in fair value of the New Aera earnout liability.

Other income (expense)

	Three months ended March 31,		Change 2022 vs. 2021		% of Revenue	
(amounts in thousands)	2022	2021	$	%	2022	2021
Interest income	$ 29	$ 57	$ (28)	-49.1%	0.0%	0.1%
Other expense	(433)	(310)	(123)	39.7%	-0.5%	-0.4%
Total other expense, net	$ (404)	$ (253)	$ (151)	59.7%	-0.5%	-0.3%

Total other income (expense), net increased $0.2 million for the three months ended March 31, 2022 from the three months ended March 31, 2021, an increase of 59.7% from the comparable period, primarily attributable to an increase of $0.1 million in net foreign currency losses.

Income tax expense (benefit)

	Three months ended March 31,		Change 2022 vs. 2021		% of Revenue	
(amounts in thousands)	2022	2021	$	%	2022	2021
Income tax expense (benefit)	$ 224	$ (1,653)	$ 1,877	-113.6%	0.3%	-1.9%
Effective income tax rate	*-1.6%*	*69.3%*				

Income tax expense (benefit) increased $1.9 million for the three months ended March 31, 2022 from the three months ended March 31, 2021, primarily resulting from the recording of a valuation allowance on the use of deferred tax assets otherwise attributable to the current period loss.

Our effective tax rate for the three months ended March 31, 2022 decreased compared to the three months ended March 31, 2021, primarily due to the recording of a valuation allowance on the use of deferred tax assets.

Net loss

(amounts in thousands)	Three months ended March 31, 2022	2021	Change 2022 vs. 2021 $	Change 2022 vs. 2021 %	% of Revenue 2022	% of Revenue 2021
Net loss	$ (14,214)	$ (732)	$ 13,482	1841.8%	-17.7%	-0.8%

Net loss increased $13.5 million for the three months ended March 31, 2022 from the three months ended March 31, 2021, an increase of 1841.8% from the comparable period. The increase in net loss was primarily related to a decrease in gross profit and higher operating expense.

Contractual obligations

We obtain individual components for our products from a wide variety of individual suppliers. Consistent with industry practice, we acquire components through a combination of purchase orders, supplier contracts, and open orders based on projected demand information. Where appropriate, the purchases are applied to inventory component prepayments that are outstanding with the respective supplier. As of March 31, 2022, we had purchase obligations with outside vendors and suppliers of approximately $122.9 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 24, 2022.

Liquidity and capital resources

As of March 31, 2022, we had cash and cash equivalents of $213.4 million, which consisted of highly liquid investments with a maturity of three months or less. In addition, we held marketable securities of $10.0 million in available-for-sale corporate bonds which had maturities greater than three months. For the three months ended March 31, 2022 and March 31, 2021, we received $0.9 million and $4.8 million, respectively, in proceeds related to stock option exercises and our employee stock purchase plan.

Our principal uses of cash for liquidity and capital resources in the three months ended March 31, 2022 consisted of cash used in operating activities of $18.1 million and capital expenditures of $4.1 million including additional rental equipment, other property, and plant and equipment.

The COVID-19 pandemic and related PHE has not materially impacted 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)	Three months ended March 31,		Change 2022 vs. 2021	
Summary of consolidated cash flows	**2022**	**2021**	**$**	**%**
Cash provided by (used in) operating activities	$ (18,098)	$ 2,860	$ (20,958)	-732.8%
Cash provided by (used in) investing activities	(4,052)	986	(5,038)	-511.0%
Cash provided by (used in) financing activities	(108)	4,427	(4,535)	-102.4%
Effect of exchange rates on cash	133	(221)	354	-160.2%
Net increase (decrease) in cash and cash equivalents	$ (22,125)	$ 8,052	$ (30,177)	-374.8%

(amounts in thousands)	March 31,	December 31,
Summary of working capital	**2022**	**2021**
Total current assets	$ 318,122	$ 329,186
Total current liabilities	59,823	61,512
Net working capital	$ 258,299	$ 267,674

Operating activities

Historically, 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 used in operating activities for the three months ended March 31, 2022 consisted primarily of our net loss of $14.2 million, partially offset by non-cash expense items such as depreciation of equipment and leasehold improvements and amortization of intangibles of $5.8 million, provision for sales returns and doubtful accounts of $3.0 million, stock-based compensation expense of $2.7 million, provision for inventory obsolescence and other inventory losses of $0.9 million, net loss on disposal of rental equipment and other fixed assets of $0.7 million, and the change in fair value of earnout liability of $0.6 million. The net changes in operating assets and liabilities resulted in a net use of cash of $17.5 million.

Net cash provided by operating activities for the three months ended March 31, 2021 consisted primarily of our non-cash expense items, such as depreciation of equipment and leasehold improvements and amortization of our intangibles of $5.1 million, provision for sales returns and doubtful accounts of $2.5 million, stock-based compensation expense of $2.5 million, provision for rental revenue adjustments of $1.0 million, provision for inventory obsolescence and other inventory losses of $0.5 million, change in fair value of earnout liability of $0.3 million, and net loss on disposal of rental equipment and other fixed assets of $0.2 million; partially offset by the net changes in operating assets and liabilities of $6.9 million, $1.5 million increase in deferred tax assets and our net loss of $0.7 million.

Investing activities

Net cash provided by (used in) investing activities generally includes the production and purchase of rental assets, property, plant and equipment, and intangibles to support our expanding business as well as maturities or purchases of marketable securities.

For the three months ended March 31, 2022, we invested $4.1 million in the production and purchase of rental assets and other property and equipment.

For the three months ended March 31, 2021, we received $6.1 million in maturities of marketable securities. In addition, we invested $5.2 million in the production and purchase of rental assets and other property, equipment, and intangible assets.

We expect to continue investing in property, equipment and leasehold improvements as we expand our operations. Our business is inherently capital intensive. 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 and maintenance 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 three months ended March 31, 2022, net cash used in financing activities consisted of the payment of employment taxes related to the vesting of restricted stock awards and restricted stock units of $1.1 million, partially offset by $0.9 million from the proceeds received from stock options that were exercised and purchases under our employee stock purchase program.

