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

FORM 10-Q

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

For the quarterly period ended June 30, 2024
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: 001-39562

PULMONX CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**77-0424412**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**

700 Chesapeake Drive
Redwood City, California 94063
1-650-364-0400
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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 per share	LUNG	The Nasdaq Stock Market LLC

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 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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

As of July 31, 2024 there were 39,152,553 shares of the Registrant's Common Stock, par value $0.001 per share, outstanding.

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FORWARD-LOOKING STATEMENTS

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, and Section 21E of the Securities Exchange Act of 1934, as amended, about us and our industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q, including statements regarding our future results of operations and financial condition, business strategy, plans, and objectives of management for future operations and statements that are necessarily dependent upon future events are forward-looking statements. In some cases, you can identify forward-looking statements by words such as "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "anticipate," "project," "target," "design," "estimate," "predict," "potential," "plan" or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words.

We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy, and financial needs. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q and are subject to a number of known and unknown risks, uncertainties, and assumptions, including risks described in the section entitled "Risk Factors." These risks are not exhaustive. Other sections of this Quarterly Report on Form 10-Q include additional factors that could harm our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time, and it is not possible for our management to predict all risk factors 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 from those contained in, or implied by, any forward-looking statements.

You should not rely on these forward-looking statements as predictions of future events. We cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance, or achievements. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason after the date of this Quarterly Report on Form 10-Q or to conform these statements to actual results or to changes in our expectations, whether as a result of any new information, future events, changed circumstances or otherwise. Forward-looking statements contained in this Quarterly Report on Form 10-Q include, but are not limited to, statements about:

- our ability to design, develop, manufacture and market innovative products to treat patients with challenging medical conditions, particularly those with severe chronic obstructive pulmonary disease ("COPD") and emphysema;
- our expected future growth, including growth in international sales;
- our expected future growth of our sales and marketing organization;
- the size and growth potential of the markets for our products, and our ability to serve those markets;
- the rate and degree of market acceptance of our products;
- coverage and reimbursement for procedures performed using our products;
- the performance of third parties in connection with the development of our products, including third-party suppliers;
- regulatory developments in the United States and foreign countries;
- our ability to obtain and maintain regulatory approval or clearance of our products on expected timelines;

- our plans to research, develop and commercialize our products and any other approved or cleared product;
- our ability to retain and hire our senior management and other highly qualified personnel;
- the development, regulatory approval, efficacy and commercialization of competing products and technologies in our industry;
- our ability to develop and maintain our corporate infrastructure, including an effective system of internal controls;
- our financial performance and capital requirements;
- our expectations regarding our ability to obtain and maintain intellectual property protection for our products, as well as our ability to operate our business without infringing the intellectual property rights of others; and
- our expectations regarding the impact of any public health crises, such as COVID-19, on our business, financial condition and results of operations.

You should read this Quarterly Report on Form 10-Q and the documents that we reference in this Quarterly Report on Form 10-Q and have filed as exhibits to this report with the understanding that our actual future results, levels of activity, performance and achievements may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

All brand names or trademarks appearing in this Quarterly Report on Form 10-Q are the property of their respective holders. Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q to "Pulmonx" the "Company," "we," "us," and "our" refer to Pulmonx Corporation.

Part I. Financial Information

Item 1. Financial Statements

Pulmonx Corporation

Condensed Consolidated Balance Sheets

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

	June 30, 2024	December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	$ 63,464	$ 83,547
Restricted cash	257	237
Short-term marketable securities	51,081	33,555
Accounts receivable, net	11,080	12,105
Inventory	16,980	16,743
Prepaid expenses and other current assets	3,297	4,235
Total current assets	146,159	150,422
Long-term marketable securities	—	14,390
Long-term inventory	2,300	2,580
Property and equipment, net	2,830	4,028
Goodwill	2,333	2,333
Intangible assets, net	—	31
Right of use assets	18,490	3,406
Other long-term assets	515	591
Total assets	$ 172,627	$ 177,781
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 3,181	$ 1,497
Accrued liabilities	11,783	16,234
Income taxes payable	66	93
Deferred revenue	107	104
Short-term debt	93	2,155
Current lease liabilities	1,071	3,074
Total current liabilities	16,301	23,157
Deferred tax liability	118	114
Long-term lease liabilities	17,914	1,106
Long-term debt	37,110	35,089
Total liabilities	71,443	59,466
Commitments and contingencies (Note 8)		

Stockholders' equity		
Preferred stock, $0.001 par value, 10,000,000 shares authorized; no shares issued and outstanding as of June 30, 2024 and December 31, 2023	—	—
Common stock, $0.001 par value, 200,000,000 shares authorized as of June 30, 2024 and December 31, 2023; 39,151,861 shares issued and outstanding as of June 30, 2024 and 38,516,383 shares issued and outstanding as of December 31, 2023	39	39
Additional paid-in capital	539,408	526,797
Accumulated other comprehensive income	1,973	2,640
Accumulated deficit	(440,236)	(411,161)
Total stockholders' equity	101,184	118,315
Total liabilities and stockholders' equity	$ 172,627	$ 177,781

The accompanying notes are an integral part of these unaudited interim condensed consolidated financial statements.

Pulmonx Corporation

Condensed Consolidated Statements of Operations and Comprehensive Loss

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenue	$ 20,783	$ 17,194	$ 39,637	$ 31,729
Cost of goods sold	5,476	4,460	10,252	8,406
Gross profit	15,307	12,734	29,385	23,323
Operating expenses				
Research and development	5,615	5,710	9,825	9,963
Selling, general and administrative	25,314	23,463	49,718	46,199
Total operating expenses	30,929	29,173	59,543	56,162
Loss from operations	(15,622)	(16,439)	(30,158)	(32,839)
Interest income	1,306	1,410	2,747	2,537
Interest expense	(891)	(864)	(1,774)	(1,435)
Other (expense) income, net	(35)	(162)	380	(54)
Net loss before tax	(15,242)	(16,055)	(28,805)	(31,791)
Income tax expense	84	140	270	264
Net loss	(15,326)	(16,195)	(29,075)	(32,055)
Other comprehensive income (loss)				
Currency translation adjustment	40	170	(509)	242
Change in unrealized (losses) gains on marketable securities	(30)	(34)	(158)	139
Total other comprehensive income (loss)	10	136	(667)	381
Comprehensive loss	$ (15,316)	$ (16,059)	$ (29,742)	$ (31,674)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.39)	$ (0.43)	$ (0.75)	$ (0.85)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	38,943,066	37,818,256	38,789,548	37,696,001

The accompanying notes are an integral part of these unaudited interim condensed consolidated financial statements.

Pulmonx Corporation

Condensed Consolidated Statements of Stockholders' Equity

(in thousands, except share amounts)
(unaudited)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount				
Balances at January 1, 2024	38,516,383	$ 39	$ 526,797	$ 2,640	$ (411,161)	$ 118,315
Issuance of common stock upon vesting of restricted stock units	177,610	—	—	—	—	—
Issuance of common stock upon exercise of stock options	28,116	—	57	—	—	57
Issuance of shares pursuant to employee stock purchase plan	90,066	—	808	—	—	808
Stock-based compensation expense	—	—	5,744	—	—	5,744
Currency translation adjustment	—	—	—	(549)	—	(549)
Change in unrealized losses on marketable securities	—	—	—	(128)	—	(128)
Net loss	—	—	—	—	(13,749)	(13,749)
Balances at March 31, 2024	38,812,175	39	533,406	1,963	(424,910)	110,498
Issuance of common stock upon vesting of restricted stock units	328,336	—	—	—	—	—
Issuance of common stock upon exercise of stock options	11,350	—	22	—	—	22
Stock-based compensation expense	—	—	5,980	—	—	5,980
Currency translation adjustment	—	—	—	40	—	40
Change in unrealized losses on marketable securities	—	—	—	(30)	—	(30)
Net loss	—	—	—	—	(15,326)	(15,326)
Balances at June 30, 2024	39,151,861	$ 39	$ 539,408	$ 1,973	$ (440,236)	$ 101,184

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount				
Balances at January 1, 2023	37,555,565	$ 38	$ 502,712	$ 1,575	$ (350,318)	$ 154,007
Issuance of common stock upon vesting of restricted stock units	66,895	—	—	—	—	—
Issuance of common stock upon exercise of stock options	23,006	—	46	—	—	46
Issuance of shares pursuant to employee stock purchase plan	85,210	—	676	—	—	676
Change in shares subject to repurchase	—	—	56	—	—	56
Stock-based compensation expense	—	—	4,764	—	—	4,764
Currency translation adjustment	—	—	—	72	—	72
Change in unrealized gains on marketable securities	—	—	—	173	—	173
Net loss	—	—	—	—	(15,860)	(15,860)
Balances at March 31, 2023	37,730,676	38	508,254	1,820	(366,178)	143,934
Issuance of common stock upon vesting of restricted stock units	222,598	—	—	—	—	—
Issuance of common stock upon exercise of stock options	63,503	—	139	—	—	139
Change in shares subject to repurchase	—	—	47	—	—	47
Repurchase of early exercised common stock options	(106)	—	—	—	—	—
Stock-based compensation expense	—	—	5,891	—	—	5,891
Currency translation adjustment	—	—	—	170	—	170
Change in unrealized losses on marketable securities	—	—	—	(34)	—	(34)
Net loss	—	—	—	—	(16,195)	(16,195)
Balances at June 30, 2023	38,016,671	$ 38	$ 514,331	$ 1,956	$ (382,373)	$ 133,952

The accompanying notes are an integral part of these unaudited interim condensed consolidated financial statements.

Pulmonx Corporation

Condensed Consolidated Statements of Cash Flows

(in thousands)
(unaudited)

	Six Months Ended June 30,	
	2024	**2023**
Cash flows from operating activities		
Net loss	$ (29,075)	$ (32,055)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation expense	11,593	10,500
Loss on disposal of fixed assets	—	1
Impairment of capitalized software development costs	1,717	—
Change in allowance for credit losses	40	(1)
Inventory write-downs	284	380
Depreciation and amortization expense	823	846
Amortization of debt discount and debt issuance costs	30	22
Net accretion of discounts on marketable securities	(871)	(437)
Non-cash lease expense	1,211	1,324
Net changes in operating assets and liabilities:		
Accounts receivable	792	(184)
Inventory	(672)	(267)
Prepaid expenses and other current assets	622	25
Other assets	66	17
Accounts payable	1,630	350
Accrued liabilities	(4,246)	501
Income taxes payable	(22)	19
Lease liabilities	(1,492)	(1,550)
Deferred revenue	5	(26)
Net cash used in operating activities	(17,565)	(20,535)
Cash flows from investing activities		
Purchases of investments	(20,837)	(25,624)
Maturities of investments	18,415	25,500
Purchases of property and equipment and internal software development costs	(920)	(115)
Net cash used in investing activities	(3,342)	(239)
Cash flows from financing activities		
Proceeds from borrowing under term loan	—	20,000
Repayment of credit agreement	(46)	(47)
Proceeds from exercise of common stock options	80	183
Proceeds from issuance of common stock under the employee stock purchase plan	808	676
Net cash provided by financing activities	842	20,812
Effect of exchange rate changes on cash and cash equivalents	2	42
Net (decrease) increase in cash, cash equivalents, and restricted cash	(20,063)	80
Cash, cash equivalents, and restricted cash at beginning of the period	83,784	101,967
Cash, cash equivalents, and restricted cash at end of the period	$ 63,721	$ 102,047
Reconciliation of cash, cash equivalents, and restricted cash to consolidated balance sheets:		
Cash and cash equivalents	$ 63,464	$ 101,581
Restricted cash	257	466
Cash, cash equivalents, and restricted cash in consolidated balance sheets	$ 63,721	$ 102,047

Supplemental non-cash items:				
Lapse in repurchase rights of common stock	$	—	$	103
Purchases of property and equipment in accounts payable and accrued liabilities	$	169	$	450
Supplemental disclosure of cash flow information:				
Cash paid for income taxes	$	276	$	206
Cash paid for interest	$	1,778	$	1,235

The accompanying notes are an integral part of these unaudited interim condensed consolidated financial statements.

1. Formation and Business of the Company

The Company

Pulmonx Corporation (the "Company") was incorporated in the state of California in December 1995 as Pulmonx and reincorporated in the state of Delaware in December 2013. The Company is a commercial-stage medical technology company that provides a minimally invasive treatment for patients with severe emphysema, a form of chronic obstructive pulmonary disease ("COPD"). The Company's solution, which is comprised of the Zephyr Endobronchial Valve ("Zephyr Valve"), the Chartis Pulmonary Assessment System ("Chartis System") and the StratX Lung Analysis Platform ("StratX Platform", which is called the LungTraX Platform in the United States), is designed to treat a broad pool of patients for whom medical management has reached its limits and either do not want or are ineligible for surgical approaches. The Company has subsidiaries in Germany, Switzerland, Australia, the United Kingdom, Italy, France, Hong Kong and Japan.

Liquidity and Going Concern

The Company has incurred operating losses and negative cash flows from operations to date and has an accumulated deficit of $440.2 million as of June 30, 2024. During the six months ended June 30, 2024 and June 30, 2023, the Company used $17.6 million and $20.5 million of cash in its operating activities, respectively. As of June 30, 2024, the Company had cash, cash equivalents and marketable securities of $114.5 million. Historically, the Company's activities have been financed through the sale of equity securities, debt financing arrangements and sales of its products.

The Company's unaudited interim condensed consolidated financial statements have been prepared on the basis of the Company continuing as a going concern for the next 12 months. Management believes that the Company's existing cash, cash equivalents and marketable securities will allow the Company to continue its planned operations for at least the next 12 months from the date of the issuance of these unaudited interim condensed consolidated financial statements.

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company's unaudited interim condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

Principles of Consolidation

The unaudited interim condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Unaudited Interim Financial Information

The condensed consolidated balance sheet as of December 31, 2023 was derived from the Company's audited financial statements, but does not include all disclosures required by U.S. GAAP. The accompanying unaudited interim condensed consolidated financial statements as of June 30, 2024 and for the three and six months ended June 30, 2024 and June 30, 2023, have been prepared by the Company, pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC"), for interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to such rules and regulations. However, the Company believes that the disclosures are adequate to make the information presented not misleading. Accordingly, these financial statements should be read in

conjunction with the audited financial statements as of and for the fiscal year ended December 31, 2023 and notes thereto, included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023 filed with the SEC on February 27, 2024. In the opinion of management, all adjustments, consisting only of normal recurring adjustments necessary for a fair statement of the Company's condensed consolidated financial position as of June 30, 2024 and condensed consolidated results of operations for the three and six months ended June 30, 2024 and June 30, 2023 and condensed consolidated cash flows for the six months ended June 30, 2024 and June 30, 2023 have been made. The results of operations for the three and six months ended June 30, 2024 are not necessarily indicative of the results of operations that may be expected for the fiscal year ending December 31, 2024.

Use of Estimates

The preparation of unaudited interim condensed 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 unaudited interim condensed consolidated financial statements and the reported amounts of revenues and expenses during the reporting periods. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

Significant estimates and assumptions include reserves and write-downs related to inventories, classification of short-term and long-term inventories, the recoverability of long-term assets, stock-based compensation, intangible assets, goodwill, deferred tax assets and related valuation allowances and impact of contingencies.

Fair Value of Financial Instruments

The carrying amounts of the Company's financial instruments consisting of cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities approximate fair value due to their relatively short maturities. Based on the borrowing rates currently available to the Company for debt with similar terms and consideration of default and credit risk, the carrying value of the term loan approximates their fair value. The fair value of marketable debt securities is estimated using Level 1 and Level 2 inputs (Note 4).

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of risk consist principally of cash, cash equivalents and accounts receivable. The Company maintains its cash and cash equivalents balances with established financial institutions and, at times, such balances with any one financial institution may be in excess of the Federal Deposit Insurance Corporation ("FDIC") insured limits. As of June 30, 2024 and December 31, 2023, the Company also had cash on deposit with foreign banks of approximately $5.7 million and $4.7 million, respectively, that was not federally insured.

The Company earns revenue primarily from the sale of its products to hospitals and other customers such as distributors. Sales of Zephyr Valves and delivery catheters accounted for most of the Company's revenue for the six months ended June 30, 2024 and June 30, 2023. The Company's accounts receivable are derived from revenue earned from customers. The Company performs ongoing credit evaluations of its customers' financial condition and generally requires no collateral from its customers. As of June 30, 2024 and December 31, 2023, no customer accounted for more than 10% of accounts receivable. For the three and six months ended June 30, 2024 and June 30, 2023, no customer accounted for more than 10% of revenue.

The Company relies on single source suppliers for the components, sub-assemblies and materials for its products. These components, sub-assemblies and materials are critical and there are no or relatively few alternative sources of supply. The Company's suppliers have generally met the Company's demand for their products and services on a timely basis in the past.

Foreign Currency Translation and Transaction Gains and Losses

The functional currencies of the Company's wholly owned subsidiaries in Switzerland, Germany, Australia, the United Kingdom, France and Hong Kong are the Swiss franc. The functional currency of the Company's subsidiaries in Italy and Japan is the Euro and Yen, respectively. Accordingly, asset and liability accounts of Switzerland, France, Germany, Australia, the United Kingdom, Italy, Hong Kong and Japan operations are translated into U.S. dollars using the current exchange rate in effect at the balance sheet date and equity accounts are translated into U.S. dollars using historical rates. The revenues and expenses are translated using the average exchange rates in effect during the period, and gains and losses from foreign currency translation adjustments are included as a component of accumulated other comprehensive income in the condensed consolidated balance sheet. Foreign currency translation adjustments are recorded in other comprehensive income (loss) in the condensed consolidated statements of operations and comprehensive loss and was less than $0.1 million and $0.2 million during the three months ended June 30, 2024 and June 30, 2023, respectively, and $(0.5) million and $0.2 million during the six months ended June 30, 2024 and June 30, 2023, respectively.

Foreign currency transaction gains and losses are included in other (expense) income, net in the condensed consolidated statements of operations and comprehensive loss and was less than $(0.1) million and $(0.2) million during the three months ended June 30, 2024 and June 30, 2023, respectively, and $0.3 million and $(0.2) million during the six months ended June 30, 2024 and June 30, 2023, respectively.

Credit Losses—Accounts Receivable

Accounts receivable are recorded at the amounts billed less estimated allowances for credit losses for any potential uncollectible amounts. The Company continually monitors customer payments and maintains an allowance for estimated losses resulting from a customer's inability to make required payments. The Company considers factors such as historical experience, credit quality, age of the accounts receivable balances, geographic related risks and economic conditions that may affect a customer's ability to pay. Accounts receivable are written-off and charged against an allowance for credit losses when the Company has exhausted collection efforts without success. As of June 30, 2024 and December 31, 2023, accounts receivable is presented net of an allowance for credit losses of less than $0.1 million and $0, respectively.

Net Loss per Share Attributable to Common Stockholders

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common stock outstanding during the period, without consideration of potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common stock and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, stock options and common stock subject to repurchase related to early exercise of stock options are considered to be potentially dilutive securities. Basic and diluted net loss attributable to common stockholders per share is presented in conformity with the two-class method required for participating securities. The Company considers the shares issued upon the early exercise of stock options subject to repurchase to be participating securities, because holders of such shares have non-forfeitable dividend rights in the event a dividend is paid on common stock. The holders of the shares issued upon early exercise of stock options subject to repurchase do not have a contractual obligation to share in the Company's losses. As such, the net loss was attributed entirely to common stockholders. Because the Company has reported a net loss for all periods presented, diluted net loss per common share is the same as basic net loss per common share for those periods.

3. Recent Accounting Pronouncements

Recent Accounting Pronouncements Not Yet Adopted

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*. The amendments in this ASU require disclosures, on an annual and interim basis, of

significant segment expenses that are regularly provided to the chief operating decision maker (CODM), as well as the aggregate amount of other segment items included in the reported measure of segment profit or loss. This ASU requires that a public entity disclose the title and position of the CODM and an explanation of how the CODM uses the reported measure(s) of segment profit or loss. Public entities will be required to provide all annual disclosures currently required by Topic 280 in interim periods, and entities with a single reportable segment are required to provide all the disclosures required by the amendments in the update and existing segment disclosures in Topic 280. This ASU is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact that this update will have on its disclosures in the consolidated financial statements.