For the three months ended March 31, 2021, net cash provided by financing activities consisted of $4.8 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 $0.4 million.

Sources of funds

Our cash used in operating activities in the three months ended March 31, 2022 was $18.1 million compared to cash provided by operating activities of $2.9 million in the three months ended March 31, 2021. As of March 31, 2022, we had cash and cash equivalents of $213.4 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 cash flows from customer collections have remained consistent and our annual cash provided by operating activities has generally 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 (loss) 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 loss, 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 (loss) 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 financial results, 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 loss, the most comparable U.S. GAAP measure, for each of the periods indicated:

(amounts in thousands)	**Three months ended March 31,**	
Non-GAAP EBITDA and Adjusted EBITDA	**2022**	**2021**
Net loss	$ (14,214)	$ (732)
Non-GAAP adjustments:		
Interest income	(29)	(57)
Provision (benefit) for income taxes	224	(1,653)
Depreciation and amortization	5,760	5,098
EBITDA (non-GAAP)	(8,259)	2,656
Stock-based compensation	2,665	2,516
Change in fair value of earnout liability	630	265
Adjusted EBITDA (non-GAAP)	$ (4,964)	$ 5,437

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to various market risks, including fluctuation in foreign currency exchange rates 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 March 31, 2022 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 began entering into foreign exchange forward contracts in December 2015 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 March 31, 2022, 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 $2.0 million decline in revenue for the three months ended March 31, 2022. 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 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 $213.4 million as of March 31, 2022, which consisted of highly liquid investments with a maturity of three months or less, and $10.0 million of marketable securities with maturity dates of greater than three months. The primary goals of our investment policy are liquidity and capital preservation. We do not enter into investments for trading or speculative purposes. We believe that we do not have any material exposure to changes in the fair value of these assets as a result of changes in interest rates due to the short-term nature of our cash and cash equivalents. Declines in interest rates, however, would reduce future investment income. 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 March 31, 2022 and March 31, 2021. 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 months ended March 31, 2022 or March 31, 2021.

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 March 31, 2022. Based upon the evaluation described above, our Chief Executive Officer and Chief Financial Officer concluded that, as of March 31, 2022, 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

We are party to various legal proceedings arising in the normal course of business. We carry insurance, subject to specified deductibles under the policies, to protect against losses from certain types of legal claims. At this time, we do not anticipate that any of these other 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.

Risk factors include, but are not limited to, statements concerning the following:

Risks related to our business and strategy:

- the intense international, national, regional and local competition we face in our industry;
- our dependence on a limited number of customers for a significant portion of our sales revenue;
- the lack of availability of certain components needed to manufacture and assemble our devices and our reliance on a single source or a limited group of manufacturers or suppliers;
- the lack of long-term supply contracts with many of our third-party suppliers;
- the possibility our manufacturing facilities could become unavailable or inoperable and other potential manufacturing problems or delays;
- our reliance upon a third-party contract manufacturer for certain manufacturing and repair operations;
- the need to continue to enhance our existing products and develop and market new products;
- risks associated with public health threats and epidemics, including the COVID-19 pandemic and related public health emergency (PHE);
- the competitive bidding process or other reimbursement policy changes under Medicare or other third-party payors, including recently enacted and potential future changes in the reimbursement rates or payment methodologies under Medicare, Medicaid and other government programs;
- healthcare reform measures;
- the complex and lengthy reimbursement process we depend upon for a significant portion of our revenue;
- potential failure to maintain or obtain new private payor contracts and future reductions in reimbursement rates from private payors;
- our ability to hire and retain highly qualified individuals;
- our ability to manage our anticipated growth effectively;
- potential acquisitions of, or investments in, other companies;
- our international sales and manufacturing activities;
- warranty or product liability claims or other litigation;
- increases in our operating costs;
- our dependence on the services of our senior executives and other key technical personnel;
- variance in our financial condition and results of operations; and
- the market opportunities for our products.

Risks related to the regulatory environment:

- extensive federal, state, and international regulations related to our business by numerous government agencies, including the U.S. Food and Drug Administration, or FDA, and the European Medical Device Regulation;
- the potential need to seek additional clearances or approvals for our products; and
- potential FDA, state, or international regulatory enforcement action.

Risks related to our intellectual property:

- our ability to secure and maintain patent or other intellectual property protection for the intellectual property used in our products;
- the possibility that any of our patents may be challenged, invalidated, circumvented or rendered unenforceable; and
- patent and other intellectual property litigation if our products infringe or appear to infringe the intellectual property rights of others.

Risks related to being a public company:

- increased costs as a result of operating as a public company and the substantial time our management will be required to devote to compliance initiatives and corporate governance practices; and
- our ability to maintain effective internal controls.

Risks related to our common stock:

- the volatility of the trading price of our common stock;
- the publication of research reports by securities or industry analysts;
- potential sales of a large number of shares of our common stock;
- anti-takeover provisions in our charter documents and under Delaware law; and
- our intention not to pay dividends for the foreseeable future.

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 is a highly competitive industry. 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.

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), Nidek Medical, 3B Medical, SysMed, and Belluscura. Given the relatively straightforward regulatory path in the oxygen therapy device manufacturing market, we expect that the industry will become increasingly competitive in the future. 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), Owens & Minor (formerly Apria Healthcare, Inc.), AdaptHealth Corp., Rotech Healthcare, Inc., and Viemed 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. In addition, providers may reduce or eliminate purchases from us due to our increased focus on building out a prescriber sales team and pursuing rentals directly, which could be in competition with our providers in the United States. 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. Consequently, 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 to new or changing opportunities, technologies, standard regulatory and reimbursement development and customer requirements or changing or uncertain business conditions or macroeconomic trends, including supply chain challenges. 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 March 31, 2022 and March 31, 2021, sales revenue to our top 10 customers accounted for approximately 29.4% and 33.4%, respectively, of our total revenue. The Medicare service reimbursement programs represented more than 10% of our total revenue for the three months ended March 31, 2022. No single sales revenue customer represented more than 10% of our total revenue for the three months ended March 31, 2022 and one single customer represented more than 10% of our total revenue for the three months ended March 31, 2021. 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 and other home medical equipment providers. 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 in some cases components required to manufacture and assemble our products are available in only limited supplies from limited manufacturers or suppliers, and the partial or complete loss of one or more of these manufacturers or suppliers or the further limitation on availability could cause significant production delays or stoppages, 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® Ventilator (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, and some molded plastic components. Many of our products also utilize components that are available from a limited number of suppliers. Our dependence on single-source or limited-source suppliers of components may expose us to several risks, including, among other things:

- our suppliers or their component sub-suppliers may be unable to meet demands due to global supply chain disruptions;
- we may experience delays in delivery by our suppliers due to customs clearing delays, shipping delays, scarcity of raw materials and components 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 pandemic and related PHE or due to acts of terrorism, hostilities, military conflict or war, including the war in Ukraine;

- we may not be able to find new or alternative components, even at elevated prices, or reconfigure our system and manufacturing processes in a timely manner if the necessary components become unavailable, which could lead to a production slowdown or temporary stoppage;
- 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, cause delays in supplying of our products to our customers, or result in regulatory enforcement against us or our suppliers;
- 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 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; and
- our suppliers may wish to discontinue supplying components or services to us.

We have experienced supply problems with one or more of our suppliers and may again experience problems in the future. For example, we have seen supply chain disruptions in 2021 and the first quarter of 2022 and expect to continue to see these disruptions through the remainder of 2022 and into the first quarter of 2023, primarily associated with semiconductor chips used in our batteries and printed circuit boards, which are components of our portable oxygen concentrators. However, we recognize that there could be supply shortages for other components used in our products. These shortages are being experienced across many industries, placing additional pressure on existing supplies. While we have taken steps to attempt to mitigate the impact of supply shortages, it has had and will likely continue to have an increased negative impact on our ability to manufacture products (including with respect to the production halt discussed below). We are continuing to focus our mitigation efforts on product redesign, seeking increased commitments on shipment dates from our regular suppliers, canvassing the open market for supplies, and using the price increases we implemented on September 1, 2021 and March 1, 2022 to help offset some of the increased costs, but in spite of these efforts we have been supply constrained and with these components facing extremely high demand, we expect continued challenges in terms of supply constraint and pricing inflation moving forward. Additionally, we believe that the war in Ukraine will result in added supply constraint pressures through at least the remainder of 2022.

The inflated costs related to the supply shortage negatively impacted our cost of goods sold in the third and fourth quarter of 2021 and the first quarter of 2022, and we expect this to have an increased impact on our material costs in the remainder of 2022. Even though we paid significant costs in the second half of 2021 and first quarter of 2022 associated with these chips, most of these costs increased our prepaid expense and inventory given that these components were either not yet delivered or not yet sold in finished products during the period. We believe based on our assessment and industry feedback that these supply shortages may continue through the remainder of 2022. In addition to the semiconductor chip limitations, we are continuing to see supply chain constraints for other components used in our products. As a result of the semiconductor chip shortages, we temporarily suspended manufacturing operations at our Texas and California locations from January 3, 2022 to February 7, 2022 and Foxconn, our Czech Republic-based OEM, suspended manufacturing due to the same supply constraints from January 3, 2022 to February 9, 2022. While we were able to resume manufacturing operations at all locations, we are still seeing challenges in terms of availability of supply and we believe the supply shortage continues to represent an increased risk to the business in the remainder of 2022, and we may suspend manufacturing again in the future due to these shortages. As a result, in the interim we expect to be supply constrained and unable to meet all customer demand for our products. This may mean that some of our customers may seek other sources of products if we cannot meet their demand.

The FDA has released guidance that requires manufacturers of certain medical devices, including ventilation-related products under product code CAW, among others, to notify FDA of a permanent discontinuance or interruption in manufacturing of an applicable device under Section 506J of the Federal Food, Drug, and Cosmetic Act during the COVID-19 PHE. To the extent we experience an interruption in our manufacturing during the COVID-19 PHE that falls within the scope of this guidance, we would be required to notify FDA. This and other regulatory requirements could increase the cost of our operations and compliance.

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 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.

The ongoing conflict between Russia and Ukraine, and implications of supply chain challenges, may adversely affect our business and results of operations. It is not possible to predict the implications of this conflict, which could also include but are not limited to further sanctions, uncertainty about economic and political stability, increases in inflation rate and energy prices, increased threat of cyberattacks, supply shortages, and adverse effects on currency exchange rates and financial markets. We are continuing to monitor the situation in Ukraine and globally as well as assess its potential impact on our business. A significant escalation or further expansion of the conflict's current scope or related disruptions to the supply chain could have a material adverse effect on our business, financial condition, and results of operations.

If we are unable to continue to enhance our existing products, develop or acquire and market our 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, acquire companies with new or different products, sell our existing products, and develop new innovative products ourselves. Product development requires significant financial, technological and other resources. While we expended $5.4 million and $4.0 million for the three months ended March 31, 2022 and March 31, 2021, 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. We also plan to incorporate the TAV technology acquired from the New Aera acquisition directly into our oxygen concentrators, with minimal expected sales of the TAV product in its current configuration.

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 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, 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 pandemic and related 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, total business-to-business demand declined in the second quarter of 2020 continuing through the first quarter of 2021 due to physician offices limiting patient interactions for COPD patient referrals, HME providers minimizing patient interactions in response to the COVID-19 pandemic and related PHE which includes replacing existing oxygen patient setups with POCs and temporary reduced operating capacity of certain respiratory assessment centers and continued delays in certain European markets due to the COVID-19 pandemic and related PHE. While it is not possible at this time to estimate the overall impact that the COVID-19 pandemic and related PHE could have on our business, the continued 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 affected 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, new variants of COVID-19 could prove to be deadlier or more transmittable, or the developed vaccines may be ineffective versus these new variants, which could negatively impact our business and financial results.