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which improves the transparency of income tax disclosures by requiring consistent categories and greater disaggregation of information in the effective tax rate reconciliation and income taxes paid disaggregated by jurisdiction. It also includes certain other amendments to improve the effectiveness of income tax disclosures. The standard is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the disclosure requirements related to the new standard.

All other newly issued accounting pronouncements not yet effective have been deemed either immaterial or not applicable.

4. Fair Value Measurements

Assets and liabilities recorded at fair value in the consolidated financial statements are categorized based upon the level of judgment associated with the inputs used to measure their fair value. Hierarchical levels which are directly related to the amount of subjectivity associated with the inputs to the valuation of these assets or liabilities are as follows:

Level 1—Inputs are unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access as of the measurement date.

Level 2—Inputs are observable, unadjusted quoted prices in active markets for similar assets or liabilities, unadjusted quoted prices for identical or similar assets or liabilities in markets that are not active or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the related assets or liabilities.

Level 3—Unobservable inputs for the asset or liability only used when there is little, if any, market activity for the asset or liability at the measurement date. This hierarchy requires the Company to use observable market data, when available, and to minimize the use of unobservable inputs when determining fair value.

Assets and Liabilities Measured and Recorded at Fair Value on a Recurring Basis—Financial assets and liabilities held by the Company measured at fair value on a recurring basis include money market funds and marketable securities.

Assets and Liabilities Measured and Recorded at Fair Value on a Nonrecurring Basis—The Company determines the fair value of long-lived assets held and used, such as intangible assets, by reference to independent appraisals, quoted market prices (e.g., an offer to purchase) and other factors. An impairment charge is recorded when the carrying value of the asset exceeds its fair value. There have been no impairment charges recorded to date. Based on the borrowing rates currently available to the Company for debt with similar terms and consideration of default and credit risk, the carrying value of the term loan approximates the fair value. The fair value of the term loan is estimated using Level 2 inputs.

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company’s assessment of the significance of a particular input to the

fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability.

The following tables summarizes the types of assets and liabilities measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands):

	June 30, 2024			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 6,191	$ —	$ —	$ 6,191
Total cash equivalents	$ 6,191	$ —	$ —	$ 6,191
Marketable securities:				
U.S. Government agency bonds	$ 8,565	$ 19,686	$ —	$ 28,251
Corporate debt securities	—	2,929	—	2,929
Commercial paper	—	19,901	—	19,901
Total marketable securities	8,565	42,516	—	51,081
Total financial assets	$ 14,756	$ 42,516	$ —	$ 57,272

	December 31, 2023			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 25,129	$ —	$ —	$ 25,129
Total cash equivalents	$ 25,129	$ —	$ —	$ 25,129
Marketable securities:				
U.S. Government agency bonds	$ 5,798	$ 29,466	$ —	$ 35,264
Commercial paper	—	12,681	—	12,681
Total marketable securities	5,798	42,147	—	47,945
Total financial assets	$ 30,927	$ 42,147	$ —	$ 73,074

There were no liabilities measured at fair value on a recurring and non-recurring basis as of June 30, 2024 and December 31, 2023.

The following table summarizes the cost, unrealized gains and losses and fair value of marketable securities (in thousands):

	June 30, 2024			
	Amortized Cost	Unrealized Losses	Unrealized Gains	Fair Value
U.S. Government agency bonds	$ 28,304	$ (53)	$ —	$ 28,251
Corporate debt securities	2,932	(3)	—	2,929
Commercial paper	19,918	(19)	2	19,901
Total	$ 51,154	$ (75)	$ 2	$ 51,081

	December 31, 2023			
	Amortized Cost	Unrealized Losses	Unrealized Gains	Fair Value
U.S. Government agency bonds	$ 35,194	$ (26)	$ 96	$ 35,264
Commercial paper	12,667	(1)	15	12,681
Total	$ 47,861	$ (27)	$ 111	$ 47,945

The following table summarizes the marketable securities with unrealized losses as of June 30, 2024 and December 31, 2023, aggregated by major security type and the length of time that individual securities have been in a continuous loss position (in thousands):

	June 30, 2024					
	Less than 12 months		12 months or greater		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
U.S. Government agency bonds	$ 25,260	$ (42)	$ 2,991	$ (11)	$ 28,251	$ (53)
Corporate debt securities	2,929	(3)	—	—	2,929	(3)
Commercial paper	11,219	(19)	—	—	11,219	(19)
Total	$ 39,408	$ (64)	$ 2,991	$ (11)	$ 42,399	$ (75)

	December 31, 2023					
	Less than 12 months		12 months or greater		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
U.S. Government agency bonds	$ 11,888	$ (23)	$ 1,745	$ (3)	$ 13,633	$ (26)
Commercial paper	996	(1)	—	—	996	(1)
Total	$ 12,884	$ (24)	$ 1,745	$ (3)	$ 14,629	$ (27)

The unrealized losses for marketable securities relate to changes in interest rates. No allowance for credit losses was recorded as of June 30, 2024 and December 31, 2023, and no impairment losses were recognized for the three and six months ended June 30, 2024 and June 30, 2023.

Accrued interest receivable on marketable securities of $0.2 million and $0.4 million as of June 30, 2024 and December 31, 2023, respectively, is included in prepaid expenses and other current assets on the condensed consolidated balance sheet. The Company elected to exclude accrued interest receivable from the estimation of expected credit losses on its marketable securities and reverse accrued interest receivable through interest income (expense) when amounts are determined to be uncollectible. The Company did not write off any accrued interest receivable during the three and six months ended June 30, 2024 and June 30, 2023.

Contractual Maturities

The following table summarizes the contractual maturities of the Company's marketable securities (in thousands):

	June 30, 2024	
	Amortized Cost	Fair Value
Due within one year	$ 51,154	$ 51,081
Due in one year to five years	—	—
Total	$ 51,154	$ 51,081

5. Balance Sheet Components

Cash and Cash Equivalents

The Company's cash and cash equivalents consist of the following (in thousands):

	June 30, 2024	December 31, 2023
Cash	$ 57,273	$ 58,418
Cash equivalents:		
Money market funds	6,191	25,129
Total cash and cash equivalents	$ 63,464	$ 83,547

Inventory

Inventory consists of the following (in thousands):

	June 30, 2024	December 31, 2023
Raw materials	$ 3,032	$ 2,924
Work in process	387	427
Finished goods	15,861	15,972
Total inventory	$ 19,280	$ 19,323
Reported as:		
Inventory	$ 16,980	$ 16,743
Long-term inventory	2,300	2,580
Total inventory	$ 19,280	$ 19,323

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following (in thousands):

	June 30, 2024	December 31, 2023
Prepaid expenses	$ 1,996	$ 1,910
Prepaid insurance	424	906
VAT and other receivable	700	915
Other current assets	177	504
Total prepaid expenses and other current assets	$ 3,297	$ 4,235

Capitalized Implementation Costs of a Hosting Arrangement

The Company has several software systems that are cloud-based hosting arrangements with service contracts. The Company accounts for costs incurred in connection with the implementation of these various software systems under ASU 2018-15, *Intangibles—Goodwill and Other—Internal Use Software (Subtopic 350–40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That is a Service Contract*. The Company expenses all costs (internal and external) that are incurred in the planning and post-implementation operation stages. As of June 30, 2024 and December 31, 2023, the Company has capitalized less than $0.1 million and $0.1 million in implementation costs, net of amortization, respectively. The capitalized costs are amortized on a straight-line basis over the non-cancelable contract terms, which are generally three years. As of June 30, 2024, the capitalized costs of less than $0.1 million were included in prepaid expenses and other current assets. Amortization expense, which was included in selling, general and administrative expenses, was less than $0.1 million and $0.1 million for the three months ended June 30, 2024 and June 30, 2023, respectively, and $0.1 million and $0.2 million for the six months ended June 30, 2024 and June 30, 2023, respectively.

Property and Equipment, Net

Property and equipment, net consist of the following (in thousands):

	June 30, 2024	December 31, 2023
Machinery and equipment	$ 2,352	$ 2,271
Computer equipment and software	2,476	1,872
Furniture and fixtures	295	264
Leasehold improvements	2,277	2,277
Construction in progress	1,002	2,199
Total	8,402	8,883
Less: accumulated depreciation	(5,572)	(4,855)
Property and equipment, net	$ 2,830	$ 4,028

In the second quarter of 2024, the Company recorded a non-cash impairment charge of $1.7 million related to certain previously capitalized software development costs that reduced the carrying value of those assets to zero. The impairment charge was recorded in research and development expenses on the Company's condensed consolidated statements of operations and comprehensive loss. This impairment charge was primarily driven by the Company's strategic decision to adopt a more cost-efficient solution in place of completing the development of the internally developed software.

Depreciation expense was $0.3 million for each of the three months ended June 30, 2024 and June 30, 2023. Depreciation expense was $0.7 million for each of the six months ended June 30, 2024 and June 30, 2023.

Goodwill

Goodwill was $2.3 million as of June 30, 2024 and December 31, 2023. There were no acquisitions or dispositions of goodwill in the six months ended June 30, 2024 and June 30, 2023. The Company assesses goodwill for impairment annually, or more frequently, when events or changes in circumstances indicate there may be impairment. Through June 30, 2024, there have been no events or changes in circumstances that indicated that the carrying value of goodwill may not be recoverable. As a result, no impairment charge was recorded during the six months ended June 30, 2024.

Intangible Assets

Amortization expense relating to intangibles was $0 and less than $0.1 million during each of the three months ended June 30, 2024 and June 30, 2023, respectively. Amortization expense relating to intangibles was less than $0.1 million and $0.1 million during each of the six months ended June 30, 2024 and June 30, 2023, respectively. The intangible assets were fully amortized as of June 30, 2024.

Intangible assets as of December 31, 2023 consist of the following (in thousands):

	December 31, 2023		
	Gross Carrying Value	Accumulated Amortization	Net Carrying Value
Developed technology	$ 1,658	$ (1,630)	$ 28
Trademarks	191	(188)	3
Total intangible assets	$ 1,849	$ (1,818)	$ 31

Accrued Liabilities

Accrued liabilities consist of the following (in thousands):

	June 30, 2024	December 31, 2023
Accrued employee bonuses and commissions	$ 3,682	$ 7,875
Accrued vacation	2,579	2,400
Other accrued personnel related expenses	2,298	2,859
Accrued professional fees	2,003	1,705
Sales taxes, franchise tax and VAT	772	763
Other	449	632
Total accrued liabilities	$ 11,783	$ 16,234

6. Long Term Debt

CIBC Loan

On February 20, 2020, the Company executed a Loan and Security Agreement with Canadian Imperial Bank of Commerce (“CIBC”), which the Company subsequently amended on April 17, 2020 and December 28, 2020 (as amended, the “CIBC Agreement”). The CIBC Agreement originally provided the Company with the ability to borrow up to $32.0 million in debt financing (“CIBC Loan”) consisting of $17.0 million advanced at the closing of

the agreement ("Tranche A"), with the option to draw up to an additional $8.0 million ("Tranche B") and an additional financing tranche ("Tranche C") of up to $7.0 million on or prior to February 20, 2022. Neither Tranche B nor Tranche C was drawn before the option expired.

The CIBC Loan originally had a five-year term maturing on February 20, 2025, which included 24 months of interest only payments followed by 36 months of equal payments of principal and interest.

In April 2020, the Company entered into a First Amendment to CIBC Agreement that changed the maturity date to March 15, 2022, which would be automatically extended to February 20, 2025 if the maturity of all outstanding convertible notes was extended to a date no earlier than May 21, 2025 or all convertible notes converted into convertible preferred stock of the Company. An amendment fee of $0.2 million was paid. The amendment was accounted for as a debt modification and no gain or loss was recognized.

In December 2020, to address certain post-close covenants for which the Company was not in compliance, the Company entered into a Second Amendment to the CIBC Agreement that extended the compliance of such covenants to June 30, 2021.

In March 2021, the Company entered into an Amended and Restated Loan and Security Agreement with CIBC (as amended, the "Amended and Restated CIBC Agreement") which, among other things, extended the loan maturity date of the CIBC Loan from March 15, 2022 to February 20, 2025, and modified certain financial covenants. Per the amended terms, 36 equal payments of principal plus accrued interest would be due beginning March 31, 2022. In connection with the Amended and Restated CIBC Agreement, the Company paid fees to CIBC of less than $0.1 million which were recorded as a discount on the CIBC Loan and are being accreted over the life of the term loan using the effective interest method. The amendment was accounted for as a debt modification and no gain or loss was recognized.

In June 2021, the Company entered into a First Amendment to the Amended and Restated CIBC Agreement that extended the compliance of certain post-close covenants to March 31, 2022.

In October 2021, the Company entered into a Second Amendment to the Amended and Restated CIBC Agreement, which extended the interest only period of the loan from 24 months to 36 months. Under the amended terms, principal repayment would begin in February 2023. There was no change to the loan interest rate or maturity date.

In October 2022, the Company entered into a Third Amendment to the Amended and Restated CIBC Agreement (the "Third Amendment") with CIBC, which amended certain provisions of the CIBC Loan. The amendment provided the option to draw up to an additional $20.0 million ("Amended Tranche B") on or prior to October 31, 2023, which can be drawn in increments of at least $5.0 million. Upon request by the Company, CIBC may, in its sole discretion, make additional term loans of up to $10.0 million ("Amended Tranche C") at any time. The Third Amendment extended the maturity date of the CIBC Loan from February 20, 2025 to October 31, 2027 and provided for a new interest-only period of 24 months from the signing date of the Third Amendment, with the possibility of an additional extension of such interest only period of up to 12 months, subject to satisfaction of certain conditions set forth in the Third Amendment. The Company paid a commitment fee of less than $0.1 million in connection with the Third Amendment. The amendment was accounted for as a debt modification and no gain or loss was recognized.

In February 2023, the Company drew $20.0 million of the Amended Tranche B which has the same interest rate and repayment terms as Tranche A of the CIBC Loan.

In May 2024, as a result of the Company satisfying certain conditions set forth in the Third Amendment, the Company extended the interest-only period of the CIBC Loan from 24 months to 36 months. Principal repayment will begin in November 2025. There was no change to the loan interest rate, maturity date, or other terms of the loan.

Upon draw of the Amended Tranche B, the financial covenants in the Amended and Restated CIBC Agreement require that, when the cash and cash equivalents of the Company as defined in the Amended and Restated CIBC Agreement is less than $100.0 million, the Company have revenue for the trailing three-month period ending on the last day of each fiscal quarter of not less than 80.0% of the revenue for the trailing three-month period, as set forth in the annual projections delivered to the CIBC. Further, the Company is required to maintain unrestricted cash in an aggregate amount equal to the greater of $20.0 million and the Adjusted EBITDA loss as defined in the Amended and Restated CIBC Agreement for the six-month period ending on any date of determination. As of June 30, 2024, the Company was in compliance with all covenants contained in Amended and Restated CIBC Agreement.

The CIBC Loan bears interest at a floating rate equal to 1.0% above the Wall Street Journal Prime Rate at any time. The CIBC Loan is collateralized by substantially all of the Company's assets, including cash and cash equivalents, accounts receivable, intellectual property and equipment. The Company may prepay the borrowings under the Amended and Restated CIBC Agreement, subject to certain conditions, including a prepayment fee equal to 2.0% of the principal amount repaid during the first year after the effective date of the Third Amendment or 1.0% of the principal amount prepaid during the second year after the effective date of the Third Amendment.

As of June 30, 2024, the CIBC Loan had an annual effective interest rate of 10.1% per year.

The CIBC Loan consists of the following (in thousands):

	June 30, 2024	December 31, 2023
Term loan	$ 37,000	$ 37,000
Less: debt issuance costs	(121)	(152)
Term loan	$ 36,879	$ 36,848
Reported as:		
Short-term debt	$ —	$ 2,056
Long-term debt	36,879	34,792
Total term loan	$ 36,879	$ 36,848

The Company paid $0.5 million fees to the lender and third parties which is reflected as a discount on the CIBC Loan and is being accreted over the life of the term loan using the effective interest method.

During the three months ended June 30, 2024 and June 30, 2023, the Company recorded interest expense related to debt discount and debt issuance costs of the CIBC Loan of less than $0.1 million and less than $0.1 million, respectively. During the six months ended June 30, 2024 and June 30, 2023, the Company recorded interest expense related to debt discount and debt issuance costs of the CIBC Loan of less than $0.1 million and less than $0.1 million, respectively.

Interest expense on the CIBC Loan was $0.9 million during each of the three months ended June 30, 2024 and June 30, 2023. Interest expense on the CIBC Loan was $1.8 million and $1.4 million during the six months ended June 30, 2024 and June 30, 2023, respectively.

Credit Agreement

In May 2020, Pulmonx International Sàrl, a wholly owned subsidiary of the Company, received 0.5 million Swiss Francs ($0.5 million U.S. dollar equivalent) from a COVID-19 Credit Agreement under a Swiss Federal Government program designed to mitigate the economic impact of the spread of the coronavirus. The COVID-19 Credit Agreement bore no interest through March 31, 2023. Beginning April 1, 2023, the COVID-19 Credit Agreement bears interest at a rate of 1.5% per year, payable at the end of each calendar quarter. The loan principal is being repaid in twelve equal installments, paid semi-annually, which began in March of 2022. Interest expense was

immaterial during the three and six months ended June 30, 2024 and June 30, 2023. As of June 30, 2024, Pulmonx International Sàrl has repaid $0.2 million to the lender.

Contractual Maturities of Financing Obligations

As of June 30, 2024, the aggregate future payments under the CIBC Loan and Credit Agreement (including interest payments) are as follows (in thousands):

Fiscal Year Ending December 31,		Amount
2024 (remaining six months)	$	1,821
2025		6,675
2026		21,005
2027		16,177
Total		45,678
Less: unamortized debt discount		(121)
Less: interest		(8,354)
Term loan and credit agreement	$	37,203

7. Revenue Recognition

The Company's contract liabilities consist of deferred revenue for remaining performance obligations by the Company to the customer after delivery, which was $0.1 million and $0.1 million as of June 30, 2024 and December 31, 2023, respectively. The deferred revenue as of December 31, 2023 of $0.1 million was recognized as revenue during the six months ended June 30, 2024. The deferred revenue as of December 31, 2022 of $0.1 million was recognized as revenue during the six months ended June 30, 2023.

The Company disaggregates its revenue by major geographic region, which has been disclosed in Note 12, "Segment Information."

8. Commitments and Contingencies

Leases

The Company has a lease for its headquarters location in Redwood City, California, which consists of approximately 24,591 square feet of office space (the "existing premises") and was scheduled to expire on July 31, 2025 (the "Office Lease"). The Company leases additional facilities in Redwood City, California, under a sublease agreement, which consist of approximately 25,254 square feet of office space (the "expansion premises") and was scheduled to expire on September 30, 2024 (the "Sublease").

In May 2024, the Company entered into a third amendment to Sublease (the "Third Amendment to Sublease") to extend the lease term of the expansion premises through May 31, 2028. The Third Amendment to Sublease contains a rent-free period between November 1, 2024 and February 28, 2025, after which rent is approximately $0.1 million per month and is subject to an annual increase of approximately 3%.

The Company also entered into a third amendment to Office Lease (the "Third Amendment to Office Lease") to extend the lease term of the existing premises through July 31, 2035. The Third Amendment to Office Lease contains a rent-free period between August 1, 2025 and November 30, 2025, after which rent is approximately $0.1 million per month and is subject to an annual increase of approximately 3.5%. Additionally, under the Third Amendment to Office Lease, the Company and the landlord have agreed to expand the existing premises to include the expansion premises, effective as of June 1, 2028, through July 31, 2035 (conterminous with the existing

premises as referenced above). Commencing on June 1, 2028, the monthly base rent for the expansion premises will be $0.1 million per month and is subject to an annual increase of approximately 3.5%.

Under the Third Amendment to Office Lease, the Company has two options to extend the lease term on the leased premises for a period of five years, respectively. The Company did not include the renewal options in the lease terms for calculating lease liability, as it was not reasonably certain that the Company will exercise these renewal options. The amendments were accounted for as modifications that resulted in additional right of use assets in exchange for lease liabilities of $16.3 million.

In 2013, the Company entered into a five-year lease for office facilities in Switzerland. The Company had an option to extend the lease through January 2022, which was not exercised by the Company. Per the lease terms, in the event the option to extend is not exercised, the lease remains in force and can be terminated with 12-months' notice. In June 2024, with the intention of seeking other premises, the Company provided notice to the landlord to terminate the lease, effective June 30, 2025.

As of June 30, 2024, the Company has leases on fourteen vehicles with an average lease term of 3.0 years.

Operating lease cost consists of the following (in thousands):

	Six Months Ended June 30,	
	2024	2023
Operating lease cost	$ 1,538	$ 1,442
Short-term lease cost	20	18
Variable lease cost	387	320
Total lease cost	$ 1,945	$ 1,780

The following table summarizes a maturity analysis of the Company's lease liabilities showing the aggregate lease payments as of June 30, 2024 (in thousands):

Fiscal Year Ending December 31,	Amount
2024 (remaining six months)	$ 1,573
2025	2,176
2026	2,569
2027	2,611
2028	2,729
Thereafter	20,624
Total minimum lease payments	32,282
Less: Amount of lease payments representing interest	13,297
Present value of future minimum lease payments	$ 18,985
Less: Current lease liabilities	1,071
Long-term lease liabilities	$ 17,914

The following table summarizes additional information related to the Company's operating leases (in thousands, except weighted average data):

	June 30, 2024	December 31, 2023
Right of use asset	$ 18,490	$ 3,406
Weighted average remaining lease term (years)	10.99	1.35
Weighted average discount rate	10.5 %	6.7 %

The following table summarizes other supplemental information related to the Company's operating leases (in thousands):

	Six Months Ended June 30,	
	2024	2023
Cash paid for amounts included in the measurement of lease liabilities included in cash flows used in operating activities	$ 1,821	$ 1,748
Right-of-use assets obtained in exchange for lease liabilities	$ 16,360	$ 224

Service Agreement

In April 2022, the Company entered into an agreement with a service provider which requires total minimum purchases of $0.6 million, $0.4 million, and $0.4 million over a three-year period. From inception of the agreement through June 30, 2024, the Company recorded $1.2 million of expense for services related to this agreement in cost of goods sold. In June 2024, the Company amended the agreement with the service provider, which eliminated the minimum purchase obligations.

Contingencies

From time to time, the Company may be a party to various litigation claims in the normal course of business. Legal fees and other costs associated with such actions are expensed as incurred. The Company assesses, in conjunction with legal counsel, the need to record a liability for litigation and contingencies. Accrual estimates are recorded when and if it is determinable that such a liability for litigation and contingencies are both probable and reasonably estimable.

In December 2022, the Company received a civil investigative demand ("CID") from the U.S. Department of Justice, Civil Division in connection with an investigation under the Anti-Kickback Statute and False Claims Act (the "Investigation"). The CID requests information and documents regarding the Company's relationships with certain health care providers, medical practices, and hospitals in connection with the sales and marketing of the Zephyr Valves and related products and services. The Company is fully cooperating with the Investigation. The Company is unable to express a view at this time regarding the ultimate outcome of the Investigation or estimate an amount or range of reasonably possible loss. Depending on the outcome of the Investigation, there could be a material impact on the Company's business, results of operations and financial condition.

9. Income Taxes

The income tax expense for the three months ended June 30, 2024 and June 30, 2023 was $0.1 million and $0.1 million, respectively. The income tax expense for the six months ended June 30, 2024 and June 30, 2023 was $0.3 million and $0.3 million, respectively. The income tax expense was determined based upon estimates of the Company's effective income tax rates in various jurisdictions. The difference between the Company's effective

income tax rate and the U.S. federal statutory rate is primarily attributable to state income taxes, foreign income taxes, and non-recognition of US tax benefit because of a full valuation allowance against US deferred tax assets.

The income tax expense for the six months ended June 30, 2024 and June 30, 2023 relates primarily to state minimum income tax and income tax on the Company's earnings in foreign jurisdictions.

10. Stockholders' Equity

Common Stock

As of June 30, 2024 and December 31, 2023, the Company's certificate of incorporation authorized the Company to issue up to 200,000,000 shares of common stock. Common stockholders are entitled to dividends as and when declared by the Company's board of directors, subject to the rights of holders of all classes of stock outstanding having priority rights as to dividends. There have been no dividends declared to date. The holder of each share of common stock is entitled to one vote.

In March and May 2024, the Company granted stock-based awards outside of the existing stock plans to its new Chief Executive Officer and new Chief Financial Officer, respectively. These awards were granted as a material inducement for accepting employment with the Company, in accordance with Nasdaq Listing Rule 5635(c)(4). The inducement awards consisted of a total of 997,681 shares of the Company's common stock, which includes an aggregate of 331,156 shares of common stock issuable upon the vesting of restricted stock unit awards and 666,525 shares of common stock issuable upon the exercise of nonqualified stock option grants generally subject to the same terms and conditions as grants that are made under the 2020 Equity Incentive Plan.

Shares Reserved for Future Issuance

The Company has reserved shares of common stock for future issuances as follows:

	June 30, 2024	December 31, 2023
Common stock options issued and outstanding	3,766,402	3,142,981
Common stock restricted stock units issued and outstanding	3,197,736	2,244,903
Common stock available for future grants	2,951,051	2,541,438
Common stock available for employee stock purchase plan	1,731,920	1,436,823
Total	11,647,109	9,366,145

Stock Option Plan

A summary of stock option activity for the existing stock plans and the inducement awards for the six months ended June 30, 2024 is set forth below:

	Outstanding Options	
	Number of Shares	Weighted Average Exercise Price
Balance, January 1, 2024	3,142,981	$ 16.40
Options granted	895,125	9.09
Options exercised	(39,466)	2.02
Options canceled	(232,238)	21.85
Balance, June 30, 2024	3,766,402	$ 14.48

The aggregate intrinsic value of options outstanding as of June 30, 2024 was $3.7 million.

	June 30, 2024		
	Number of Shares	Weighted Average Exercise Price	Weighted Average Contractual Life (in Years)
Options vested and exercisable	1,954,036	$ 15.32	6.45
Options vested and expected to vest	3,766,402	$ 14.48	7.64

Total aggregate intrinsic value of options vested and exercisable as of June 30, 2024 was $3.5 million.

Restricted Stock Units

A summary of restricted stock units activity for the existing stock plans and the inducement awards for the six months ended June 30, 2024 is set forth below:

	Number of Shares Underlying Outstanding Restricted Stock	Weighted Average Grant Date Fair Value
Unvested, January 1, 2024	2,244,903	$ 15.74
Granted	1,705,208	8.89
Vested	(505,946)	16.10
Canceled	(246,429)	14.75
Unvested, June 30, 2024	3,197,736	$ 12.11

The aggregate intrinsic value of restricted stock units outstanding as of June 30, 2024 was $20.3 million.

The fair value as of the respective vesting dates of restricted stock units that vested during the three months ended June 30, 2024 and June 30, 2023 was $2.6 million and $2.7 million, respectively. The fair value as of the respective vesting dates of restricted stock units that vested during the six months ended June 30, 2024 and June 30, 2023 was $4.2 million and $3.5 million, respectively.

Total Stock-Based Compensation

Stock-based compensation expense is reflected in the statements of operations and comprehensive loss as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Cost of goods sold	$ 435	$ 391	$ 816	$ 614
Research and development	714	760	1,487	1,326
Selling, general and administrative	4,771	4,711	9,290	8,560
Total	$ 5,920	$ 5,862	$ 11,593	$ 10,500

The above stock-based compensation expense related to the following equity-based awards (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Stock options and restricted stock units	$ 5,818	$ 5,799	$ 11,299	$ 10,339
Employee stock purchase plan	102	63	294	161
Total	$ 5,920	$ 5,862	$ 11,593	$ 10,500

Stock-based compensation of $0.5 million and $0.4 million was capitalized into inventory for the three months ended June 30, 2024 and June 30, 2023, respectively. Stock-based compensation of $0.9 million and $0.8 million was capitalized into inventory for the six months ended June 30, 2024 and June 30, 2023, respectively. Stock-based compensation capitalized in prior periods of $0.4 million and $0.4 million was recognized as cost of sales in the three months ended June 30, 2024 and June 30, 2023, respectively. Stock-based compensation capitalized in prior periods of $0.8 million and $0.6 million was recognized as cost of sales in the six months ended June 30, 2024 and June 30, 2023, respectively.

As of June 30, 2024, there was $50.6 million of unrecognized compensation costs related to unvested common stock options and restricted stock units, expected to be recognized over a weighted-average period of 2.7 years.

As of June 30, 2024, the Company had unrecognized stock-based compensation relating to the employee stock purchase plan of less than $0.1 million, which is expected to be recognized over a weighted-average period of 0.1 years.

Stock Modification

In February 2024, the Company's former Chief Executive Officer, Glendon French, resigned as President and Chief Executive Officer, effective as of March 15, 2024. Following this date, Mr. French continued as a full-time employee of the Company in the capacity of Senior Advisor to the new President and Chief Executive Officer until May 1, 2024, when his employment ceased. Thereafter, Mr. French has continued to serve as a member of the Company's board of directors, and his outstanding equity awards have continued to vest in accordance with their terms, subject to his continued service to the Company as a member of the board of directors.

The Company evaluated the change in status in accordance with ASC 718 and determined that there was a modification to the unvested awards expected to vest after March 15, 2024. The total stock-based compensation expense related to the modification, evaluated as of the modification date, was $6.3 million, to be recognized over the remaining vesting periods. The Company recorded $0.7 million and $1.1 million in stock-based compensation expenses related to the modification for the three and six months ended June 30, 2024.

11. Net Loss per Share Attributable to Common Stockholders

The following table sets forth the computation of basic and diluted net loss per share attributable to common stockholders which excludes shares which are legally outstanding, but subject to repurchase by the Company (in thousands, except share and per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Numerator				
Net loss attributable to common stockholders	$ (15,326)	$ (16,195)	$ (29,075)	$ (32,055)
Denominator				
Weighted-average common stock outstanding	38,943,110	37,846,019	38,789,609	37,738,775
Less: weighted-average common shares subject to repurchase	(44)	(27,763)	(61)	(42,774)
Weighted-average common shares used to compute basic and diluted net loss per share	38,943,066	37,818,256	38,789,548	37,696,001
Net loss per share attributable to common stockholders, basic and diluted	$ (0.39)	$ (0.43)	$ (0.75)	$ (0.85)

The following potentially dilutive securities outstanding have been excluded from the computation of diluted weighted average shares outstanding because such securities have an antidilutive impact due to the Company's net loss, in common stock equivalent shares:

	As of June 30	
	2024	2023
Options to purchase common stock	3,766,402	3,201,912
Unvested restricted stock units	3,197,736	2,556,721
Unvested early exercised common stock options	23	20,055
Shares committed under employee stock purchase plan	51,487	49,220
Total	7,015,648	5,827,908

12. Segment Information

The chief operating decision maker for the Company is the Chief Executive Officer. The Company's Chief Executive Officer reviews financial information presented on a consolidated basis, accompanied by information about revenue by geographic region, for purposes of allocating resources and evaluating financial performance. The Company has one business activity and there are no segment managers who are held accountable for operations, operating results or plans for levels or components below the consolidated unit level. Accordingly, the Company has determined that it has a single reportable and operating segment structure. The Company's Chief Executive Officer evaluates performance based primarily on revenue in the geographic locations in which the Company operates.

Revenue by geographic area is based on the billing address of the customer. The following table sets forth the Company's revenue by geographic area (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
United States	$ 13,881	$ 11,022	$ 26,750	$ 20,359
Europe, Middle-East and Africa ("EMEA")	5,961	5,312	11,077	9,843
Asia Pacific	802	792	1,500	1,388
Other International	139	68	310	139
Total	$ 20,783	$ 17,194	$ 39,637	$ 31,729

Long-lived assets by geographic area are based on physical location of those assets. The following table sets forth the Company's long-lived assets by geographic area (in thousands):

	June 30, 2024	December 31, 2023
United States	$ 2,736	$ 3,962
EMEA	45	54
Asia Pacific	49	12
Total	$ 2,830	$ 4,028

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

You should read the following discussion and analysis of our financial condition and results of operations together with our condensed consolidated financial statements and the related notes and other financial information included elsewhere in this Quarterly Report on Form 10-Q. This discussion and other parts of this Quarterly Report on Form 10-Q contain forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions, that are based on the beliefs of our management, as well as assumptions made by, and information currently available to, our management. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the sections of this Quarterly Report entitled "Forward-Looking Statements" and "Risk Factors," under Part II, Item 1A and those discussed in our Annual Report on Form 10-K for the year ended December 31, 2023 filed with the Securities and Exchange Commission ("SEC") on February 27, 2024.

Overview

We are a commercial-stage medical technology company that provides a minimally invasive treatment for patients with severe emphysema, a form of chronic obstructive pulmonary disease ("COPD"). Our solution, which is comprised of the Zephyr Endobronchial Valve ("Zephyr Valve"), the Chartis Pulmonary Assessment System ("Chartis System") and the StratX Lung Analysis Platform ("StratX Platform"), is designed to treat severe emphysema patients who, despite medical management, are still profoundly symptomatic and either do not want or are ineligible for surgical approaches.

In June 2018, we received pre-market approval ("PMA") by the U.S. Food and Drug Administration ("FDA") as a result of our breakthrough technology designation. The Zephyr Valve is commercially available in numerous countries globally. We have established reimbursement in major markets in North America, Europe and Asia Pacific and the Zephyr Valve has been included in treatment guidelines for COPD worldwide.

We market and sell our products in the United States through a direct sales organization. Our sales territory managers are focused on promoting awareness and increasing adoption of our solution primarily among the pulmonologists performing interventional pulmonary procedures across approximately 500 high-volume hospitals in the United States. We are expanding our commercial operations in the United States while continuing to foster our international growth. We employ both direct and distributor-based sales models, with 97% of our revenue generated in markets where we sell directly for the six months ended June 30, 2024.

In the United States, our solution is reimbursed based on established Category I Current Procedural Terminology ("CPT") and ICD-10 Procedure Coding System ("PCS") codes and associated APC and MS-DRG payment groupings. Current reimbursement in the United States is believed to cover the hospital costs of the procedure and related inpatient care. Commercial payors such as Aetna, Humana, and many of the largest Blue Cross Blue Shield plans including Anthem, Health Care Service Corporation, and BCBS Michigan have issued positive coverage policies for the Zephyr Valve, and United Healthcare no longer considers the procedure unproven or experimental. Medicare covers our solution for patients when medically necessary, and other commercial insurers are approving prior authorization requests on a case-by-case basis. Outside the United States, our solution is covered by major health systems across much of Europe, Australia, South Korea and Japan.

We manufacture all our products at our headquarters located in Redwood City, California. This facility supports production and distribution operations, including manufacturing, quality control, raw material and finished goods storage. We have manufactured all our products at this facility for over ten years. We also store finished goods at secondary facilities. We seek to maintain higher levels of inventory to protect ourselves from supply interruptions and have an established distribution system for both U.S. and international customers.

To date, we have financed our operations primarily through the sale of equity securities, debt financing arrangements and sales of our products. We have devoted substantially all of our resources to research and development activities related to our solution, including clinical and regulatory initiatives to obtain marketing

approval, sales and marketing activities, and investing in general and administrative infrastructure. We generated revenue of $20.8 million, with a gross margin of 73.7% and a net loss of $15.3 million, for the three months ended June 30, 2024 compared to revenue of $17.2 million, with a gross margin of 74.1% and a net loss of $16.2 million, for the three months ended June 30, 2023. For the six months ended June 30, 2024, we generated revenue of $39.6 million, with a gross margin of 74.1% and a net loss of $29.1 million, compared to revenue of $31.7 million, with a gross margin of 73.5% and a net loss of $32.1 million, for the six months ended June 30, 2023. As of June 30, 2024, we had an accumulated deficit of $440.2 million, cash, cash equivalents and marketable securities of $114.5 million, and $37.2 million of outstanding term loans and credit agreements, net of debt discount and debt issuance costs.

We have invested heavily in product development. Our research and development activities have been centered on driving continuous improvements to our solution. We have also made significant investments in clinical studies to demonstrate the safety and efficacy of the Zephyr Valve and to support regulatory submissions. We intend to continue to make significant investments in our sales and marketing organization throughout the United States, Europe and Asia Pacific. We have made, and intend to continue to make, investments in research and development efforts to develop our next generation products and support our future regulatory submissions to increase our addressable market and to expand indications and new markets. Because of these and other factors, we expect to continue to incur net losses for the next several years and we expect to require substantial additional funding, which may include future equity and debt financings.

Management believes that the Company's existing cash, cash equivalents and marketable securities will allow the Company to continue its operations for at least the next 12 months from the date of the issuance of our condensed consolidated financial statements.

Factors Affecting our Business and Results of Operations

We believe there are several important factors that have impacted and that we expect will continue to impact our business and results of operations. These factors include:

Our Ability to Recruit, Train and Retain Our Sales Force and its Productivity

We have made, and intend to continue to make, significant investments in recruiting, training and retaining our direct sales force. This process requires significant education and training for our sales personnel to achieve the level of technical competency with our products that is expected by physicians and to gain experience building demand for our products. Upon completion of the training, our sales personnel typically require time in the field to grow their network of accounts and increase their productivity to the levels we expect. Successfully recruiting, training and retaining additional sales personnel will be required to achieve growth. In addition, inability to attract qualified sales personnel or the loss of any productive sales personnel would have a negative impact on our ability to grow our business.

We have in the past and expect in the future to enter into different compensation arrangements with our sales professionals, which include minimum guaranteed commissions. This has impacted our compensation expenses in the past and we expect it will do so in the future.

Physician, Patient and Hospital Awareness and Acceptance of Our Solution

We intend to continue to promote awareness of our solution through training and educating physicians, pulmonary rehabilitation centers, key opinion leaders and various medical societies on the proven clinical benefits of Zephyr Valves. In addition, we intend to continue to publish additional clinical data in various industry and scientific journals and online and to present at various industry conferences. We plan to continue building patient awareness through our direct-to-patient marketing initiatives, which include advertising, social media and online education. We also intend to continue helping physicians in their outreach to patients and other healthcare providers. These efforts require significant investment by our marketing and sales organization, and vary depending upon the physician's practice specialization, and personal preferences and geographic location of physicians, pulmonary rehabilitation centers and patients. In order to grow our business, we will need to continue to make significant investments in

training and educating hospitals, physicians and patients on the advantages of our solution for the treatment of severe emphysema.

Third-Party Reimbursement

Since achieving regulatory approval in the United States in June 2018, we have launched the Zephyr Valve treatment and have made progress securing third-party payor reimbursement. The majority of our patients are Medicare beneficiaries. We estimate that roughly 75% of the potential Zephyr Valve patient population are Medicare/Medicaid beneficiaries, of which approximately 30% have managed Medicare/Medicaid and the remaining 45% have traditional Medicare/Medicaid. Approximately 25% of the potential Zephyr Valve patient population is under third-party commercial payor policies. We continue to work to broaden our coverage by private third-party payor policies. Commercial payors such as Aetna, Humana, and many of the largest Blue Cross Blue Shield plans including Anthem, Health Care Service Corporation, BCBS Michigan, and Highmark have issued positive coverage policies for the Zephyr Valve, and United Healthcare no longer considers the procedure unproven or experimental. Some commercial payors do not yet consider our solution medically necessary, but these same plans are approving prior authorization requests on a case-by-case basis. Medicare, currently without a public coverage policy, covers our solution for patients when medically necessary on a case-by-case basis and other commercial insurers not described above are approving prior authorization requests on a case-by-case basis.