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 allowed 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 pandemic and related 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 and related PHE. 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 pandemic and related PHE continues to rapidly evolve. The COVID-19 pandemic and related PHE has already adversely affected 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 pandemic and related PHE subsides. While the extent of the impact of the COVID-19 pandemic and related 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 pandemic and related 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 enactment of the CARES Act and related legislation, there is still a high degree of uncertainty surrounding their implementation, and the COVID-19 pandemic and related 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 pandemic and related PHE and government responses to the pandemic on our business, results of operations, financial condition and cash flows.

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 batteries are sourced from a single source supplier, and sub-components of the battery are also sourced from single source suppliers. While our printed circuit boards are sourced from dual sources, the sub-components of these boards are sourced from single source suppliers. We are experiencing limited availability of certain semiconductor chip components for our Inogen One portable oxygen concentrators in both its batteries and printed circuit boards, and we do not have long-term supply contracts that would guarantee our supply during these periods of higher demand and lower availability of these sub-components. This has led to orders not being filled in a timely manner and a temporary production halt in the first quarter of 2022 and is expected to lead to increased costs for components and limited supply availability through the remainder of 2022 and into the first quarter of 2023. Therefore, we expect to be unable to fully meet customer demand for our products during the first quarter of 2022 and we expect these supply constraints to continue through the remainder of 2022 and into the first quarter of 2023. For additional discussion of potential risks related to our inability to source components of our products, 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 in some cases those components are available in only limited supplies from limited manufacturers or suppliers, and the partial or complete loss of one or more of these manufacturers or suppliers could cause significant production delays or stoppages, an inability to meet customer demand, substantial loss in revenue, and an adverse effect on our financial condition and results of operations.*"

We may also be affected by other supply limitations during the COVID-19 pandemic and related PHE that could affect 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 pandemic and related PHE, we may be required to change suppliers or, if we are unable to find alternative suppliers in a timely manner, we may be required to further slowdown or temporarily halt production which would adversely impact our business, financial condition and results of operations.

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. 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 8.1% as of March 31, 2022 and 9.8% as of March 31, 2021. 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, 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.
- 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. The Coronavirus Preparedness and Response Supplemental Appropriations Act (H.R. 6074) also granted HHS the authority to waive certain requirements with respect to telehealth services. 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 was 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.
- In May 2020, Congress eliminated the 2% Medicare sequestration payment reduction that applies to all Medicare providers and suppliers, due to the COVID-19 PHE, and Congress extended it until March 31, 2022. The sequestration payment reduction resumed with a 1% reduction to rates from April 1, 2022 until June 30, 2022, with the full 2% Medicare sequestration resuming on July 1, 2022 and continuing through September 30, 2030.
- In addition, the CARES Act established a provider relief fund of $100 billion 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, CMS issued an Interim Final Rule (IFR) in the Federal Register for policy and regulatory revisions in response to the COVID-19 PHE. 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 Trump administration also issued a number of regulatory waivers to increase the flexibility in durable medical equipment, prosthetics, orthotics and supplies (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 for dates of services within the 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 suspended medical review of claims. 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. In August 2020, CMS resumed medical review of claims and the prior authorization program for certain DMEPOS.
- CMS also issued a final rule in December 2021 (CMS-1738-P) to establish payment amounts that will be effective after the COVID-19 PHE for DMEPOS products and services covered under Medicare. We believe that Medicare rates will not change for the length of the COVID-19 PHE, except for any net change for inflation and sequestration, as outlined above.

  CMS established three different fee schedule adjustment methodologies for non-CBAs after the termination of the COVID-19 PHE: (1) for non-contiguous non-CBAs; (2) for contiguous non-CBAs defined as rural areas; and (3) for non-rural non-CBAs within the contiguous United States. Payment methodologies (1) and (2) contemplate utilizing the 50/50 blended rates as a permanent construct, but payment methodology (3) contemplates setting the fee schedule amounts to 100% of the Medicare rates that are based upon (former) competitive bid rates. This will reduce Medicare rates after the PHE is over in the current areas that are considered non-rural but not covered by a former CBA, as those areas are currently receiving a 75/25 blended reimbursement rate.
- In January 2021, CMS announced, for informational purposes only, the payment amounts that would have been effective for the competitive bidding round 2021 as part of its effort to increase transparency into the DMEPOS Competitive Bidding Program. As a reminder, the bids for oxygen were based on the HCPCS code E1390, which is for stationary oxygen, and there were 130 regions bid. The simple average of the 2018 payment amounts for these regions for this code was $73.98. The simple average of the payment amounts for these regions for this code was $122.61, or an average increase of 65.7%. If CMS were to have implemented these rate changes, the simple average payment amounts in these regions for POCs (codes E1390 and E1392) would have been $157.60, which is significantly higher than the simple average payment amounts of $110.07 and $121.07 per month being paid as of January 1, 2021 and April 1, 2021 for these regions.
- In September 2021, CMS published a Decision Memo which revised the Home Use of Oxygen national coverage determination and removed the national coverage determination for Home Oxygen Use to Treat Cluster Headaches. This will allow the Medicare Administrative Contractors to make coverage determinations regarding the use of home oxygen and oxygen equipment for cluster headaches. CMS also expanded patient access to oxygen and oxygen equipment in the home by allowing oxygen use for acute or short-term needs instead of limiting coverage to chronic hypoxemia, removed the requirements for alternative treatment measures before dispensing of oxygen therapy, and removed the limited list of conditions for which oxygen may be covered to respiratory-related diseases, to allow the physician flexibility to make that determination. In addition, CMS defined exercise more broadly to include functional performance of the patient and allow more flexibility on pulse oximetry readings to account for differences in skin pigmentation. Lastly, CMS reduced provider burden by removing the oxygen certificate of medical necessity requirement. We believe these changes will expand coverage for patients who would benefit from oxygen therapy, reduce administrative burdens, and give more decision-making authority on proper patient care to the physicians. CMS has announced that the implementation date for the revised national coverage determination will be June 14, 2022. However, we do not yet have visibility on the details of how the Medicare Administrative Contractors will change their coverage determinations.

These legislative provisions 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 that states 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.

The competitive bidding process or other reimbursement policy changes under Medicare or other third-party payors 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.