We have a dedicated patient reimbursement support team in the United States that works collaboratively with patients and providers to help secure the appropriate prior authorization approvals in advance of treatment. We continue to educate private insurers in the United States on our clinical data and patient selection tools in an effort to continue to expand the number of positive coverage policies, in order to increase our revenue. Outside of the United States, our solution is covered by major health systems across much of Europe, Australia, South Korea and Japan.

Competition

Our industry is highly competitive and subject to rapid change from the introduction of new products and technologies and other activities of industry participants. Our goal is to establish our solution as a standard of care for severe emphysema. Existing treatments include medical management, lung volume reduction surgery (“LVRS”), lung transplantation as well as other minimally invasive treatments. Some of our competitors have several competitive advantages, including established relationships with pulmonologists who commonly treat patients with emphysema, significantly greater name recognition and significantly greater sales and marketing resources. In addition to competing for market share, we also compete against these companies for personnel, including qualified sales and other personnel that are necessary to grow our business. Certain of our competitors may challenge our intellectual property, may develop additional competing or superior technologies and processes and compete more aggressively and sustain that competition over a longer period of time than we could. In addition to existing competitors, other companies may acquire or in-license competitive products and could directly compete with us. We must continue to successfully compete in light of our competitors’ existing and future products and related pricing and their resources to successfully market to the physicians who use our products.

Leveraging Our Manufacturing Capacity is Critical to Improving Our Gross Margin

With our current operating model and infrastructure, we have the capacity to significantly increase our manufacturing production. If we grow our revenue and sell more units, our fixed manufacturing costs will be spread over more units, which we believe will reduce our manufacturing costs on a per-unit basis and in turn improve our gross margin. In addition, we intend to continue investing in manufacturing efficiencies in order to reduce our overall manufacturing costs. However, other factors will continue to impact our gross margins such as geographic mix, pricing and customer discounts, incentives, support services and potential seasonality.

Investing in Research and Development to Foster Innovation to Expand Our Addressable Market

We intend to continue investing in existing and next generation technologies to further improve our products and clinical outcomes, enhance patient selection and broaden the patient population that can be treated with our products.

In addition, we are continuing to invest in the accuracy and features of our patient assessment tools. Moreover, we continue to make progress with our CONVERT II pivotal trial of AeriSeal, a potential product in development for the treatment of severe emphysema patients who are not qualified for Zephyr Valve treatment due to excessive collateral ventilation.

While research and development and clinical testing are time consuming and costly, we believe that a pipeline of new products and product enhancements that improve efficacy, safety and cost effectiveness is critical to increasing the adoption of our solution.

Seasonality

Historically, we have experienced seasonality, primarily in the first and third quarters and anticipate this trend to continue. In addition, as our sales grow, we may experience further seasonality based on holidays, vacations and other factors because this is an elective procedure.

Components of Our Results of Operations

Revenue

We currently derive substantially all of our revenue from the sale of our products to hospitals and distributors. We market and sell our products through a direct sales organization in the United States and through direct sales and several third-party distributors in select markets outside the United States. We currently generate most of our revenue from the sales of Zephyr Valves and delivery catheters. We also generate a smaller amount of our revenue from our Chartis System, which is comprised of sales of the balloon catheters, usage fees and sales of the Chartis console. The StratX Platform, which is used to identify patients eligible for treatment with Zephyr Valves, does not independently generate any revenue for us. No single customer accounted for more than 10% of our revenue during the six months ended June 30, 2024 and June 30, 2023.

Revenue from sales of our products fluctuates based on volume of cases (procedures performed), the average number of Zephyr Valves used for a patient, pricing, discounts, incentives and mix of U.S. and international sales. Our revenue also fluctuates and will continue to fluctuate from quarter-to-quarter due to a variety of factors, including the availability of reimbursement, the size and success of our sales force, the number of hospitals and physicians who are aware of and perform the procedures using our solution and seasonality. Our revenue from international sales may also be impacted by fluctuations in foreign currency exchange rates between the U.S. dollar (our reporting currency) and the local currency.

Cost of Goods Sold and Gross Margin

Cost of goods sold consists primarily of payroll and personnel-related expenses for our manufacturing and quality assurance employees, costs related to materials, components and subassemblies, third-party costs, manufacturing overhead, equipment depreciation, and charges for excess, obsolete and non-sellable inventories. Overhead costs include the cost of quality assurance, testing, material procurement, inventory control, operations supervision and management and an allocation of facilities overhead cost, including rent and utilities. Cost of goods sold also includes certain direct costs such as those incurred for shipping our products and costs related to providing analysis services for patient scans. We record adjustments to our inventory valuation for estimated excess, obsolete and non-sellable inventories based on assumptions about future demand, past usage, changes to manufacturing processes and overall market conditions. We expect cost of goods sold to increase in absolute dollars to the extent more of our products are sold.

We calculate gross margin as gross profit divided by revenue. Our gross margin has been and will continue to be affected by a variety of factors, primarily by our manufacturing costs, pricing pressures and, to a lesser extent, the percentage of products we sell in the United States versus internationally and the percentage of products we sell to distributors versus directly to hospitals. Our gross margin is typically higher on products we sell directly to hospitals as compared to products we sell through distributors.

Our gross margin may increase over the long term to the extent our production volume increases as our fixed manufacturing costs would be spread over a larger number of units, thereby reducing our per-unit manufacturing costs. We expect our gross margin to fluctuate from period to period, however, based upon the factors described above and seasonality.

Operating Expenses

Our operating expenses have consisted solely of research and development costs and selling, general and administrative costs.

Research and Development Expenses

Our research and development activities primarily consist of engineering and research programs associated with our products under development and improvements to our existing products. Research and development expenses include payroll and personnel-related costs for our research and development employees, including expenses related to stock-based compensation, consulting services, clinical trial expenses, prototyping, testing, laboratory supplies, impairment charges associated with capitalized internally developed software, and an allocation of facility overhead costs. Our clinical trial expenses, such as those related to our AeriSeal clinical development program, include costs associated with clinical trial design, clinical trial site development and study costs, data management costs, related travel expenses and the cost of products used for clinical activities. We expense research and development costs as they are incurred. We expect our research and development expenses, including related stock-based compensation expense, to increase in absolute dollars as we hire additional personnel to develop new product offerings and product enhancements.

Selling, General and Administrative Expenses

Our selling, general and administrative expenses consist of payroll and personnel-related costs for our sales and marketing personnel, including variable sales compensation, travel expenses, consulting, public relations costs, direct marketing, customer training, trade show and promotional expenses, stock-based compensation and allocated facility overhead costs, and for administrative personnel that support our general operations such as information technology, executive management, finance and accounting, customer services and human resources personnel. We expense sales variable compensation at the time of the sale. Selling, general and administrative expenses also include costs attributable to professional fees for legal and accounting services, insurance, consulting fees, recruiting fees, travel expense, bad debt expense and depreciation.

We intend to continue to increase our sales and marketing spending to generate sales opportunities. We expect expenses to increase in absolute dollars as we increase our sales support infrastructure and add additional marketing programs in order to more fully penetrate the global opportunity. We also expect our administrative expenses, including stock-based compensation expense, to increase as we increase our headcount and expand our facilities and information technology to support our operations. Additionally, we incur expenses related to audit, legal, regulatory and tax-related services associated with being a public company, compliance with exchange listing and SEC requirements, director and officer insurance premiums and investor relations costs. Our selling, general and administrative expenses may fluctuate from period to period due to the seasonality of our business and as we continue to add direct sales territory managers in new territories.

Interest Expense and Income

Interest expense consists primarily of interest expense related to our term loan facilities, including amortization of debt discount and issuance costs. Interest income is predominantly derived from investing surplus cash in money market funds and marketable securities.

Other (Expense) Income, Net

Other (expense) income, net primarily consists of foreign currency exchange gains and losses.

Results of Operations:

Comparison of the Three Months Ended June 30, 2024 and June 30, 2023

The following table summarizes our results of operations for the period indicated:

	Three Months Ended June 30,			
	2024	2023	$ Change	% Change
	(in thousands)			
Revenue	$ 20,783	$ 17,194	$ 3,589	20.9 %
Costs of goods sold	5,476	4,460	1,016	22.8 %
Gross profit	15,307	12,734	2,573	20.2 %
Operating expenses:				
Research and development	5,615	5,710	(95)	(1.7)%
Selling, general and administrative	25,314	23,463	1,851	7.9 %
Total operating expenses	30,929	29,173	1,756	6.0 %
Loss from operations	(15,622)	(16,439)	817	(5.0)%
Interest income	1,306	1,410	(104)	(7.4)%
Interest expense	(891)	(864)	(27)	3.1 %
Other (expense) income, net	(35)	(162)	127	(78.4)%
Net loss before tax	(15,242)	(16,055)	813	(5.1)%
Income tax expense	84	140	(56)	(40.0)%
Net loss	$ (15,326)	$ (16,195)	$ 869	(5.4)%

Revenue

Revenue increased by $3.6 million, or 20.9%, to $20.8 million during the three months ended June 30, 2024, compared to $17.2 million during the three months ended June 30, 2023. The sale of products in the United States increased by $2.9 million to $13.9 million during the three months ended June 30, 2024, compared to $11.0 million for the three months ended June 30, 2023. The sale of products in international markets increased by $0.7 million to $6.9 million during the three months ended June 30, 2024, compared to $6.2 million for the three months ended June 30, 2023. The increase in revenue was primarily attributable to the continued growth of Zephyr Valve procedure volumes in the United States and in international markets.

Cost of Goods Sold and Gross Margin

Cost of goods sold increased by $1.0 million, or 22.8%, to $5.5 million during the three months ended June 30, 2024, compared to $4.5 million during the three months ended June 30, 2023. The increase was mainly due to an increase in the number of products sold and increased manufacturing costs as we invested to support anticipated growth. Gross margin was 73.7% during the three months ended June 30, 2024, compared to 74.1% during the three months ended June 30, 2023.

Research and Development Expenses

Research and development expenses decreased by $0.1 million, or 1.7%, to $5.6 million during the three months ended June 30, 2024, compared to $5.7 million during the three months ended June 30, 2023. The decrease in research and development expense was primarily due to a decrease of $1.0 million in services and other expenses in support of product development, a decrease of $0.5 million in costs associated with our clinical trials, including fees paid to clinical research organizations, and a decrease of $0.3 million in personnel related expenses including stock-

based compensation. These decreases were offset by a non-cash impairment charge of $1.7 million related to certain previously capitalized software development costs recorded in the second quarter of 2024.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $1.9 million, or 7.9%, to $25.3 million during the three months ended June 30, 2024, compared to $23.5 million during the three months ended June 30, 2023. The increase in selling, general and administrative expenses was primarily due to an increase of $1.1 million in advertising and marketing related expenses, an increase of $0.4 million in global travel and conference related expenses, and an increase of $0.3 million in payroll and personnel-related expenses including stock-based compensation for our sales, marketing and administrative personnel.

Interest Expense and Income

Interest expense was $0.9 million during each of the three months ended June 30, 2024 and June 30, 2023. Interest income decreased by $0.1 million to $1.3 million during the three months ended June 30, 2024 compared to $1.4 million during the three months ended June 30, 2023, primarily as a result of lower returns on cash, cash equivalents and marketable securities balances.

Other (Expense) Income, Net

Other (expense) income, net was less than ($0.1) million during the three months ended June 30, 2024 and ($0.2) million during the three months ended June 30, 2023, primarily due to foreign currency exchange losses.

Comparison of the Six Months Ended June 30, 2024 and June 30, 2023

The following table summarizes our results of operations for the period indicated:

	Six Months Ended June 30,			
	2024	2023	$ Change	% Change
	(in thousands)			
Revenue	$ 39,637	$ 31,729	$ 7,908	24.9 %
Costs of goods sold	10,252	8,406	1,846	22.0 %
Gross profit	29,385	23,323	6,062	26.0 %
Operating expenses:				
Research and development	9,825	9,963	(138)	(1.4)%
Selling, general and administrative	49,718	46,199	3,519	7.6 %
Total operating expenses	59,543	56,162	3,381	6.0 %
Loss from operations	(30,158)	(32,839)	2,681	(8.2)%
Interest income	2,747	2,537	210	8.3 %
Interest expense	(1,774)	(1,435)	(339)	23.6 %
Other (expense) income, net	380	(54)	434	(803.7)%
Net loss before tax	(28,805)	(31,791)	2,986	(9.4)%
Income tax expense	270	264	6	2.3 %
Net loss	$ (29,075)	$ (32,055)	$ 2,980	(9.3)%

Revenue

Revenue increased by $7.9 million, or 24.9%, to $39.6 million during the six months ended June 30, 2024, compared to $31.7 million during the six months ended June 30, 2023. The sale of products in the United States

increased by $6.4 million to $26.8 million during the six months ended June 30, 2024, compared to $20.4 million during the six months ended June 30, 2023. The sale of products in international markets increased by $1.5 million to $12.9 million during the six months ended June 30, 2024, compared to $11.4 million for the six months ended June 30, 2023. The increase in revenue reflects continued growth of Zephyr Valve procedure volumes in the United States and in international markets.

Cost of Goods Sold and Gross Margin

Cost of goods sold increased by $1.8 million, or 22.0%, to $10.3 million during the six months ended June 30, 2024, compared to $8.4 million during the six months ended June 30, 2023. The increase was mainly due to an increase in the number of products sold and increased manufacturing costs as we invested to support anticipated growth. Gross margin was 74.1% during the six months ended June 30, 2024, compared to 73.5% during the six months ended June 30, 2023.

Research and Development Expenses

Research and development expenses decreased by $0.1 million, or 1.4%, to $9.8 million during the six months ended June 30, 2024, compared to $10.0 million during the six months ended June 30, 2023. The decrease in research and development expense was primarily due to a decrease of $1.2 million in services and other expenses in support of product development, and a decrease of $0.7 million in costs associated with our clinical trials, including fees paid to clinical research organizations. These decreases were offset by a non-cash impairment charge of $1.7 million related to certain previously capitalized software development costs recorded in the second quarter of 2024.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $3.5 million, or 7.6%, to $49.7 million during the six months ended June 30, 2024, compared to $46.2 million during the six months ended June 30, 2023. The increase in selling, general and administrative expenses was primarily due to an increase of $1.4 million in payroll and personnel-related expenses including stock-based compensation for our sales, marketing and administrative personnel, an increase of $1.3 million in advertising and marketing related expenses, an increase of $0.6 million in global travel and conference related expenses, and an increase of $0.3 million in legal and other professional expenses. These increases were offset by a decrease of $0.4 million in insurance costs.

Interest Expense and Income

Interest expense increased by $0.4 million to $1.8 million during the six months ended June 30, 2024 compared to $1.4 million during the six months ended June 30, 2023 due to higher outstanding debt principal and higher interest rates. Interest income increased by $0.2 million to $2.7 million during the six months ended June 30, 2024 compared to $2.5 million during the six months ended June 30, 2023, primarily as a result of higher returns on cash, cash equivalents and marketable securities balances.

Other (Expense) Income, Net

Other (expense) income, net increased by $0.5 million to $0.4 million income during the six months ended June 30, 2024, compared to $(0.1) million expense during the six months ended June 30, 2023, primarily due to foreign currency exchange gains.

Liquidity and Capital Resources; Plan of Operation

To date, we have financed our operations primarily through our initial public offering, private placements of equity securities, debt financing arrangements and sales of our products. As of June 30, 2024, we had cash, cash equivalents and marketable securities of $114.5 million, an accumulated deficit of $440.2 million, and $37.2 million outstanding under the CIBC Loan and Credit Agreement, net of debt discount and debt issuance costs.

CIBC Loan

On February 20, 2020, we executed a Loan and Security Agreement with Canadian Imperial Bank of Commerce ("CIBC"), which we subsequently amended on April 17, 2020 and December 28, 2020 (as amended, the "CIBC Agreement"). The CIBC Agreement originally provided us with the ability to borrow up to $32.0 million in debt financing consisting of $17.0 million advanced at the closing of the agreement ("Tranche A"), with the option to draw up to an additional $8.0 million ("Tranche B") on or before February 20, 2022 and an additional $7.0 million ("Tranche C") on or before February 20, 2022. Neither Tranche B nor Tranche C was drawn before the February 2022 expiration date.

In March 2021, we entered into an Amended and Restated Loan and Security Agreement with CIBC (as amended, the "Amended and Restated CIBC Agreement") which, among other things, extended the loan maturity date under the CIBC Agreement from March 15, 2022 to February 20, 2025, and modified certain financial covenants.

In June 2021, we entered into a First Amendment to the Amended and Restated CIBC Agreement that extended the compliance of certain post-close covenants to March 31, 2022.

In October 2021, we entered into a Second Amendment to the Amended and Restated CIBC Agreement, which extended the interest only period of the loan from 24 months to 36 months. Under the amended terms, principal repayment would begin in February 2023. There was no change to the loan interest rate or maturity date.

In October 2022, we entered into a Third Amendment to the Amended and Restated CIBC Agreement (the "Third Amendment"), which, among other things, extended the maturity date to October 31, 2027; provided a commitment for a new $20.0 million tranche of term loans that may be drawn at our option through October 31, 2023, subject to the satisfaction of certain conditions; and provided for a new interest only period of 24 months from the signing date of the Third Amendment, with the possibility of an additional extension of such interest only period of up to 12 months, subject to satisfaction of certain conditions.

In February 2023, we drew $20.0 million of the Amended Tranche B which has the same interest rate and repayment terms as Tranche A of the CIBC Loan.

In May 2024, as a result of us satisfying certain conditions set forth in the Third Amendment, we extended the interest-only period of the CIBC Loan from 24 months to 36 months. Principal repayment will begin in November 2025. There was no change to the loan interest rate, maturity date, or other terms of the loan.

The loans provided under the Amended and Restated CIBC Agreement bear interest at a floating rate equal to 1.0% above the Wall Street Journal Prime Rate at any time. The loans are collateralized by substantially all of our assets, including cash and cash equivalents, accounts receivable, intellectual property and equipment. We may prepay the loans, subject to certain conditions, including a prepayment fee equal to 2.0% of the principal amount prepaid during the first year after the effective date of the Third Amendment or 1.0% of the principal amount prepaid during the second year after the effective date of the Third Amendment. The Amended and Restated CIBC Agreement contains financial covenants that require us to maintain minimum cash and minimum revenue amounts, and the Amended and Restated CIBC Agreement contains other customary restrictive covenants, representations and warranties, events of default and other customary terms and conditions.

We paid $0.5 million fees to the lender and third parties which is reflected as a discount on the loans provided under the Amended and Restated CIBC Agreement and is being accreted over the life of the loan using the effective interest method. During the three months ended June 30, 2024 and June 30, 2023, we recorded interest expense related to debt discount and debt issuance costs of the CIBC Loan of less than $0.1 million and less than $0.1 million, respectively. During the six months ended June 30, 2024 and June 30, 2023, we recorded interest expense

related to debt discount and debt issuance costs of the CIBC Loan of less than $0.1 million and less than $0.1 million, respectively.

Interest expense on the CIBC Loan was $0.9 million during each of the three months ended June 30, 2024 and June 30, 2023. Interest expense on the CIBC Loan was $1.8 million and $1.4 million during the six months ended June 30, 2024 and June 30, 2023, respectively.

Credit Agreement

In May 2020, Pulmonx International Sàrl, our wholly owned subsidiary, received 0.5 million Swiss Francs ($0.5 million U.S. dollar equivalent) from a COVID-19 Credit Agreement under a Swiss Federal Government program designed to mitigate the economic impact of the spread of the coronavirus. The COVID-19 Credit Agreement bore no interest through March 31, 2023. Beginning April 1, 2023, the loan bears interest at a rate of 1.5% per year, payable at the end of each calendar quarter. The loan principal is being repaid in twelve equal installments, paid semi-annually, which began in March of 2022. As of June 30, 2024, Pulmonx International Sàrl has repaid $0.2 million to the lender.

Summary Statement of Cash Flows

The following table sets forth the primary sources and uses of cash and cash equivalents for the period presented below:

	Six Months Ended June 30,	
	2024	2023
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (17,565)	$ (20,535)
Investing activities	(3,342)	(239)
Financing activities	842	20,812
Effect of exchange rate changes on cash and cash equivalents	2	42
Net (decrease) increase in cash and cash equivalents	$ (20,063)	$ 80

Cash Flows from Operating Activities

Net cash used in operating activities was $17.6 million for the six months ended June 30, 2024. Cash used in operating activities was primarily a result of the net loss of $29.1 million, a decrease in accrued liabilities of $4.2 million due to payment of incentive compensation expense associated with the achievement of performance objectives, a decrease in lease liabilities of $1.5 million due to lease payments, amortization of premiums and discounts on marketable securities of $0.9 million, and an increase in inventory of $0.7 million due to continued production to build inventory to meet projected increase in sales and to protect against potential supply interruptions. This is partially offset by stock-based compensation expense of $11.6 million, a non-cash impairment charge of $1.7 million related to certain previously capitalized software development costs recorded in the second quarter of 2024, an increase in accounts payable of $1.6 million due to timing of payments to our vendors, non-cash lease expense of $1.2 million, depreciation and amortization expense of $0.8 million, a decrease in accounts receivable of $0.8 million due to the timing of payments from our customers, and a decrease in prepaid expenses and other current assets of $0.6 million.

Net cash used in operating activities was $20.5 million for the six months ended June 30, 2023. Cash used in operating activities was primarily a result of the net loss of $32.1 million, an increase in inventory of $0.3 million due to continued production to build inventory to meet projected increase in sales and to protect against potential supply interruptions, an increase in accounts receivable of $0.2 million, a decrease in lease liabilities of $1.6 million due to lease payments, and amortization of premiums and discounts on marketable securities of $0.4 million,

partially offset by an increase in accounts payable of $0.4 million due to timing of payments to our vendors, an increase in accrued liabilities of $0.5 million, stock-based compensation expense of $10.5 million, non-cash lease expense of $1.3 million, depreciation and amortization expense of $0.8 million and write-down of inventory of $0.4 million.

Cash Flows from Investing Activities

Net cash used in investing activities in the six months ended June 30, 2024 was $3.3 million, consisting of purchases of marketable securities of $20.8 million and purchases of property and equipment of $0.9 million, offset by proceeds from maturities of marketable securities of $18.4 million.

Net cash used in investing activities in the six months ended June 30, 2023 was $0.2 million, consisting of purchases of marketable securities of $25.6 million and purchases of property and equipment of $0.1 million partially offset by proceeds from maturities of marketable securities of $25.5 million.

Cash Flows from Financing Activities

Net cash provided by financing activities in the six months ended June 30, 2024 was $0.8 million, consisting of proceeds from the issuance of common stock under the employee stock purchase plan of $0.8 million and proceeds from the exercise of common stock options of $0.1 million, offset by repayment of debt under the Credit Agreement of less than $0.1 million.

Net cash provided by financing activities in the six months ended June 30, 2023 of $20.8 million primarily relates to proceeds of $20.0 million from borrowing under the Amended and Restated CIBC Agreement, proceeds from issuance of common stock under the employee stock purchase plan of $0.7 million and proceeds from exercise of common stock options of $0.2 million.

Material Cash Requirements

Our net cash operating expenditures were $17.6 million in the six months ended June 30, 2024 and $20.5 million in the six months ended June 30, 2023. We intend to continue to make investments in the development of our products, including ongoing research and development programs. Our cash outflows for capital expenditures were $0.9 million and $0.1 million in the six months ended June 30, 2024 and June 30, 2023, respectively, and we expect to maintain the level of expenditures in the future to support our commercial infrastructure, sales force and other commercialization efforts. Recent and expected working and other capital requirements include amounts related to future lease payments for operating lease obligations, which totaled $32.3 million as of June 30, 2024, with $2.9 million expected to be paid within the next 12 months, and amounts related to future short-term and long-term debt which totaled $37.2 million, with $3.6 million due within the next 12 months. Lastly, we may undertake additional expenses to further expand our commercial organization and efforts, enhance our research and development efforts and pursue product expansion opportunities.

In May 2024, we entered into a Third Amendment to Office Lease and a Third Amendment to Sublease to extend the lease terms of our lease premises located in Redwood City, California through July 31, 2035. See Note 8, *Commitments and Contingencies*, to our condensed consolidated financial statements for more information.

As of June 30, 2024, we had cash, cash equivalents and marketable securities of $114.5 million. Based on our current planned operations, we expect that our cash, cash equivalents and marketable securities will enable us to fund our operating expenses for at least 12 months from the issuance of our condensed consolidated financial statements as of and for the six months ended June 30, 2024. We believe we will meet longer-term expected future cash requirements and obligations through a combination of available cash, cash equivalents and marketable securities, sales of our products, debt financings, and access to other public or private equity offerings. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect.

Because of the numerous risks and uncertainties associated with research, development and commercialization of medical devices, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on many factors, including:

- the costs of commercialization activities related to commercializing our products in the United States and elsewhere, including expanding territories, increasing sales and marketing personnel, actual and anticipated product sales, marketing programs, manufacturing and distribution costs;
- the impact of any public health crises, such as COVID-19, on our business, financial condition and results of operations;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the research and development activities we intend to undertake, product enhancements that we intend to pursue;
- whether or not we pursue acquisitions or investments in businesses, products or technologies that are complementary to our current business;
- the degree and rate of market acceptance of our products in the United States and elsewhere;
- changes or fluctuations in our inventory supply needs and forecasts of our supply needs;
- our need to implement additional infrastructure and internal systems;
- our ability to hire additional personnel to support our operations as a public company; and
- the emergence of competing technologies or other adverse market developments.

Until such time, if ever, as we can generate product revenue sufficient to achieve profitability, we expect to finance our cash needs through a combination of public or private equity offerings, debt financings and collaborations or licensing arrangements. There can be no assurance that our efforts to procure additional financing will be successful or that, if they are successful, the terms and conditions of such financing will be favorable to us or our stockholders. If we do raise additional capital through public or private equity or convertible debt offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional capital through collaborations agreements, licensing arrangements or marketing and distribution arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses that may not be favorable to us. If we are unable to raise capital when needed, we will need to delay, limit, reduce or terminate planned commercialization or product development activities, or grant rights to develop and commercialize products or product candidates that we would otherwise prefer to develop and market ourselves in order to reduce costs.

Critical Accounting Estimates

Our financial statements have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses incurred during the reporting periods. Our estimates are based on our knowledge of current events and actions we may undertake in the future and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making

judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may materially differ from these estimates under different assumptions or conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Our critical accounting policies are described under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations —Critical Accounting Estimates" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, filed with the SEC on February 27, 2024, and the notes to the unaudited condensed consolidated financial statements included in "Part I, Item 1 — Financial Statements" of this Quarterly Report on Form 10-Q. During the six months ended June 30, 2024, except as described in Note 2 to the unaudited interim condensed financial statements appearing elsewhere in this Quarterly Report on Form 10-Q, there were no material changes to our critical accounting estimates from those discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, filed with the SEC on February 27, 2024.

Recent Accounting Pronouncements

See "Recent Accounting Pronouncements" in Note 3 to our consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for additional information.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

We are exposed to certain market risks in the ordinary course of our business. Our market risk exposure is primarily a result of exposure resulting from interest rates, currency exchange rates, and effects of inflation.

Interest Rate Risk

We are exposed to interest rate risks related to our cash, cash equivalents and borrowings. We had cash and cash equivalents of $63.5 million as of June 30, 2024, which consist of cash and money market funds. We held cash in foreign banks of approximately $5.7 million as of June 30, 2024 that was not federally insured. Interest-earning money market funds carry a degree of interest rate risk; however, historical fluctuations in interest income have not been significant.

We had outstanding debt of $36.9 million under the CIBC Agreement with an annual effective interest rate of 10.1% as of June 30, 2024. In the ordinary course of business, we may enter into contractual arrangements to reduce our exposure to interest rate risks. We believe that a 10% change in interest rates would not have a significant impact on our consolidated financial statements.

Foreign Currency Exchange Risk

We operate in countries other than the United States and are exposed to foreign currency risks. Revenue from sales outside of the United States represented 32.5% and 35.8% of our total revenue for the six months ended June 30, 2024 and June 30, 2023, respectively. We bill most direct sales outside of the United States in local currencies, which are mostly comprised of the Swiss franc, the Euro, the British pound, and the Australian dollar. Operating expenses related to these sales are largely denominated in the same respective currency, thereby limiting our transaction risk exposure. We therefore believe that the risk of a significant impact on our operating income from foreign currency fluctuations is not significant. The risk of a significant impact on our operating income from foreign currency fluctuations will further diminish as revenue from sales to customers in the United States increases and represents a greater proportion of total revenues. A 10% change in weighted average foreign currency exchange rates would have changed our revenues and operating expenses for the six months ended June 30, 2024 by approximately $1.3 million and $1.0 million, respectively, with a net impact of $0.3 million on our net loss. A 10% change in weighted average foreign currency exchange rates would have changed our revenues and operating expenses for the six months ended June 30, 2023 by approximately $1.1 million and $0.9 million, respectively, with a net impact of $0.2 million on our net loss. We do not currently hedge our exposure to foreign currency exchange rate fluctuations; however, we may choose to hedge our exposure in the future.

Inflation Risk

High inflation rates in the U.S. and overseas have resulted in increased transportation, wages, and other costs. Inflation may generally affect us by increasing our cost of labor, commercial support, manufacturing and clinical trial expenditures. Although we do not believe that inflation has had a material impact on our financial position or results of operations to date, if our costs become subject to significant inflationary pressures, we may not be able to fully offset such higher costs with increased revenues. Our inability or failure to do so could harm our business, financial condition, and results of operations.

Item 4. Controls and Procedures

Evaluation of Our Disclosure Controls and Procedures

Disclosure controls and procedures, as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), are controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. Based upon that evaluation, our management, including our Chief Executive Officer and Chief Financial Officer, has concluded that our disclosure controls and procedures were effective as of June 30, 2024.

Changes in Internal Controls

There were no changes in our internal control over financial reporting that occurred during the three months ended June 30, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Our management, including our Chief Executive Officer and Chief Financial Officer, believes that our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving their objectives and are effective at the reasonable assurance level. Further, our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our consolidated financial statements for external purposes in accordance with U.S. GAAP. Our internal control over financial reporting includes those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of our consolidated financial statements in accordance with U.S. GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our consolidated financial statements.

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our control system will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered 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, within the Company have been detected. Also, any evaluation of the effectiveness of controls in future periods are subject to the risk that those controls may become inadequate because of changes in business conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Part II. Other Information

Item 1. Legal Proceedings

We are not a party to any material legal proceedings at this time. From time to time, we may be subject to various legal proceedings and claims that arise in the ordinary course of business. Although the results of litigation and claims cannot be predicted with certainty, we do not believe we are party to any claim or litigation the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to 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. Please see also the matters under “Commitments and Contingencies—Contingencies” in Note 8 to the unaudited interim condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

Item 1A. Risk Factors

Our business involves significant risks, some of which are described below. You should carefully consider these risks, as well as the other information in this Quarterly Report on Form 10-Q, including the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the financial statements and the related notes. The occurrence of any of the events or developments described below could have a material adverse effect on our business, results of operations, financial condition, prospects and stock price. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. 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 Quarterly Report on Form 10-Q.

Summary Risk Factors

Our business involves significant risks, some of which are described below. The principal factors and uncertainties that make investing in our common stock risky include, among others:

- We have a history of significant net losses, which we expect to continue, and we may not be able to achieve or sustain profitability in the future;
- We have limited experience marketing and selling our solution;
- We currently rely on a single product, the Zephyr Endobronchial Valve ("Zephyr Valve"), which can only be marketed for limited indications, and if we are not successful in commercializing the Zephyr Valve, our business, financial condition and results of operations will be negatively affected;
- Our business is dependent on hospital, physician and patient adoption of our solution as a treatment for severe emphysema. If hospitals, physicians or patients are unwilling to change current practices to adopt our solution, it will negatively affect our business, financial condition and results of operations;
- If we fail to receive access to hospital facilities our sales may decrease;
- Use of the Zephyr Valve involves risks and may result in complications, including pneumothorax or death, and is contraindicated in certain patients, which may limit adoption and negatively affect our business, financial condition and results of operations;
- If we are unable to achieve and maintain adequate levels of coverage or reimbursement for our solution, or any future products we may seek to commercialize, or if patients are left with significant out-of-pocket costs, our commercial success may be severely hindered;
- If we fail to retain marketing and sales personnel and, as we grow, fail to increase our marketing and sales capabilities or develop broad awareness of our solution in a cost-effective manner, we may not be able to generate revenue growth;
- We have limited long-term data regarding the safety and effectiveness of our solution, including the Zephyr Valve. The only safety and effectiveness data of our solution, including the Zephyr Valve, is limited to one year following placement and we are required to conduct extension studies to follow up on safety and effectiveness out to five years;
- We have limited experience manufacturing our products in significant commercial quantities and we face manufacturing risks that may adversely affect our ability to manufacture our products, reduce our gross margins and negatively affect our business, financial condition and results of operations;

- Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide;

- The sizes of the markets for our current and future products have not been established with precision and may be smaller than we estimate and may decline. Certain patients may not have regions of the lung with little to no collateral ventilation, making them poor candidates for the Zephyr Valve. In addition, if the overall rate of smokers continues to decline, this may eventually decrease the number of patients suffering from COPD and emphysema and, accordingly, who would benefit from our solution;

- We expect to continue to incur net losses for the next several years and we expect to require substantial additional capital to finance our planned operations, which may include future equity and debt financings. This additional capital may not be available to us on acceptable terms or at all. Our failure to obtain additional financing when needed on acceptable terms, or at all, could force us to delay, limit, reduce or eliminate our commercialization, sales and marketing efforts, product development programs or other operations;

- Our products and operations are subject to extensive government regulation and oversight both in the United States and abroad. If we fail to obtain and maintain necessary regulatory approvals for the Zephyr Valve and related products, or if approvals for future products and indications are delayed or not issued, it will negatively affect our business, financial condition and results of operations; and

- We may become a party to intellectual property litigation or administrative proceedings that could be costly and could interfere with our ability to sell and market our products.

Risks Related to Our Business and Strategy

We have a history of significant net losses, which we expect to continue, and we may not be able to achieve or sustain profitability in the future.

We have incurred net losses since our inception. For the six months ended June 30, 2024 and June 30, 2023, we had net losses of $29.1 million and $32.1 million, respectively, and we expect to continue to incur additional losses. As of June 30, 2024, we had an accumulated deficit of $440.2 million. We expect to continue to incur significant sales and marketing, research and development, regulatory and other expenses as we grow our sales force and expand our marketing efforts to increase adoption of our products, expand existing relationships with our customers, obtain regulatory clearances, certification or approvals for our planned or future products, conduct clinical trials on our existing and planned or future products and develop new products or add new features to our existing products. The net losses that we incur may fluctuate significantly from period to period. We will need to generate significant additional revenue in order to achieve and sustain profitability. Even if we achieve profitability, we cannot be sure that we will remain profitable for any substantial period of time.

We have limited experience marketing and selling our solution.

We began commercializing our solution and the Zephyr Valve in the United States in 2018 and, through our predecessors, in the European Union (the "EU") and other European countries in 2003. Our limited commercialization experience and limited number of approved or cleared products make it difficult to evaluate our current business and predict our future prospects. These factors also make it difficult for us to forecast our future financial performance and growth, and such forecasts are subject to a number of uncertainties, including our ability to successfully complete clinical trials and obtain pre-market approval or 510(k) clearance by the FDA for future planned products in the United States or in key international markets. Our commercialization efforts will depend on the efforts of our management and sales team, our third-party suppliers, physicians and hospitals, and general economic conditions, among other factors, including the following:

- the effectiveness of our marketing and sales efforts in the United States and internationally;

- our success in educating physicians and patients about the benefits, administration and use of the Zephyr Valves;
- the acceptance by physicians, patients and payors of the safety and effectiveness of the Zephyr Valves, including the long-term data;
- our third-party suppliers' ability to supply the components of the Zephyr Valves in a timely manner, in accordance with our specifications and in compliance with applicable regulatory requirements, and to remain in good standing with regulatory agencies;
- the impact of any public health crisis, such as COVID-19, on our business, financial condition and results of operations;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing therapies;
- our ability to obtain, maintain and enforce our intellectual property rights in and to the Zephyr Valves;
- the emergence of competing technologies and other adverse market developments, and our need to enhance the Zephyr Valves or develop new products to maintain market share in response to such competing technologies or market developments;
- our ability to raise additional capital on acceptable terms, or at all, if needed to support the commercialization of the Zephyr Valves; and
- our ability to achieve and maintain compliance with all regulatory requirements applicable to the Zephyr Valves.

If our assumptions regarding the risks and uncertainties we face, which we use to plan our business, are incorrect or change due to circumstances in our business or our markets, or if we do not address these risks successfully, it will negatively affect our business, financial condition and results of operations.

We currently rely on a single product, the Zephyr Valve, which can only be marketed for limited indications, and if we are not successful in commercializing the Zephyr Valve, our business, financial condition and results of operations will be negatively affected.

Our business currently depends entirely on our ability to successfully commercialize the Zephyr Valve, as well as our overall solution, in a timely manner. We have no other therapeutic products currently approved for sale in the United States and we may never be able to develop additional marketable products or enhancements to the Zephyr Valve solution. Currently, our solution is only available to treat patients with severe emphysema in the United States and additional limited indications internationally where we have obtained the necessary regulatory approvals, certification or clearances. Therefore, we are dependent on widespread market adoption of our solution for this limited use-case and we will continue to be dependent on this use-case for the foreseeable future. There can be no assurance that our solution will gain a substantial degree of market acceptance among specialty physicians, patients or healthcare providers. Our failure to successfully increase sales of our solution or develop solutions that address forms of COPD beyond severe emphysema and obtain any necessary regulatory approvals, certification or clearances in connection therewith could negatively affect our business, financial condition and results of operations.

Our success depends in large part on the success of the Zephyr Valve. If we are unable to successfully market and sell the Zephyr Valves, as well as our overall solution, to patients with severe emphysema, it will negatively affect our business, financial condition and results of operations.

Our success will depend on our ability to bring awareness to our solution, and the Zephyr Valve in particular, and educate hospitals and physicians regarding the benefits of our solution over existing products and services and to encourage those parties to recommend our solution to their patients. Sales of Zephyr Valves and delivery catheters accounted for most of our revenue for the six months ended June 30, 2024 and June 30, 2023 and we expect that sales of Zephyr Valves and delivery catheters will continue to account for most of our revenue going forward. We do not know if our solution will be successful over the long term. Moreover, market acceptance may be hindered if physicians are not presented with compelling data demonstrating the efficacy of our solution compared to alternative procedures and technologies. Any studies we, or third parties which we sponsor, may conduct comparing our solution with alternative treatments for severe emphysema will be expensive, time consuming and may not yield positive results. Additionally, adoption will be directly influenced by a number of financial factors, including the ability of providers to obtain sufficient reimbursement from payors for deploying our solution. The safety, efficacy, performance and cost-effectiveness of our solution, on a stand-alone basis and relative to competing treatments and services, will determine the willingness of payors to cover the procedure. While we have established positive coverage policies with major national private payors, such as Aetna, Anthem Blue Cross Blue Shield, Blue Cross Blue Shield of Michigan, Humana, Health Care Service Corporation, and Highmark, other commercial payors, including other plans in the Blue Cross Blue Shield family of plans, do not currently consider our solution medically necessary. No matter the level of coverage by the commercial payor, each patient is generally considered on a case-by-case basis. In addition, Medicare, currently without a public coverage policy, covers our solution for patients when medically necessary on a case-by-case basis. Physicians may be reluctant to recommend our solution to patients covered by such plans with no specific policies because of the uncertainty surrounding reimbursement, rates and the administrative burden of interfacing with patients to answer their questions and support their efforts to obtain adequate reimbursement for our solution. If physicians do not adopt and recommend our solution, it will negatively affect our business, financial condition and results of operations.