We rely significantly on reimbursement from Medicare and private payors, including Medicare Advantage plans, Medicaid and patients for our rental revenue. For the three months ended March 31, 2022 and March 31, 2021, approximately 79.0% and 83.9%, 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 Healthcare Common Procedure Coding System (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 former competitive bidding areas (CBAs) in the prior five years are outlined in the table below for E1390 and E1392, which are the two primary codes that we bill to Medicare and other payors for our oxygen product rentals. These rates are typically updated annually each January as they are subject to Consumer Price Index (CPI) and sequestration adjustments, but can also be subject to adjustments during the year due to legislative rulings. Competitive bidding contracts were scheduled to go into effect on January 1, 2021; however, on October 27, 2020, CMS announced that competitive bidding contracts would not be awarded for most product categories, including oxygen, due to the payment amounts not achieving the expected savings and the current COVID-19 pandemic and related PHE. Effective April 1, 2021, rates were adjusted to remove a percentage reduction that was put in place to meet the budget neutrality requirement previously mandated by section 1834(a)(9)(D)(ii) of the Social Security Act. See the table below for average Medicare rates in former CBAs, using a simple average of rates in each CBA.

Average Medicare reimbursement rates in former CBAs	**E1390**	**E1392**
As of January 1, 2022	$ 85.31	$ 41.81
As of April 1, 2021	$ 81.25	$ 39.82
As of January 1, 2021	$ 73.88	$ 36.20
As of January 1, 2020	$ 73.98	$ 36.25
As of January 1, 2019	$ 72.92	$ 35.72
As of January 1, 2018	$ 77.03	$ 36.06

CMS also issued a final rule in December 2021 (CMS-1738-P) to establish payment methodologies that will be effective after the COVID-19 PHE for DMEPOS products and services covered under Medicare. We believe that Medicare rates will not change for the length of the PHE, except for inflation and sequestration adjustments that typically occur annually each January but have not yet been announced.

CMS established three different fee schedule adjustment methodologies for non-CBAs after the termination of the COVID-19 PHE: (1) for non-contiguous non-CBAs; (2) for contiguous non-CBAs defined as rural areas; and (3) for non-rural non-CBAs within the contiguous United States. The final payment methodology sets the fee schedule amounts to 100% of the Medicare rates in all non-rural areas. This will reduce Medicare rates after the PHE is over in the current areas that are considered non-rural but not covered by a former CBA, as those areas are currently receiving a 75/25 blended reimbursement rate.

In January 2021, CMS announced what would have been the payment amounts for the competitive bidding round 2021. As a reminder, the bids for oxygen were based on the HCPCS code E1390, which is for stationary oxygen, and there were 130 regions bid. The simple average of the 2018 single payment amounts for these regions for this code was $73.98. The simple average of the payment amounts for these regions for this code was $122.61, or an average increase of 65.7%. If CMS were to have implemented these rate changes, the average payment amounts in these regions for POCS (codes E1390 and E1392) would have been $157.60, which is significantly higher than the $110.07 per month being paid as of January 1, 2021.

Medicare payment rates are based upon whether the beneficiary resides in a (former) CBA, or in a rural or non-rural non-CBA, or in non-contiguous states. Non-CBA payment rates are based on regional pricing, that are derived from former competitive bidding payment rates. In rural areas and non-contiguous states, payment rates are based on a higher 50-50 blended rate, to account for higher servicing costs in those areas. We estimate that approximately 18% of our patients are eligible to receive the higher reimbursement rates based on the geographic locations of our current patient population. Effective March 1, 2021, CMS announced that the rates as of January 1, 2021 were incorrectly calculated, and retroactively adjusted the rates, which are reflected in the table below. The Medicare rates announced previously were a simple average of $136.24 for HCPCS code E1390 and $44.69 for HCPCS code E1392, which were increased to $136.84 and $44.99, respectively. Effective April 1, 2021, rates were adjusted to remove a percentage reduction that was put in place to meet the budget neutrality requirement previously mandated by section 1834(a)(9)(D)(ii) of the Social Security Act. See the table below for average Medicare rates in rural areas, using a simple average of rates in each state.

Average Medicare reimbursement rates in rural areas	E1390	E1392
As of January 1, 2022	$ 151.15	$ 48.39
As of April 1, 2021	$ 143.48	$ 47.13
As of January 1, 2021 (retroactively revised March 1, 2021)	$ 136.84	$ 44.99
As of January 1, 2020	$ 136.71	$ 44.93
As of January 1, 2019	$ 134.71	$ 44.32
As of January 1, 2018	$ 76.31	$ 41.91

Rates in non-former CBAs that are not defined as rural are set based on the rates in former CBAs. See the table below for average Medicare rates in these non-former CBAs, non-rural areas, using a simple average of rates in each state. These rates are typically updated annually each January as they are subject to the Consumer Price Index (CPI) and sequestration adjustments, but are also subject to adjustments during the year due to legislative rulings. Effective April 1, 2021, rates were adjusted to remove a percentage reduction that was put in place to meet the budget neutrality requirement previously mandated by section 1834(a)(9)(D)(ii) of the Social Security Act. Note that the 2021 rates listed below include CARES Act increased rates due to the COVID-19 PHE, which may not be in place for all of 2022. Once the Administration ends the COVID-19 PHE, the rates in these non-former CBAs, non-rural areas are expected to adjust down to the former CBA rates listed in the table above.

Average Medicare reimbursement rates in non-former CBAs, non-rural areas	E1390	E1392
As of January 1, 2022	$ 115.14	$ 43.69
As of April 1, 2021	$ 109.39	$ 42.12
As of January 1, 2021 (retroactively revised March 1, 2021)	$ 104.07	$ 40.06
As of January 1, 2020	$ 74.84	$ 36.87
As of January 1, 2019	$ 72.32	$ 35.64
As of January 1, 2018	$ 69.31	$ 38.10

CMS is required to conduct future rounds of competitive bidding, which could reduce reimbursement rates, negatively impact the premium for POCs over other oxygen modalities, or limit beneficiary access to our technologies. 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. 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, 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 12.8% of our total revenue in the three months ended March 31, 2022 and 9.5% in the three months ended March 31, 2021.