Our business is dependent on hospital, physician and patient adoption of our solution as a treatment for severe emphysema. If hospitals, physicians or patients are unwilling to change current practices to adopt our solution, it will negatively affect our business, financial condition and results of operations.

Our primary strategy to grow our revenue is to take a stepwise approach to market development across key stakeholders in severe emphysema treatment, such as hospitals, physicians and patients. To succeed, our sales force must build deep relationships with pulmonary physicians to encourage them and their hospitals to develop emphysema centers of excellence, where physicians are instructed in the workup of advanced COPD and performance of bronchoscopic lung volume reduction using our solution. In addition, we utilize direct-to-patient marketing initiatives to increase demand through patient empowerment. While the number of hospitals incorporating our solution has increased in recent years, there is a significant group of hospitals and physicians who have not yet adopted our solution, and additional hospitals and physicians may choose not to adopt our solution for a number of reasons, including:

- inadequate recruiting or training of talented sales force in existing and new markets to facilitate outreach and further adoption and awareness of Zephyr Valve;
- lack of experience with our solution and the Zephyr Valve as a treatment alternative;
- the failure of key opinion leaders to continue to provide recommendations regarding the Zephyr Valve, or to assure physicians, patients and healthcare payors of the benefits of the Zephyr Valve as an attractive alternative to other treatment options;
- perceived inadequacy of evidence supporting clinical benefits or cost-effectiveness of our solution over existing alternatives;

- a perception among some physicians of patients' inability to tolerate the procedure required to implant our solution;
- liability risks generally associated with the use of new products and procedures;
- the training required to use new products;
- lack of availability of adequate third-party payor coverage or reimbursement;
- access to hospital bidding processes;
- a decrease or delay in the number of procedures performed using our solution as a result of a public health crisis, such as COVID-19;
- competing products and alternatives; and
- introduction of other novel alternative therapies to treat severe emphysema.

We focus our sales, marketing and training efforts primarily on pulmonologists. However, physicians from other disciplines, including primary care physicians, as well as other medical professionals, such as nurse practitioners, respiratory technicians, radiologists and community physicians, are often the initial point of contact for patients with severe emphysema.

These physicians and other medical professionals commonly screen and treat patients with severe emphysema, and are likely to recommend medical management, inhaled medications, pulmonary rehabilitation and supplemental oxygen, or more invasive LVRS or lung transplantations. We believe that educating physicians in these disciplines and other medical professionals about the clinical merits and patient benefits of our solution as a minimally invasive treatment for severe emphysema is a key element of increasing the adoption of our solution. If additional physicians or other medical professionals do not adopt, or existing physician customers cease referring patients to, our solution for any reason, including those listed above, our ability to execute our growth strategy will be impaired, and it will negatively affect our business, financial condition and results of operations.

In addition, patients will not qualify for our solution if, among other potential reasons, their lung anatomy has collateral ventilation that does not allow for effective treatment with the Zephyr Valve. Patients may not adopt our solution if they are reluctant to undergo a minimally invasive procedure, if they are worried about potential adverse effects of our solution, such as infection, discomfort or weakness, or if they are unable to obtain adequate third-party coverage or reimbursement.

If we fail to receive access to hospital facilities, our sales may decrease.

In the United States, in order for physicians to use the Zephyr Valve, we expect that the hospital facilities where these physicians treat patients will typically require us to enter into purchasing contracts setting forth the terms and conditions under which the hospital facilities will purchase Zephyr Valves. This process can be lengthy and time-consuming and require extensive negotiations and management time, and potentially result in delays and increases to the sales cycle before we can sell the Zephyr Valve to these hospitals. In the European Union, certain institutions may require us to engage in a contract bidding process in the event that such institutions are considering making purchase commitments that exceed specified cost thresholds, which vary by jurisdiction. These processes are only open at certain periods of time, and we may not be successful in the bidding process. If we do not receive access to hospital facilities via these contracting processes or otherwise, or if we are unable to secure contracts or tender successful bids, our sales may decrease, and our operating results may be harmed. Furthermore, we may expend significant effort in these time-consuming processes and still may not obtain a purchase contract from such hospitals.

Use of our solution requires appropriate physician training, and inadequate training may lead to negative patient outcomes and negatively affect our business, financial condition and results of operations.

The successful implantation of the Zephyr Valve depends in part on the training and skill of the physician performing the procedure and on adherence to appropriate patient selection and proper techniques provided in training sessions conducted by our training faculty. For example, we train physicians to ensure correct patient selection and treatment planning using the StratX Platform and Chartis System, and proper placement of the Zephyr Valve. Physicians could experience difficulty with the technique necessary to successfully implant the valve and may not achieve the technical competency necessary to complete the training program, or they could fail to properly learn how to interpret our StratX Platform or Chartis System. Moreover, physicians rely on their previous medical training and experience when using our solution, and we cannot guarantee that all such physicians will have the necessary skills to properly identify ideal candidates and to perform the procedure. We do not control which physicians use our solution or how much training they receive, and physicians who have not completed our training sessions may nonetheless attempt to use our solution. If physicians implant the Zephyr Valve incorrectly, or do so in a manner that is inconsistent with its labeled indications, with components that are not our products, in patients who are not good candidates, or without adhering to or completing our training sessions, their patient outcomes may not be consistent with the outcomes achieved in our clinical trials. This result may negatively impact the perception of patient benefit and safety, and limit adoption of our solution as a treatment for severe emphysema and our products that facilitate the procedure, which will negatively affect our business, financial condition and results of operations.

In addition, we may experience difficulty growing the number of physicians who complete our training program if patient demand is low, if the length of time necessary to train each physician is longer than expected, if the capacity of our commercial organization to train physicians is less than expected or if we are unable to sufficiently grow our sales force. All these events would lead to fewer trained physicians qualified to implant the Zephyr Valve, which could negatively affect our business, financial condition and results of operations.

Use of the Zephyr Valve involves risks and may result in complications, including pneumothorax or death, and is contraindicated in certain patients, which may limit adoption and negatively affect our business, financial condition and results of operations.

The most common serious complications relating to the use of the Zephyr Valve include pneumothoraces, worsening of COPD symptoms, hemoptysis, pneumonia, dyspnea, respiratory failure and, in rare cases, death. Pneumothoraces occur when a lung collapses due to an air leak inside the lung and may result from rapid shifts in air volume in the chest as the target lobe deflates and the neighboring lobe expands following the Zephyr Valve treatment. A pneumothorax typically requires placement of a chest tube to manage the air leak. While most pneumothoraces can be readily managed with standard medical care, in rare cases they can be life-threatening, particularly if left untreated. In the event the pneumothorax does not resolve with standard management, one or more valves can be removed to re-inflate the lung; these are typically replaced later when the pneumothorax has resolved.

In our clinical trials, pneumothoraces occurred in 18-34% of patients treated with the Zephyr Valve, and in the LIBERATE study, 17% of the pneumothorax events required no intervention and resolved on their own. Patients who have had their pneumothoraces successfully treated had comparable outcomes to those who did not experience a pneumothorax, other than that their hospital stays were extended by approximately a week compared to the three nights for patients without pneumothoraces.

In the LIBERATE study, the majority of pneumothoraces (76%) occurred within three days following a bronchoscopy procedure. During the Treatment Period (day of procedure to 45 days), there were a total of four deaths (3.1%) in the Zephyr Valve Group (which received Zephyr Valves plus medical management) and none in the Control Group (which received medical management alone). Three of the four deaths were deemed by the investigators to be definitely related to treatment with Zephyr Valves and the remaining one was deemed by the investigators to be probably related to treatment with Zephyr Valves. Each patient that died experienced pneumothorax, with three deaths directly attributed to the pneumothorax and the fourth death the result of respiratory failure, after the pneumothorax had resolved. Two of the pneumothorax-related deaths occurred early in the study when patients were being kept in the hospital for one night after the procedure. In order to more closely

monitor patients, the study protocol was subsequently amended to keep patients in the hospital for five nights. Based on the full study data, current practice is to keep patients in the hospital for a minimum of three nights post-treatment. Post-hoc analysis has helped to identify risk factors for the group of patients at a higher risk of having a complex pneumothorax event (complex pneumothorax defined as requiring removal of all valves or resulting in death) should one occur. Such high-risk patients include those who are not treated in the most diseased lobe and have greater than 60% destruction of the untreated lung. All four patients who experienced a pneumothorax and died were within this high-risk group. This learning is incorporated in our physician training program for physicians to identify such high-risk patients and to consider alternative targets or other risk mitigation strategies. During the Longer-Term Period (46 days after procedure to 12 months), there was one death (0.8%) in the Zephyr Valve Group from a COPD exacerbation, deemed by the investigators not to be related to treatment with Zephyr Valves, and one cardiac arrhythmia-related death in the Control Group (1.6%).

Outside of clinical trials, patients treated with the Zephyr Valve have also experienced serious complications, including pneumothoraces and death related to the Zephyr Valve.

Serious complications as a result of treatment with Zephyr Valves, and any increase in the rate of complications in or outside of clinical trials, could cause doctors, hospitals and patients to limit adoption of our solution and subject us to costly litigation, require us to pay substantial amounts of money to patients, delay, negatively impact or end our opportunity to receive or maintain regulatory approval to market our products, or require us to suspend or abandon our commercialization efforts, which may negatively impact adoption as well as our business, financial condition and results of operations. Even in a circumstance in which we do not believe that a complication is related to the Zephyr Valve or treatment with the Zephyr Valve, the investigation into the circumstance may be time-consuming or inconclusive and may interrupt our sales efforts or impact and limit the type of regulatory approvals the Zephyr Valve receives or maintains and any related claims may negatively impact adoption as well as our business, financial condition and results of operations. Moreover, perceptions regarding the safety of the Zephyr Valve could be affected even if such complications are unrelated to the Zephyr Valve or treatment with the Zephyr Valve.

Further, our current products are contraindicated, and therefore should not be used, in certain patients, including those for whom bronchoscopic procedures are contraindicated, with evidence of active pulmonary infection, with known allergies to Nitinol (nickel-titanium) or its constituent metals (nickel or titanium) or silicone, who have not quit smoking, or with large bullae encompassing greater than 30% of either lung, and such contraindication may limit adoption and, as a result, negatively impact our business, financial condition and results of operations.

If we are unable to achieve and maintain adequate levels of coverage or reimbursement for our solution, or any future products we may seek to commercialize, or if patients are left with significant out-of-pocket costs, our commercial success may be severely hindered.

We currently derive substantially all of our revenue from the sale of our products to hospitals and distributors and expect this to continue for the foreseeable future. We primarily sell Zephyr Valves through a direct sales force that primarily engages with pulmonologists in the United States, Europe and Asia Pacific. Hospitals typically bill various third-party payors to cover all or a portion of the costs and fees associated with the procedures in which our solution is used and bill patients for any deductibles or co-payments. As of June 30, 2024, commercial payors such as Aetna, Humana, and many of the largest Blue Cross Blue Shield plans including Anthem, Health Care Service Corporation, BCBS Michigan, and Highmark have issued positive coverage policies for endobronchial valve procedures. United Healthcare removed the endobronchial valve codes from their non-covered list, and as such no longer considers the procedure unproven or experimental. Other commercial payors, including other plans in the Blue Cross Blue Shield family of plans, do not yet consider our solution medically necessary. Medicare, currently without a public coverage policy, covers our solution for patients when medically necessary on a case-by-case basis, and other commercial insurers not described above are approving prior authorization requests on a case-by-case basis.

The Centers for Medicare & Medicaid Services (“CMS”) have established guidelines for the coverage and reimbursement of certain products and procedures by Medicare. In general, in order to be reimbursed by Medicare, a healthcare procedure furnished to a Medicare beneficiary must be reasonable and necessary for the diagnosis or

treatment of an illness or injury, or to improve the functioning of a malformed body part. The methodology for determining coverage status and the amount of Medicare reimbursement varies based upon, among other factors, the setting in which a Medicare beneficiary received healthcare products and services. Any changes in federal legislation, regulations and policy affecting CMS coverage and reimbursement relative to the procedure using our products could have a material effect on our performance. While no national coverage determination ("NCD") or local coverage determination ("LCD") exists for endobronchial valves currently, CMS could develop an NCD, or one or more Medicare contractors could develop an LCD that either restricts coverage or restricts the patient population deemed appropriate for the treatment.

Physicians that insert the Zephyr Valve, or the hospitals for which they work, may be subject to reimbursement claim denials upon submission of the claim. Physicians or hospitals may also be subject to recovery of overpayments if a payor makes payment for the claim and subsequently determines that the payor's coding, billing or coverage policies were not followed. Whenever possible, prior authorization for coverage for the procedure is recommended before the procedure is performed. When prior authorization is not obtained or not allowed, and the procedure is performed and not covered by third-party payors, physicians or hospitals typically directly bill patients enrolled with these third-party payors for the costs and fees associated with the procedures in which our products are used. Moreover, because there is often no separate reimbursement for supplies used in surgical procedures, the additional cost associated with the use of our solution can affect the profit margin of the hospital or surgery center where the procedure is performed. Some of our target physicians and hospitals may be unwilling to adopt our products in light of the additional associated cost. Further, any decline in the amount payors are willing to reimburse physicians and hospitals could make it difficult for existing physicians and hospitals to continue using or to adopt our solution and could create additional pricing pressure for us. If we are forced to lower the price we charge for our solution, our gross margins will decrease, which will negatively affect our business, financial condition and results of operations.

Outside of the United States, reimbursement levels vary significantly by country and by patient. Reimbursement is obtained from a variety of sources, including government sponsors, hospital budgets, or private health insurance plans, or combinations thereof. We have established market access in countries across Europe and Asia Pacific, including Australia, Austria, Belgium, France, Germany, Japan, the Netherlands, the United Kingdom (the "UK"), Scotland, Switzerland and South Korea, and other countries. Even if we succeed in bringing our products to market in additional foreign countries, uncertainties regarding future healthcare policy, legislation and regulation, as well as private market practices, could affect our ability to sell our products in commercially acceptable quantities at acceptable prices. For example, in some markets, such as France, coverage and reimbursement are currently available for procedures using our products but are subject to constraints such as price controls or unit sales limitations.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, no uniform policy of coverage and reimbursement for procedures using our solution exists among third-party payors. Therefore, coverage and reimbursement for procedures using our products can differ significantly from payor to payor. Payors continually review new and existing technologies for possible coverage and can, without notice, deny or reverse coverage for new or existing products and procedures. There can be no assurance that third-party payor policies will provide coverage for procedures in which our products are used. If we are not successful in reversing existing non-coverage policies, if third-party payors that currently cover or reimburse our products and related procedures reverse or limit their coverage in the future or if other third-party payors issue similar policies, this will negatively affect our business, financial condition and results of operations. Further, coverage policies and third-party payor reimbursement rates may change at any time. Therefore, even if favorable coverage is established on one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Further, we believe that future coverage and reimbursement may be subject to increased restrictions, such as additional prior authorization requirements, both in the United States and in international markets. Third-party coverage and reimbursement for procedures using our solution or any of our products in development for which we may receive regulatory approval may not be available or adequate in either the United States or international markets, which will negatively affect our business, financial condition and results of operations.

Third-party payors and physicians who do not cover or use the Zephyr Valve may require additional clinical data prior to maintaining coverage of or adopting the Zephyr Valve.

Our success depends on physician and third-party payor acceptance of our solution as an effective treatment option for patients with severe emphysema. If physicians or payors do not find our body of published clinical evidence and data compelling or wish to wait for additional studies, they may choose not to use or provide coverage and reimbursement for our solution.

In addition, the long-term effects of use of the Zephyr Valve to treat severe emphysema are not yet known. Certain physicians, hospitals and payors may prefer to see longer-term safety and efficacy data published than we have produced. Further, we cannot provide assurance that any data that we or others may generate in the future will be consistent with that observed in our existing clinical studies.

If we fail to retain marketing and sales personnel and, as we grow, fail to increase our marketing and sales capabilities or develop broad awareness of our solution in a cost-effective manner, we may not be able to generate revenue growth.

We have limited experience marketing and selling our solution. We currently rely on our direct sales force to sell our solution in targeted geographic regions and distributors in certain regions outside the United States, and any failure to maintain and grow our direct sales force will negatively affect our business, financial condition and results of operations. The members of our direct sales force are highly trained and possess substantial technical expertise, which we believe is critical in increasing adoption of our solution. The members of our U.S. sales force are at-will employees. The loss of these personnel to competitors, or otherwise, will negatively affect our business, financial condition and results of operations. If we are unable to retain our direct sales force personnel or replace them with individuals of equivalent technical expertise and qualifications, or if we are unable to successfully instill such technical expertise in replacement personnel, it may negatively affect our business, financial condition and results of operations.

In order to generate future growth, we plan to continue to expand and leverage our sales and marketing infrastructure to increase the number of customers and emphysema centers of excellence. Identifying and recruiting qualified sales and marketing personnel and training them on our solution, on applicable federal and state laws and regulations and on our internal policies and procedures requires significant time, expense and attention. It often takes several months or more before a sales representative is fully trained and productive. Our sales force may subject us to higher fixed costs than those of companies with competing techniques or products that utilize independent third parties, which could place us at a competitive disadvantage. It will negatively affect our business, financial condition and results of operations if our efforts to expand and train our sales force do not generate a corresponding increase in revenue, and our higher fixed costs may slow our ability to reduce costs in the face of a sudden decline in demand for our solution. Any failure to hire, develop and retain talented sales personnel, to achieve desired productivity levels in a reasonable period of time or timely reduce fixed costs, could negatively affect our business, financial condition and results of operations. Our ability to increase our customer base and achieve broader market acceptance of our solution will depend to a significant extent on our ability to expand our marketing efforts. We plan to dedicate significant resources to our marketing programs. It will negatively affect our business, financial condition and results of operations if our marketing efforts and expenditures do not generate a corresponding increase in revenue. In addition, we believe that developing and maintaining broad awareness of our solution in a cost-effective manner is critical to achieving broad acceptance of our solution and expanding domestically and internationally. Promotion activities may not generate patient or physician awareness or increase revenue, and even if they do, any increase in revenue may not offset the costs and expenses we incur in building our brand. If we fail to successfully promote, maintain and protect our brand, we may fail to attract or retain the physician acceptance necessary to realize a sufficient return on our brand building efforts, or to achieve the level of brand awareness that is critical for broad adoption of our solution.

We have limited long-term data regarding the safety and effectiveness of our solution, including the Zephyr Valve. The only safety and effectiveness data of our solution, including the Zephyr Valve, is limited to one year

following placement and we are required to conduct extension studies to follow up on safety and effectiveness out to five years.

Although we have demonstrated the safety, effectiveness and clinical advantages of our solution in multiple clinical trials in approximately 450 patients selected using the Chartis System, the Zephyr Valve is still a relatively new treatment for severe emphysema. The long-term effects of using our solution in a large number of patients are currently being studied, and the results of short-term clinical use of such products do not necessarily predict long-term clinical benefits or reveal long-term adverse effects. We were required to conduct the LIBERATE extension study to follow up on safety and effectiveness out to five years. After the completion of the one-year follow up, 115 Zephyr Valve patients and 47 crossover patients (162 total patients) entered the LIBERATE extension study. Patient follow up and data analysis for this extension study has been completed. Our ability to interpret the data from the LIBERATE extension study may be limited by the fact that the matched control group exited the study after one year. In addition to the LIBERATE extension study, registry studies evaluating the safety and effectiveness of our solution out to three years in the United States, France and Japan are ongoing, with a total enrollment of over 300 patients. The results of clinical trials of our solution conducted to date and ongoing or future studies and trials of our current, planned or future products may not be predictive of the results of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Our interpretation of data and results from our clinical trials do not ensure that we will achieve similar results in future clinical trials in other patient populations. In addition, pre-clinical and clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their products performed satisfactorily in pre-clinical studies and earlier clinical trials have nonetheless failed to replicate results in later clinical trials and subsequently failed to obtain marketing approval. Products in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through nonclinical studies and earlier clinical trials.