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 March 31, 2022 and March 31, 2021. Our capped patients as a percentage of total patients on service was approximately8.1% as of March 31, 2022 and 9.8% as of March 31, 2021. 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 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, and we can deploy used assets in working order as long as the prescription requirements are met. We must also procure a renewal 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.

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.

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 substantially changed healthcare financing by both governmental and private insurers, and significantly impacts 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 sequestration 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 and subsequent federal laws had paused the 2% Medicare sequestration reduction for claims dated from May 1, 2020 through March 31, 2022. On April 1, 2022, and expected through June 30, 2022, there has been a 1% sequestration reduction, and the full 2% sequestration reduction is expected to resume on July 1, 2022 and continue through September 30, 2030. We expect that additional state and federal healthcare policy 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 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 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 March 31, 2022 and March 31, 2021, approximately 16.2% and 11.3%, 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 which would 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 Plano, 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 pandemic and related 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 pandemic and related 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 and for repair services for these products. Since 2018, our contract manufacturer has produced the vast majority of the concentrators required to support our European demand and we expect this to continue in 2022 and 2023. 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 pandemic and related 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 33% 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 plan to hire additional inside sales representatives at a more controlled pace across all three facilities to expand sales capacityIn 2022, we expect hiring will continue to be challenging and do not expect to increase our inside sales forceand instead expect to offset attrition with replacement hiring. 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, and to the extent they are not effective, it may negatively affect our financial condition and results of operations.

In addition, we plan to hire additional sales representatives in our prescriber sales organization, primarily through Ashfield, our contract sales organization, to enhance our go-to-market capabilities in the U.S. The employment market is very challenging and there is no guarantee that they, or we, will be able to hire all of the required employees to our prescriber sales organization in the future or retain existing staff. Additionally, Ashfield will provide access to its best-in-class data-driven sales management disciplines, proprietary prescriber insights, and analytics to support our growth strategy and drive performance in the clinician sales channel. While we believe that our investments in the prescriber sales organization will enhance our growth in direct-to-consumer sales and rental revenue, it will take time for these sales representatives to be fully trained and ramped up to full productivity, and it will take time for the sales tools to be implemented across our existing prescriber sales representatives. To the extent that the sales tools being implemented, or the sales representatives hired either through us or Ashfield are not effective or our relationship with Ashfield was to terminate, or the number of sales representatives does not reach the number anticipated, it may negatively affect our future growth and results of operations.

We also have experienced increased demand for our products in various markets associated with rising rates of COVID-19, since physicians may prescribe supplemental oxygen as a treatment for COVID-19. As a result, in these periods we 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 Plano, Texas and Goleta, California, which commenced 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 and perform product repairs, is expected to be sufficient to meet our manufacturing needs provided that these facilities remain operational. However, 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 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 completed our integration process. We made certain assumptions relating to the New Aera acquisition, which assumptions may have been inaccurate, including the failure to realize the expected benefits of the acquisition, failure to realize expected revenue, higher than expected operating costs, and general economic and business conditions that adversely affect the combined company following the acquisition. After integration of New Aera, and partially as a result of the negative litigation outcome in our case against the Department of Health and Human Services, we believe that our assumptions regarding New Aera will not be fully realized. We believe that there are still many risks associated with the TAV product, including whether we will be able to successfully incorporate TAV into our existing products, what sort of competition there may be for the TAV product, if and when implemented, and the other risks identified in this Quarterly Report on Form 10-Q.

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, three single customers each represented more than 10% of our net accounts receivable balance with accounts receivable balances of $5.8 million, $4.3 million and $3.7 million, respectively, as of March 31, 2022, and one single customer with an accounts receivable balance of $5.9 million as of December 31, 2021. Challenging economic conditions, including those associated with the COVID-19 pandemic and related 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 pandemic and related 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 three months ended March 31, 2022 and March 31, 2021, approximately 34.8% and 18.1%, 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.

A portion 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 three months ended March 31, 2022 and March 31, 2021, we experienced net foreign currency losses of $0.4 million and $0.3 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, 2021. Additional information on our hedging arrangements is also contained in Note 3 – Fair value measurements and Item 3 – Quantitative and Qualitative Disclosures About Market Risk in the notes in our consolidated financial statements in the Annual Report on Form 10-K.

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 pandemic and related 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. The war in Ukraine has adversely affected some shipping pathways and we anticipate that this conflict will result in further disruptions to our supply chain and shipping channels

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 fifty-nine 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 we face the risk that individual actions 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 be set, in part, to federal and state government budgetary constraints. As a result, with respect to Medicare and Medicaid related revenue, we may not be able to offset the effects of general inflation on our operating costs through increases in prices for our products, as these inflation adjustments are subject to annual approval outside of our control. 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, which we experienced in 2021 as the labor market has tightened and there is increased competition for certain roles. As a result, increases in our operating costs including personnel-related costs 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. Our President and Chief Executive Officer, Nabil Shabshab, joined us in February 2021, our Executive Vice President, Chief Commercial Officer, George Parr, joined us in April 2021, our Executive Vice President, Chief Technology Officer, Stanislav Glezer, joined us in June 2021, our Executive Vice President, General Counsel, Jason Somer, joined us in July 2021, and our Executive Vice President, Chief Financial Officer, Kristin Caltrider, joined us in March 2022.

If experienced employees leave, we could experience inefficiencies or a lack of business continuity due to loss of historical knowledge and a lack of familiarity of the new employees with business processes, operating requirements, policies and procedures. It is important to our success that these key employees quickly adapt to and excel in their new roles. If they are unable to do so, our business and financial results could be materially adversely affected. In addition, 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 have experienced increased turnover at all levels since the start of the COVID-19 pandemic and general labor shortages in various areas of our business, all of which could have a material adverse impact on our business. We may need to increase employee wages and benefits in order to attract and retain the personnel necessary to achieve our goals, and our business, operations, and financial results may suffer if we are unable to do so. 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, cybersecurity risks and data security incidents, or other information technology failures in the future.

Due to the COVID-19 pandemic and related PHE, we have an increased number of employees working remotely. As a result, we may have increased cybersecurity or 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 cybersecurity 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 General Data Protection Regulation (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 us 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) and in 2021, Virginia passed the Consumer Data Protection Act (CDPA), 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 and CDPA 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.

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.

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

Our projections regarding (i) the size of the oxygen therapy market, both in the United States and internationally, (ii) the size and percentage of the long-term oxygen therapy market that is subject to competitive bidding in the United States, (iii) the number of oxygen therapy patients, (iv) the number of patients requiring ambulatory and stationary oxygen, (v) the number of patients who rely on the delivery model, (vi) the percentage of the long-term oxygen therapy market 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, and (ix) the impact of the COVID-19 pandemic and related PHE on our business and our markets generally are based on estimates that we believe are reliable. These estimates may prove to be incorrect, new data or studies may change the estimated incidence or prevalence of patients requiring long-term oxygen therapy, or the type of long-term oxygen therapy patients. The COVID-19 pandemic and related PHE 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 or change in U.S. tax laws 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 of concentrators and accessories may be subject to sales and use tax in certain other states, but that there are exemptions from sales and use tax in most states. 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 recognize the benefits of deferred tax assets is dependent on future cash flows and taxable income.

We recognize the expected future tax benefit from deferred tax assets when the tax benefit is considered to be more likely than not of being realized; otherwise, a valuation allowance is applied against deferred tax assets. Assessing the recoverability of deferred tax assets requires management to make significant estimates related to expectations of future taxable income. Estimates of future taxable income are based on forecasted cash flows from operations and the application of existing tax laws in each jurisdiction. To the extent that future cash flows and taxable income differ significantly from estimates, our ability to realize the deferred tax assets could be impacted. In the future, our estimates could change requiring a valuation allowance or impairment of our deferred tax assets. Additionally, future changes in tax laws could limit our ability to obtain the future tax benefits represented by our deferred tax assets. See Note 7 – Income taxes in the condensed notes of our consolidated financial statements in this Quarterly Report on Form 10-Q for additional information and factors that could impact the Company's ability to realize the deferred tax assets.

The adoption and interpretation of new tax legislation, tax rulings, or exposure to additional tax liabilities, could materially affect our financial condition, results of operations, and cash flows.

We are subject to income and other taxes in the U.S. and other foreign jurisdictions in which we do business. As a result, our provision for income taxes is derived from a combination of applicable tax rates in the various places we operate. Significant judgment is required for calculating our income tax provision.

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. The new Administration and Congress could make changes to existing tax law, including an increase in the corporate tax rate or the tax rate on foreign earnings. 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. Changes to existing tax law in the U.S. or other foreign jurisdictions could adversely affect our 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% sequestration reduction in Medicare payments, 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 paused the 2% Medicare sequestration reduction for claims dated from May 1, 2020 through December 31, 2020 and the CARES Act also extends the end date of the Medicare sequestration reduction by one year, through 2030, in order to offset the 2020 suspension. The Consolidated Appropriations Act of 2021 was signed into law on December 27, 2020 and extended the suspension period to March 31, 2021. U.S. House of Representatives bill H.R. 1868 was signed into law on April 14, 2021 and extended the suspension period to December 31, 2021, but increased the fiscal year 2030 sequestration cuts. In December 2021 through the Protecting Medicare and American Farmers from Sequester Cuts Act, the 2% Medicare sequestration benefit that was set to expire December 31, 2021 was extended until March 31, 2022. The sequestration then resumed with a 1% reduction to rates from April 1, 2022 until June 30, 2022, with the full 2% Medicare sequestration resuming starting July 1, 2022 and continuing through September 30, 2030. Once the sequestration reduction is reinstated, 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" and that have an average purchase fee of $1,000 or greater, or an average rental fee schedule of $100 or greater. 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 (code E1390) was included on the master list, but was later removed. On April 22, 2019, stationary oxygen (E1390) was again added to the list of potential codes that could be subject to PA. On November 8, 2019, CMS revised the criteria for inclusion on the master list and added 212 DMEPOS items, including portable oxygen concentrators (E1392), to the master list. 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 selects 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. 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.

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 practice 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 laws or 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 and such approvals may be revoked or revised if an agency like the FDA believes it necessary.

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, 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, depending on the specific action, could cause the majority of our sales to decline or cease altogether. 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. We plan to make similar determinations regarding modifications to our 510(k) products, which may include the redesign of the Inogen One G5 system motherboard pending validation testing. If the FDA disagrees with our determinations 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 penalties or fines.

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 commercialize 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 34.8% and 18.1% of our total revenue was from sales outside of the United States for the three months ended March 31, 2022 and March 31, 2021, respectively. We have sold our products in a total of 59 international countries and overseas regions outside of the United States through our wholly owned subsidiary, distributors and 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 European 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 had a three-year implementation period, with full application of the regulation occurring in May 2021 and replacing the pre-existing directives on medical devices in the European Union. Since May 2021, medical devices marketed in the European Union require certification according to these new requirements, except those devices with valid CE Marks, issued pursuant to the Medical Device Directive before May 2021, including our oxygen therapy products with CE Marks issued under the Medical Device Directive (MDD), may be placed on the market until May 2024. Only medical devices that comply with certain conformity requirements of the Medical Device Directive are currently allowed to be marketed within the European Union and our products will be required to comply with the European Medical Device Regulation (MDR). New products that failed to be certified with the MDR by May 2021 may not be marketed or sold in the European Union. Similarly, existing products with CE Marks issued under the MDD may not be placed on the market in the European Union after May 2024. The extension of the existing certificates under the MDD or obtaining a new certificate under the MDR is required for continued marketing in the European Union after May 18, 2022. Inogen products are commercialized in the European Union and United Kingdom under MDD certificates, expiring on May 18, 2022. The extension of the existing certificates under the MDD or obtaining a new certificate under the European MDR is required for continued marketing in the European Union after May 18, 2022. Our EU MDR Generic Device Group submission has been filed for our POCs and is under review. In addition, United Kingdom Conformity Assessed has been filed and accepted. The Swiss Medic Submissions has been filed and awaiting final steps. Derogation requests have also been filed in Germany, France, Spain, Italy, Belgium and Netherlands. Additional requests are in the process of preparation. Due to the expected reduced availability of products in Europe in the second quarter and second half of 2022 due to the delay in MDR approval, we will place intentional focus on fulfilling European orders in our international business-to-business sales channel until May 18, 2022 when the MDR certificate expires

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.