The continuing development of our products depends upon our maintaining strong working relationships with physicians.

The research, development, marketing and sale of our current products and potential new and improved products or future product indications for which we receive regulatory clearance, certification or approval depend upon our maintaining working relationships with physicians. We rely on these professionals to provide us with considerable knowledge and experience regarding the development, marketing and sale of our products. Physicians assist us in clinical trials and in marketing, and as researchers, product consultants and public speakers. If we cannot maintain our strong working relationships with these professionals and continue to receive their advice and input, the development and marketing of our products could suffer, which could negatively affect our business, financial condition and results of operations. At the same time, the medical device industry's relationship with physicians is under increasing scrutiny by the U.S. Department of Health and Human Services Office of Inspector General ("OIG"), the U.S. Department of Justice ("DOJ"), the state attorneys general and other foreign and domestic government agencies. Our failure to comply with requirements governing the industry's relationships with physicians or an investigation into our compliance by the OIG, the DOJ, state attorneys general and other government agencies, could negatively affect our business, financial condition and results of operations. Additional information regarding the laws impacting our relationships with physicians and other healthcare professionals can be found below under "Risks Related to Government Regulation and Our Industry."

We rely on third parties to perform certain aspects of the CT scan analysis within the StratX Platform.

We rely on third-party service providers to upload and analyze CT scan data on the StratX Platform. In order to make the StratX Platform available to physicians, we contract with a third-party cloud service. This third-party cloud service enables physicians to upload CT scan data while removing protected health information ("PHI") of patients from that data, in case the physicians have, inadvertently, not removed the PHI themselves. We also contract with additional third-party service providers to analyze the CT scan data using their proprietary software, and provide quantitative results via an easy-to-read StratX Lung Report. The StratX Lung Report is then made available to physicians in the third-party cloud service.

This service is critical and there are relatively few alternatives. These third-party service providers may be unwilling or unable to provide the necessary services reliably and at the levels we anticipate or that are required by the market. While these third-party service providers have generally met our demand for their services on a timely basis in the past, we cannot guarantee that they will in the future be able to meet our demand for their services, either because of acts of nature, the nature of our agreements or potential disputes with those service providers or our relative importance to them as a customer, and our service providers may decide in the future to discontinue or reduce the level of business they conduct with us. If we are required to change service providers for any reason, including due to any change in or termination of our relationships with these third parties, we may lose sales, experience delays, incur increased costs or otherwise experience impairment to our customer relationships. We cannot guarantee that we will be able to establish alternative relationships on similar terms, without delay or at all.

We depend on a limited number of single-source suppliers to manufacture our products, which makes us vulnerable to supply shortages and price fluctuations that could negatively affect our business, financial condition and results of operations.

We rely on single-source suppliers for the components, sub-assemblies and materials for our products. These components, sub-assemblies and materials are critical and there are no or relatively few alternative sources of supply. These single-source suppliers may be unwilling or unable to supply the necessary materials and components or manufacture and assemble our products reliably and at the levels we anticipate or that are required by the market. While our suppliers have generally met our demand for their products and services on a timely basis in the past, we cannot guarantee that they will in the future be able to meet our demand for their products, either because of acts of nature, the nature of our agreements with those manufacturers or our relative importance to them as a customer, and our suppliers may decide in the future to discontinue or reduce the level of business they conduct with us. If we are required to change suppliers due to any change in or termination of our relationships with these third parties, or if our suppliers are unable to obtain the materials they need to produce our products at consistent prices or at all, we may lose sales, experience manufacturing or other delays, incur increased costs or otherwise experience impairment to our customer relationships. We cannot guarantee that we will be able to establish alternative relationships on similar terms, without delay or at all.

We have not qualified or obtained necessary regulatory approvals for additional suppliers for most of these components, sub-assemblies and materials, and we do not carry a significant inventory of these items. While we believe that alternative sources of supply may be available, we cannot be certain whether they will be available if and when we need them, or that any alternative suppliers would be able to provide the quantity and quality of components and materials that we would need to manufacture our products if our existing suppliers were unable to satisfy our supply requirements. To utilize other supply sources, we would need to identify and qualify new suppliers to our quality standards and obtain any additional regulatory approvals required to change suppliers, which could result in manufacturing delays and increase our expenses.

Although we require our third-party suppliers to supply us with components that meet our specifications and comply with applicable provisions of the FDA's Quality System Regulation ("QSR") and other applicable legal and regulatory requirements in our agreements and contracts, and we perform incoming inspection, testing or other acceptance activities to ensure the components meet our requirements, there is a risk that our suppliers will not always act consistent with our best interests, and may not always supply components that meet our requirements or supply components in a timely manner.

We have limited experience manufacturing our products in significant commercial quantities and we face manufacturing risks that may adversely affect our ability to manufacture our products, reduce our gross margins and negatively affect our business, financial condition and results of operations.

Our business strategy depends on our ability to manufacture our current and future products in sufficient quantities and on a timely basis to meet customer demand, while adhering to product quality standards, complying with regulatory quality system requirements and managing manufacturing costs. We have a facility located in Redwood City, California, where we assemble, inspect, package, release and ship our products. We currently produce the Zephyr Valve and Chartis System at this facility, and we do not have redundant facilities. We also store finished

goods at secondary facilities in Redwood City, California, Memphis, Tennessee and the Netherlands. If these facilities suffer damage, or a force majeure event, this could materially impact our ability to operate.

We are also subject to numerous other risks relating to our manufacturing capabilities, including:

- quality and reliability of components, sub-assemblies and materials that we source from third-party suppliers, that are required to meet our quality specifications, many of whom are our single source suppliers for the products they supply;
- our inability to secure components, sub-assemblies and materials in a timely manner, in sufficient quantities or on commercially reasonable terms;
- our inability to maintain compliance with quality system requirements or pass regulatory quality inspections;
- disruptions in our production schedule and ability to manufacture and assemble products;
- our failure to increase production capacity or volumes to meet demand;
- our inability to design or modify production processes to enable us to produce future products efficiently or implement changes in current products in response to design or regulatory requirements; and
- difficulty identifying and qualifying, and obtaining new regulatory approvals, for alternative suppliers for components in a timely manner.

These risks are likely to be exacerbated by our limited experience with our current products and manufacturing processes. As demand for our solution increases, we will have to invest additional resources to purchase components, sub-assemblies and materials, hire and train employees and enhance our manufacturing processes. If we fail to increase our production capacity efficiently, we may not be able to fill customer orders on a timely basis, our sales may not increase in line with our expectations and our operating margins could fluctuate or decline. In addition, even if future products in development share product features, components, sub-assemblies and materials with our existing products, the manufacture of these products may require modification of our current production processes or unique production processes, the hiring of specialized employees, the identification of new suppliers for specific components, sub-assemblies and materials or the development of new manufacturing technologies. It may not be possible for us to manufacture these products at a cost or in quantities sufficient to make these products commercially viable or to maintain current operating margins, all of which will negatively affect our business, financial condition and results of operations.

Our results of operations will be materially harmed if we are unable to accurately forecast customer demand for our solution and manage our inventory.

To ensure adequate inventory supply, we must forecast inventory needs and manufacture the Zephyr Valve and Chartis System based on our estimates of future demand for our solution. Our ability to accurately forecast demand for our solution could be negatively affected by many factors, including our failure to accurately manage our expansion strategy, product introductions by competitors, an increase or decrease in customer demand for our solution or for products of our competitors, our failure to accurately forecast customer acceptance of new products, unanticipated changes in general market conditions or regulatory matters and weakening of economic conditions or consumer confidence in future economic conditions. Inventory levels in excess of customer demand may result in inventory write-downs or write-offs, which would cause our gross margin to be adversely affected and could impair the strength of our brand. Conversely, if we underestimate customer demand for our solution, our internal manufacturing team may not be able to deliver products to meet our requirements, and this could result in damage to our reputation and customer relationships. In addition, if we experience a significant increase in demand, additional supplies of raw materials or additional manufacturing capacity may not be available when required on terms that are

acceptable to us, or at all, or suppliers or may not be able to allocate sufficient capacity in order to meet our increased requirements, which will negatively affect our business, financial condition and results of operations.

We seek to maintain sufficient levels of inventory in order to protect ourselves from supply interruptions. As a result, we are subject to the risk that a portion of our inventory will become obsolete or expire, which could have a material adverse effect on our earnings and cash flows due to the resulting costs associated with the inventory impairment charges and costs required to replace such inventory.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide.

Our quarterly and annual operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. Accordingly, the results of any one quarter or period should not be relied upon as an indication of future performance. Our quarterly and annual operating results may fluctuate as a result of a variety of factors, many of which are outside our control and, as a result, may not fully reflect the underlying performance of our business. These fluctuations may occur due to a variety of factors, many of which are outside of our control, including, but not limited to:

- the level of demand for our products and any future products, which may vary significantly;
- expenditures that we may incur to acquire, develop or commercialize additional products and technologies;
- the timing and cost of obtaining regulatory approvals, certification or clearances for planned or future products or indications;
- unanticipated pricing pressures;
- the rate at which we grow our sales force and the speed at which newly hired salespeople become effective, and the cost and level of investment therein;
- our ability to expand the geographic reach of our sales force;
- the rate at which treating centers expand procedural capacity as they build a bronchoscopic lung volume reduction program;
- the degree of competition in our industry and any change in the competitive landscape of our industry, including consolidation among our competitors or future partners;
- coverage and reimbursement policies with respect to our products, and potential future products that compete with our products;
- the timing and success or failure of pre-clinical studies or clinical trials for our products or any future products we develop or competing products;
- positive or negative coverage in the media or clinical publications of our products or products of our competitors or our industry;
- the timing of customer orders or medical procedures using our products and the number of available selling days in any quarterly period, which can be impacted by holidays, the mix of products sold and the geographic mix of where products are sold, including any related foreign currency impact;
- seasonality, including possible seasonal slowing of demand for our products in the beginning and end of the year and summer months based on the elective nature of procedures performed using our products, and which may become more pronounced in the future as our business grows;

- the impact of a public health crisis, such as COVID-19, on our business, financial condition and results of operations;
- the timing and cost of, and level of investment in, research, development, licenses, regulatory approval, commercialization activities, acquisitions and other strategic transactions, or other significant events relating to our products, which may change from time to time;
- the cost of manufacturing our products, which may vary depending on the quantity of production and the terms of our agreements with third-party suppliers and manufacturers which are subject to macroeconomic factors including inflation;
- the number of patients treated with Zephyr Valves, including the average number of Zephyr Valves used for a patient, pricing, discounts and incentives; and
- future accounting pronouncements or changes in our accounting policies.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Further, our historical results are not necessarily indicative of results expected for any future period, and quarterly results are not necessarily indicative of the results to be expected for the full year or any other period, and accordingly should not be relied upon as indicative of future performance.

This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, it will negatively affect our business, financial condition and results of operations.

The sizes of the markets for our current and future products have not been established with precision and may be smaller than we estimate and may decline. Certain patients may not have regions of the lung with little to no collateral ventilation, making them poor candidates for the Zephyr Valve. In addition, if the overall rate of smokers continues to decline, this may eventually decrease the number of patients suffering from COPD and emphysema and, accordingly, who would benefit from our solution.

Our estimates of the annual total addressable markets for our current solution and products under development are based on a number of internal and third-party estimates, including, without limitation, the number of patients with severe emphysema treatable by our solution and the assumed prices at which we can sell our solution in markets that have not yet been established. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors.

For example, certain of these patients may not have regions of the lung with little to no collateral ventilation, making them poor candidates for the Zephyr Valve. As a result, our estimates of the annual total addressable market for our current or future products may prove to be incorrect.

Further, cigarette smoking is one of the leading causes of COPD and emphysema. It is estimated that smoking accounts for as many as 80% of COPD-related deaths and 38% of the nearly 16 million adults in the United States diagnosed with COPD report being current smokers. The overall rate of smoking among the U.S. adult population has been steadily declining from 42.4% in 1965 to a record low of 13.7% in 2018 and there are increased efforts to decrease the rate of smoking globally. If the overall rate of smokers continues to decline, this may eventually decrease the number of patients suffering from COPD and emphysema and, accordingly, who would benefit from our solution.

If the actual number of patients who would benefit from our solution, the price at which we can sell future products, or the annual total addressable market for our solution is smaller than we have estimated, it may impair our sales growth and negatively affect our business, financial condition and results of operations.

Failure of an information technology system, process, or site could negatively affect our business, financial condition and results of operations.

We depend on our information technology systems for the efficient functioning of our business, including the manufacture, distribution, and maintenance of our products, as well as for accounting, data storage, compliance, purchasing, and inventory management. We also depend on the information technology systems of third parties for the analysis, data storage, and communication associated with the StratX Platform. We currently do not have redundant information technology systems. Our information technology systems, and those of third parties, may be subject to computer viruses, ransomware or other malware, attacks by computer hackers, failures during the process of upgrading or replacing software, databases or components thereof, power outages, damage or interruption from fires or other natural disasters, hardware failures, telecommunication failures and user errors, among other malfunctions. We, or the third parties we rely upon, could be subject to an unintentional event that involves a third party gaining unauthorized access to our or its systems, which could disrupt our operations, corrupt our data or result in release of our confidential information. Technological interruptions could disrupt our operations, including our ability to timely ship and track product orders, project inventory requirements, manage our supply chain and otherwise adequately service our customers or disrupt our customers' ability use our products for treatments.

Moreover, a disruption in access to the system that controls the StratX Platform would prevent physicians using our solution from receiving the StratX Lung Report indicating whether their patients are good candidates for the Zephyr Valve. In the event we experience significant disruptions, we may be unable to repair our systems in an efficient and timely manner. Accordingly, such events may disrupt or reduce the efficiency of our entire operation and negatively affect our business, financial condition, and results of operations. Currently, we carry business interruption coverage and cyber insurance to mitigate certain potential losses but this insurance is limited in amount, and we cannot be certain that such potential losses will not exceed our policy limits. We are increasingly dependent on complex information technology to manage our infrastructure. Our information systems require an ongoing commitment of significant resources to maintain, protect and enhance our existing systems. Failure to maintain or protect our information systems and data integrity effectively could negatively affect our business, financial condition, and results of operations.

Litigation against us could be costly and time-consuming to defend and could result in additional liabilities.

We may from time to time be subject to legal proceedings and claims that arise in the ordinary course of business or otherwise, such as claims brought by our customers in connection with commercial disputes and employment claims made by our current or former employees. Claims may also be asserted by or on behalf of a variety of other parties, including government agencies, patients or vendors of our customers, or stockholders. Further, in the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities, and this risk is especially relevant to industries that experience significant stock price volatility. Any litigation involving us may result in substantial costs, operationally restrict our business, and may divert management's attention and resources, which may negatively affect our business, financial condition and results of operations.

We face the risk of product liability claims that would be expensive, divert management's attention and harm our reputation and business. We may not be able to maintain adequate product liability insurance.

Our business exposes us to the risk of product liability claims that are inherent in the testing, manufacturing and marketing of medical devices. This risk exists even if a device is cleared or approved for commercial sale by the FDA and manufactured in facilities licensed and regulated by the FDA or an applicable foreign regulatory authority. The Zephyr Valve is designed to affect, and any future products will be designed to affect, important bodily functions and processes. Any side effects, manufacturing defects, misuse or abuse associated with the Zephyr Valve could result in patient injury or death. The medical device industry has historically been subject to extensive

litigation over product liability claims, and we cannot offer any assurance that we will not face product liability suits. There were procedure-related deaths in our LIBERATE Study and we may be subject to product liability claims if the Zephyr Valve causes, or merely appears to have caused, patient injury or death. In addition, an injury that is caused by the activities of our suppliers, such as those who provide us with components and raw materials, may be the basis for a claim against us. Product liability claims may be brought against us by patients, physicians, or others selling or otherwise coming into contact with the Zephyr Valve, among others. If we cannot successfully defend ourselves against product liability claims, we will incur substantial liabilities and reputational harm. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- costs of litigation;
- distraction of management's attention from our primary business;
- the inability to commercialize our solution or new products;
- decreased demand for our products;
- damage to our business reputation;
- product recalls or withdrawals from the market;
- withdrawal of clinical trial participants;
- substantial monetary awards to patients or other claimants; or
- loss of sales.

While we may attempt to manage our product liability exposure by proactively recalling or withdrawing from the market any defective products, any recall or market withdrawal of our products may delay the supply of those products to our customers and may impact our reputation. We can provide no assurance that we will be successful in initiating appropriate market recall or market withdrawal efforts that may be required in the future or that these efforts will have the intended effect of preventing product malfunctions and the accompanying product liability that may result. Such recalls and withdrawals may also be used by our competitors to harm our reputation for safety or be perceived by patients as a safety risk when considering the use of our solution, either of which could negatively affect our business, financial condition and results of operations.

Our insurance policies are expensive and protect us only from some business risks, which leaves us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. Although we have product liability and clinical study liability insurance that we believe is appropriate, this insurance is subject to deductibles and coverage limitations. Our current product liability insurance may not continue to be available to us on acceptable terms, if at all, and, if available, coverage may not be adequate to protect us against any future product liability claims. If we are unable to obtain insurance at an acceptable cost or on acceptable terms or otherwise protect against potential product liability claims, we could be exposed to significant liabilities. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could negatively affect our business, financial condition and results of operations. We do not carry specific hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended. Additionally, we do not carry cyber insurance, which may expose us to certain potential losses for damages or result in penalization with fines in an amount exceeding our resources.

We also expect that operating as a public company will make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, on our board committees or as executive officers. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would negatively affect our business, financial condition and results of operations.

Our indebtedness may limit our flexibility in operating our business and negatively affect our business, financial condition, results of operations and competitive position.

In March 2021, we entered into an Amended and Restated Loan and Security Agreement (as amended, the "CIBC Agreement") with Canadian Imperial Bank of Commerce ("CIBC"), under which we have borrowed $37.0 million in debt financing as of June 30, 2024. See the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources; Plan of Operation—CIBC Loan" and the notes to our unaudited interim condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

In order to service this indebtedness and any additional indebtedness we may incur in the future, we need to generate cash from our operating activities. Our ability to generate cash is subject, in part, to our ability to successfully execute our business strategy, as well as general economic, financial, competitive, regulatory and other factors beyond our control. We cannot assure you that our business will be able to generate sufficient cash flow from operations or that future borrowings or other financings will be available to us in an amount sufficient to enable us to service our indebtedness and fund our other liquidity needs. To the extent we are required to use cash from operations or the proceeds of any future financing to service our indebtedness instead of funding working capital, capital expenditures or other general corporate purposes, we will be less able to plan for, or react to, changes in our business, industry and in the economy generally. This will place us at a competitive disadvantage compared to our competitors that have less indebtedness.

In addition, the CIBC Agreement contains, and any agreements evidencing or governing other future indebtedness may contain, certain covenants that limit our ability to engage in certain transactions that may be in our long-term best interests. Subject to certain limited exceptions, these covenants limit our ability to, among other things:

- convey, sell, lease, transfer, assign, dispose of or otherwise make cash payments consisting of all or any part of our business or property;
- effect certain changes in our business, management, ownership or business locations;
- merge or consolidate with, or acquire all or substantially all of the capital stock or assets of, any other company;
- create, incur, assume or be liable for any additional indebtedness, or create, incur, allow or permit to exist any additional liens;
- pay cash dividends on, make any other distributions in respect of, or redeem, retire or repurchase, any shares of our capital stock;
- make certain investments;
- enter into transactions with our affiliates; and
- under certain circumstances, settle pending or threatened litigation for greater amounts than are disclosed to CIBC in writing from time to time.

There can be no guarantee that we will not breach these covenants. Our ability to comply with these covenants may be affected by events and factors beyond our control. In the event that we breach one or more covenants, our lender may choose to declare an event of default and require that we immediately repay all amounts outstanding, terminate any commitment to extend further credit and foreclose on the collateral granted to it to collateralize such indebtedness. The occurrence of any of these events could negatively affect our business, financial condition and results of operations.