If the FDA disagrees with us that certain of our data collection and analysis methods do not constitute clinical trials, our business may be harmed.

We gather and analyze certain de-identified retrospective patient data as part of our product development and improvement. We believe that these data collection methods do not constitute clinical trials and, therefore, typically do not pursue or obtain regulatory permission from the FDA or institutional review boards (IRBs) before collecting or analyzing such data. If the FDA disagrees with our interpretation, we may be subject to regulatory enforcement including warning letters, fines, injunctions, consent decrees and civil penalties. In addition, we may be required to collect these types of data under the clinical trial regulatory framework.

Clinical development is a long, expensive, and uncertain process and is subject to delays and the risk that products may ultimately prove unsafe or ineffective in treating the indications for which they are designed. Completion of clinical trials may take several years or more. We may experience numerous unforeseen events in relation to a clinical trial process that could delay or prevent us from receiving regulatory clearance or approval for new products or modifications of existing products, including new indications for existing products, including:

- delays or failure in obtaining approval of our clinical trial protocols from the FDA, other regulatory authorities, or IRBs;

- we, the applicable IRBs, the Data Safety Monitoring Board for such trial, or the FDA or other applicable regulatory authorities may require that we or our investigators suspend or terminate our data collection for various reasons, including, among others (i) failure to conduct the clinical trial in accordance with regulatory requirements, including the FDA's current Good Clinical Practice (GCP), regulations, or our clinical protocols, (ii) by the FDA or other applicable regulatory authority resulting in the imposition of a clinical hold, or (iii) lack of adequate patient informed consent; and
- delays if the FDA concludes that our financial relationships with our data collection partners result in a perceived or actual conflict of interest that may have affected the interpretation or integrity of the data collected. If these relationships and any related compensation to or ownership interest by our data collection partners carrying out the study result in perceived or actual conflicts of interest, or if the FDA concludes that the financial relationship may have affected interpretation of the data, the integrity of the data collected or analyzed may be questioned and the utility of the data itself may be jeopardized, which could result in the delay or rejection by the FDA. Any such delay or rejection could prevent us from commercializing any of our products currently in development.

Any delays in completing our data collection and analysis will increase our costs, slow down our product development and regulatory authorization process and jeopardize our ability to commence sales and generate associated revenue with respect to the applicable product. Any of these occurrences may significantly harm our business, financial condition, results of operations and prospects.

We are subject to 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 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 Unified 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.

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. Changes and updates to HIPAA transaction standards 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 of the physician) 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 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 that 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 can be comparable to those under their federal equivalents.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation 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 Promotes 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 $0.19 million per year (and up to an aggregate of $1.265 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 may 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 $0.022 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 March 17, 2022 sets forth adjusted civil monetary penalty amounts that apply to penalties assessed on or after March 17, 2022, 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 have sold our products in a total of 59 international countries and overseas regions 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 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 March 31, 2022, we have twenty-seven pending U.S. and international patent applications, forty-seven issued U.S. patents, and nineteen issued foreign patents relating to the design and construction of our oxygen concentrators, our intelligent delivery technology and our TAV product, 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, or challenges to inventorship in court. Foreign patents may be subject to opposition or comparable proceedings in the corresponding foreign patent offices and courts. 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, inventorship, 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. 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. While we settled our lawsuit with Breathe in January 2021, 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 a pending application for “Inogen” with the United States Patent and Trademark Office. We own trademark registrations for the mark “Inogen” in Argentina, Australia, Canada, Chile, China, Columbia, Ecuador, South Korea, Mexico, Europe (European Union registration), the United Kingdom, Iceland, India, Israel, Japan, Kuwait, New Zealand, Norway, Paraguay, Peru, Turkey, Singapore, Switzerland, and Uruguay. We own pending applications for the mark “Inogen” in Brazil, India, Malaysia, and South Africa. 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, Europe (European Union registration), and the United Kingdom. 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) and the United Kingdom. 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 a trademark application for the Inogen design in Bolivia. We own a trademark registration for the Inogen design in China. We own a trademark registration 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 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. While we settled our lawsuit with Breathe, 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 $3.0 million and $5.0 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 market;
- reimbursement or legislative changes in the oxygen therapy market;

- failure to complete significant sales;
- manufacturing disruptions that could occur if we were unable to successfully expand our production in our current or an alternative facility 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.

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

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

As of March 31, 2022, 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 53.3% 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 Chairperson 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 ended March 31, 2022 and March 31, 2021.

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(1)	Employment and Severance Agreement by and between the Company and Kristin A. Caltrider, effective March 21, 2022	8-K	10.1	03/04/22
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(2)	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(2)	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) Indicates a management contract or compensatory plan.

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

SIGNATURES

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

INOGEN, INC.

Dated: May 5, 2022

By: /s/ Nabil Shabshab
Nabil Shabshab
Chief Executive Officer
President
Director
(Principal Executive Officer)

Dated: May 5, 2022

By: /s/ Kristin Caltrider
Kristin Caltrider
Executive Vice President,
Chief Financial Officer
Treasurer
(Principal Financial and Accounting Officer)

Exhibit 31.1

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

I, Nabil Shabshab, 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: May 5, 2022

By: /s/ Nabil Shabshab
Nabil Shabshab
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, Kristin Caltrider, 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: May 5, 2022

By: /s/ Kristin Caltrider
Kristin Caltrider
Chief Financial Officer
Executive Vice President
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, Nabil Shabshab, 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 March 31, 2022 (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.

May 5, 2022

By: /s/ Nabil Shabshab
Nabil Shabshab
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, Kristin Caltrider, 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 March 31, 2022 (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.

May 5, 2022

By: /s/ Kristin Caltrider
Kristin Caltrider
Chief Financial Officer
Executive Vice President
Treasurer