Our industry is highly competitive, and we may not be able to compete successfully with larger companies, companies with longer operating histories or more established products, or companies with greater resources.

Our industry is subject to rapid change from the introduction of new products and technologies and other activities of industry participants. Our goal is to establish our solution as a standard of care for severe emphysema. Existing treatments include medical management, LVRS, lung transplantation as well as other minimally invasive treatments. The major competitive products include the Spiration Valve System (Olympus Corporation) and the InterVapor System (Broncus Medical, Inc.; not approved for use in the United States). The Spiration Valve System is an endobronchial technology designed to offer patients with severe emphysema a minimally invasive treatment option for lung volume reduction by redirecting air away from diseased areas of the lung to healthier tissue so that patients may breathe easier. Like Zephyr Valves, the Spiration Valve System is indicated to treat patients with heterogeneous emphysema; however, the Spiration Valve System is contraindicated for patients with homogeneous emphysema. The InterVapor System offers a non-surgical and non-implant therapy developed for lung disease including emphysema and lung cancer where vapor ablation is simply the application of heated pure water to tissue. These technologies, other products that are in current clinical trials, new drugs or additional indications for existing drugs could demonstrate better safety, effectiveness, clinical results, lower costs or greater physician and patient acceptance.

We compete, or may compete in the future, against other companies which have longer operating histories, more established products and greater resources, which may prevent us from achieving significant market penetration or improved operating results. These companies enjoy several competitive advantages, including established relationships with pulmonologists who commonly treat patients with emphysema, significantly greater name recognition and significantly greater sales and marketing resources.

In addition to existing competitors, other larger and more established companies may acquire or in-license competitive products and could directly compete with us. These competitors may also try to compete with us on price both directly, through rebates and promotional programs to high volume physicians and coupons to patients, and indirectly, through attractive product bundling with complementary products that offer convenience and an effectively lower price compared to the total price of purchasing each product separately. Larger competitors may also be able to offer greater customer loyalty benefits to encourage repeat use of their products and finance a sustained global advertising campaign to compete with commercialization efforts of our products. Our competitors may seek to discredit our products by challenging our short operating history or relatively limited number of scientific studies and publications. Smaller companies could also launch new or enhanced products and services that we do not offer and that could gain market acceptance quickly. Additionally, certain of our competitors may challenge our intellectual property, may develop additional competing or superior technologies and processes and compete more aggressively and sustain that competition over a longer period of time than we could. Our technologies and products may be rendered obsolete or uneconomical by technological advances or entirely different approaches developed by one or more of our competitors. As more companies develop new intellectual property in our market, there is the possibility of a competitor acquiring patents or other rights that may limit our ability to update our technologies and products which may impact demand for our products.

We have increased the size of our organization and expect to further increase it in the future. If we are unable to manage the anticipated growth, our business, financial condition and results of operations will be negatively affected.

Any growth that we experience in the future will require us to expand our sales personnel and manufacturing operations and general and administrative infrastructure. Future growth will impose significant added

responsibilities on management, including the need to identify, recruit, train and integrate additional employees. Rapid expansion in personnel could mean that less experienced people manufacture, market and sell our solution, which could result in inefficiencies and unanticipated costs, reduced quality and disruptions to our operations. In addition, rapid and significant growth may strain our administrative and operational infrastructure. Our ability to manage our business and growth will require us to continue to improve our operational, financial and management controls, reporting systems and procedures. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy and negatively affect our business, financial condition and results of operations.

As demand for our solution or any of our future products increases, we will need to continue to scale our capacity, expand customer service, billing and systems processes and enhance our internal quality assurance program. We cannot assure you that any increases in scale, related improvements and quality assurance will be successfully implemented or that appropriate personnel will be available to facilitate the growth of our business. Failure to implement necessary procedures, transition to new processes or hire the necessary personnel could result in higher costs of processing data or inability to meet increased demand. If we encounter difficulty meeting market demand, quality standards or physician expectations, our reputation will be harmed and negatively affect our business, financial condition and results of operations.

We expect to continue to incur net losses for the next several years and we expect to require substantial additional capital to finance our planned operations, which may include future equity and debt financings. This additional capital may not be available to us on acceptable terms or at all. Our failure to obtain additional financing when needed on acceptable terms, or at all, could force us to delay, limit, reduce or eliminate our commercialization, sales and marketing efforts, product development programs or other operations.

Since inception, we have incurred significant net losses and expect to continue to incur net losses for the foreseeable future. Since our inception, our operations have been financed primarily through the sale of equity securities, debt financing arrangements and sales of our products. As of June 30, 2024, we had $114.5 million in cash, cash equivalents and marketable securities, and an accumulated deficit of $440.2 million. Based on our current planned operations, we expect our cash, cash equivalents and short-term marketable securities will enable us to fund our operating expenses for at least the next twelve months. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect.

We expect to continue to make substantial investments in clinical trials that are designed to provide clinical evidence of the safety and efficacy of our solution. We intend to continue to make significant investments in our sales and marketing organization by increasing the number of U.S. sales territory managers and expanding our international sales and marketing programs to help promote awareness and increase adoption of our solution primarily among the pulmonologists performing interventional pulmonary procedures across approximately 500 high volume hospitals. In order to continue to grow our business, we will need to hire additional sales personnel to efficiently serve the market. We also expect to continue to make investments in research and development, regulatory affairs and clinical studies to develop future generations of our solution, broaden the addressable market and expand indications, support regulatory submissions and demonstrate the clinical efficacy of our solution. Moreover, we expect to incur additional expenses associated with operating as a public company, including legal, accounting, insurance, exchange listing and Securities and Exchange Commission (“SEC”) compliance, investor relations and other expenses. Because of these and other factors, we expect to continue to incur substantial net losses and negative cash flows from operations for the foreseeable future. Our future capital requirements will depend on many factors, including:

- the cost, timing and results of our clinical trials and regulatory reviews;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the terms and timing of any other collaborative, licensing and other arrangements that we may establish;
- the timing, receipt and amount of sales from our current solution and potential future products;
- the degree of success we experience in continuing to commercialize our solution;

- the emergence of competing or complementary technologies;
- the cost of preparing, filing, prosecuting, maintaining, defending and enforcing any patent claims and other intellectual property rights;
- the extent to which we acquire or invest in businesses, products or technologies, although we currently have no commitments or agreements relating to any of these types of transactions; and
- the impact of public health crises, such as COVID-19, on our business, financial condition, and results of operations.

We will require additional financing to fund working capital and pay our obligations. We may seek to raise any necessary additional capital through a combination of public or private equity offerings or debt financings. There can be no assurance that we will be successful in acquiring additional funding at levels sufficient to fund our operations or on terms favorable to us. If adequate funds are not available on acceptable terms when needed, we may be required to significantly reduce operating expenses, which may negatively affect our business, financial condition and results of operations. If we do raise additional capital through public or private equity or convertible debt offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Additional capital may not be available on reasonable terms, or at all.

If the quality of our solution does not meet the expectations of physicians or patients, then our business and reputation may be harmed.

In the course of conducting our business, we must adequately address quality issues that may arise with our solution, including defects in third-party components included in our solution. Although we have established internal procedures designed to minimize risks that may arise from quality issues, there can be no assurance that we will be able to eliminate or mitigate occurrences of these issues and associated liabilities. In addition, even in the absence of quality issues, we may be subject to claims and liability if the performance of the Zephyr Valves does not live up to the expectations of physicians or patients as a result of the physician's implantation of the valve. For example, a physician may improperly implant the Zephyr Valve. If the quality of our solution does not meet the expectations of physicians or patients, then our business and reputation with those physicians or patients may negatively affect our business, financial condition and results of operations.

If our facilities become damaged or inoperable, we will be unable to continue to research, develop and supply our solution which could negatively affect our business, financial condition and results of operations until we are able to secure a new facility and rebuild our inventory.

We do not have redundant facilities. We perform substantially all of our manufacturing, research and development and back office activity in a single location at our headquarters in Redwood City, California. We store our finished goods inventory at our headquarters and secondary facilities in Redwood City, California, Memphis, Tennessee, and the Netherlands. Our facilities, equipment and inventory would be costly to replace and could require substantial lead time to repair or replace. The facilities will be harmed or rendered inoperable by natural or man-made disasters, including, but not limited to, earthquakes, flooding, fire and power outages, which may render it difficult or impossible for us to perform our research, development and commercialization activities for some period of time. The inability to perform those activities, combined with the time it may take to rebuild our manufacturing capabilities, inventory of finished product, may result in the loss of customers or harm to our reputation. Although we possess insurance for damage to our property and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and this insurance may not continue to be available to us on acceptable terms, or at all.

Performance issues, service interruptions or price increases by our shipping carriers could negatively affect our business, financial condition and results of operations and harm our reputation and the relationship between us and the hospitals with which we work.

Expedited, reliable shipping is essential to our operations. We rely heavily on providers of transport services for reliable and secure point-to-point transport of the Zephyr Valve and Chartis System to our customers and for tracking of these shipments. Should a carrier encounter delivery performance issues such as loss, damage or destruction of any systems, it would be costly to replace such systems in a timely manner and such occurrences may damage our reputation and lead to decreased demand for our solution and increased cost and expense to our business. In addition, any significant increase in shipping rates could adversely affect our operating margins and results of operations. Similarly, strikes, severe weather, natural disasters or other service interruptions affecting delivery services we use would adversely affect our ability to process orders for the Zephyr Valve on a timely basis.

We depend on our senior management team and the loss of one or more key employees or an inability to attract and retain highly skilled employees will negatively affect our business, financial condition and results of operations.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and other personnel. We are highly dependent upon our management team, particularly our Chief Executive Officer, the rest of our senior management, and other key personnel. From time to time, there have been and may in the future be changes in our management team or other key employees resulting from the hiring or departure of these personnel. For example, in March 2024, Glendon French retired as the President and Chief Executive Officer of the Company. Our board of directors appointed Steven Williamson as our President and Chief Executive Officer and as a member of our board of directors. Additionally, in April 2024, Mehul Joshi was appointed as Chief Financial Officer of the Company and John McKune, our Interim Chief Financial Officer, returned to his prior position as the Company's Vice President Finance and Corporate Controller. The failure to successfully execute this leadership transition could negatively impact our business and results of operations. Although we have entered into employment letter agreements with our executive officers, each of them may terminate their employment with us at any time. The replacement of any of our key personnel likely would involve significant time and costs and may significantly delay or prevent the achievement of our business objectives and could therefore negatively affect our business, financial condition and results of operations. In addition, we do not carry any key person insurance policies that could offset potential loss of service under applicable circumstances.

In addition, our research and development programs and clinical operations depend on our ability to attract and retain highly skilled engineers and medical researchers. We may not be able to attract or retain qualified engineers and medical researchers in the future due to the competition for qualified personnel. We have from time to time experienced, and we expect to continue to experience, difficulty in hiring and retaining employees with appropriate qualifications. Many of the companies with which we compete for experienced personnel have greater resources than us. If we hire employees from competitors or other companies, their former employers may attempt to assert that these employees or we have breached legal obligations, resulting in a diversion of our time and resources and, potentially, damages.

Further, job candidates and existing employees, particularly in the San Francisco Bay Area, often consider the value of the stock awards they receive in connection with their employment. If the perceived value of our stock awards declines, it may harm our ability to recruit and retain highly skilled employees. Many of our employees have become or will soon become vested in a substantial amount of our common stock or a number of common stock options. Our employees may be more likely to leave us if the shares they own have significantly appreciated in value relative to the original purchase prices of the shares, or if the exercise prices of the options that they hold are significantly below the market price of our common stock. Our future success also depends on our ability to continue to attract and retain additional executive officers and other key employees. If we fail to attract new personnel or fail to retain and motivate our current personnel, it will negatively affect our business, financial condition and results of operations.

We have significant international operations, and to successfully market and sell our products in such international markets we must address international business risks with which we have limited experience.

Sales in markets outside of the United States accounted for approximately 32.5% and 35.8% of our revenue for the six months ended June 30, 2024 and June 30, 2023, respectively. We currently focus our international sales and marketing efforts in Australia, Austria, Belgium, China, Denmark, France, Germany, Ireland, Italy, Japan, the Netherlands, South Korea, Spain, Switzerland and the United Kingdom. International sales are subject to a number of risks, including:

- difficulties in staffing and managing our international operations;
- increased competition as a result of more products and procedures receiving regulatory approval or otherwise free to market in international markets;
- longer accounts receivable payment cycles and difficulties in collecting accounts receivable;
- reduced or varied protection for intellectual property rights in some countries;
- export restrictions, trade regulations and foreign tax laws;
- fluctuations in currency exchange rates;
- foreign certification and regulatory clearance or approval requirements;
- difficulties in developing effective marketing campaigns in unfamiliar foreign countries;
- customs clearance and shipping delays;
- political, social, and economic instability abroad, including as a result of armed conflict, war or the threat of war, terrorist activity and other security concerns in general;
- the impact of public health crises, such as COVID-19;
- preference for locally produced products;
- potentially adverse tax consequences, including the complexities of foreign value-added tax systems, tax inefficiencies related to our corporate structure, and restrictions on the repatriation of earnings;
- differing payment and reimbursement regimes;
- the burdens of complying with a wide variety of foreign laws and different legal standards; and
- increased financial accounting and reporting burdens and complexities.

A public health crisis, such as COVID-19, could adversely affect the economies and financial markets worldwide, resulting in an economic downturn that could affect demand for our products and impact our business, financial condition and results of operations.

If one or more of these risks are realized, they may negatively affect our business, financial condition and results of operations.

If our information technology systems or data, or those third parties upon which we rely, are or were compromised, we could experience adverse impacts resulting from such compromise, including, but not limited

to, interruptions to our operations such as our clinical trials, claims that we breached our data protection obligations, harm to our reputation, and a loss of customers or sales.

In the ordinary course of business, we or the third parties upon whom we rely, collect, store, receive, generate, use, transfer, disclose, make accessible, protect, secure, dispose of or transmit (collectively, "process") proprietary, confidential, and sensitive data (including but not limited to intellectual property, proprietary business information and personal data).

We rely extensively on information technology ("IT") systems, networks and services, including internet sites, data hosting and processing facilities and tools, physical security systems and other hardware, software and technical applications and platforms, some of which are managed, hosted, provided or used by third parties or their vendors, to assist in conducting our business. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

Although we have implemented policies and procedures designed to ensure compliance with applicable data privacy and information security laws and regulations and we take measures to protect sensitive information from unauthorized access or disclosure, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate, and remediate vulnerabilities in our IT systems (such as our hardware and/or software, including that of third parties upon which we rely). We may not, however, detect and remediate all such vulnerabilities including on a timely basis. Unremediated high risk or critical vulnerabilities pose material risks to our business. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Our IT and infrastructure, and other third parties, including technology partners and providers, may be vulnerable to a variety of evolving threats, including but not limited to social engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), ransomware attacks, software bugs, server malfunction, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fire, flood, and other similar threats. In addition to traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel misconduct or error (such as theft or misuse), sophisticated nation-state and nation-state supported actors now engage and are expected to continue to engage in cyberattacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon whom we rely may be vulnerable to a heightened risk of these attacks, including retaliatory cyberattacks that could materially disrupt our systems, operations and supply chain.

Ransomware attacks, including those perpetrated by organized criminal threat actors, nation-states, and nation-state supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. To alleviate the financial, operational and reputational impact of a ransomware attack, it may be preferable to make extortion payments, but we may be unwilling or unable to do so (including, for example, if applicable laws or regulations prohibit such payments). Similarly, supply chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our platform, systems and networks or the systems and networks of third parties that support us and our services.

Although the aggregate impact of security incidents on our operations and financial condition has not been material to date, we have occasionally been the target of events of this nature and expect them to continue as security threats have been rapidly evolving in sophistication and becoming more prevalent in the industry. Advances in computer capabilities, new technological discoveries or other developments may result in cyberattacks becoming more sophisticated and more difficult to detect. We and our third-party service providers may not have the resources or technical sophistication to anticipate or prevent all such cyberattacks. Moreover, techniques used to obtain

unauthorized access to systems or other information technology infrastructure change frequently and may not be detected until after an incident has occurred. We are investing in protections and monitoring practices related to our data and IT to reduce these risks and continue to monitor our systems on an ongoing basis for any current or potential threats. We cannot assure you, however, that our efforts will prevent breakdowns or breaches to our or our third-party providers' databases or systems, and such breakdowns and breaches could negatively affect our business, financial condition and results of operations and our reputation.

If we or our third-party service providers experience, or are perceived to have experienced, material security incidents, it may result in: government enforcement actions that could include investigations, fines, penalties, consent decrees, audits and inspections; additional reporting requirements and/or oversight; temporary or permanent bans on all or some processing of personal data; or orders to destroy or not use personal data. Applicable data privacy and information security obligations may require us to notify relevant stakeholders, including affected individuals, customers, regulators, and investors of security incidents. Such disclosures are costly, and the disclosures or the failure to comply with such requirements, could lead to adverse impacts. Further, individuals or other relevant stakeholders could sue us for our actual or perceived failure to comply with our security obligations, including, without limitation, in class action litigation. Security incidents could also result in indemnity obligations, negative publicity and financial loss.

Security incidents and vulnerabilities may cause some of our customers and users to stop using our services and our failure, or perceived failure, to meet expectations with regard to the security, integrity, availability and confidentiality of our systems and sensitive data could damage our reputation and affect our ability to retain customers, attract new customers and grow our business. Any of these results could harm our growth prospects, our business and our reputation. Moreover, security incidents can result in the diversion of funds, and interruptions, delays, or outages in our operations and services, including due to ransomware attacks. Failures or significant downtime of our information technology or telecommunication systems or those used by our third-party service providers could cause significant interruptions to our operations and adversely impact the confidentiality, integrity and availability of sensitive, proprietary or confidential information, and prevent us from administering our business. There can be no assurance that limitations of liability in our contracts are sufficient or adequate enough to protect us from liabilities, damages, or claims related to our security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, sensitive information of the Company could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel's, or vendors' use of generative artificial intelligence ("AI") technologies.

Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

We may enter into collaborations, in-licensing arrangements, joint ventures, strategic alliances or partnerships with third parties that may not result in the development of commercially viable products, product improvements or the generation of significant future revenues.

In the ordinary course of our business, we may enter into collaborations, in-licensing arrangements, joint ventures, strategic alliances, partnerships or other arrangements to develop new products or product improvements and to pursue new markets. Proposing, negotiating and implementing collaborations, in-licensing arrangements, joint ventures, strategic alliances or partnerships may be a lengthy and complex process. Other companies, including those with substantially greater financial, marketing, sales, technology or other business resources, may compete

with us for these opportunities or arrangements. We may not identify, secure, or complete any such transactions or arrangements in a timely manner, on a cost-effective basis, on acceptable terms or at all. We have limited institutional knowledge and experience with respect to these business development activities, and we may also not realize the anticipated benefits of any such transaction or arrangement. In particular, these collaborations may not result in the development of products that achieve commercial success or viable product improvements or result in significant revenues and could be terminated prior to developing any products.

Additionally, we may not be in a position to exercise sole decision-making authority regarding the transaction or arrangement, which could create the potential risk of creating impasses on decisions, and our future collaborators may have economic or business interests or goals that are, or that may become, inconsistent with our business interests or goals. It is possible that conflicts may arise with our collaborators, such as conflicts concerning the achievement of performance milestones, or the interpretation of significant terms under any agreement, such as those related to financial obligations or the ownership or control of intellectual property developed during the collaboration. If any conflicts arise with any future collaborators, they may act in their self-interest, which may be adverse to our best interest, and they may breach their obligations to us. In addition, we may have limited control over the amount and timing of resources that any future collaborators devote to our or their future products.

Disputes between us and our collaborators may result in litigation or arbitration which would increase our expenses and divert the attention of our management. Further, these transactions and arrangements will be contractual in nature and will generally be terminable under the terms of the applicable agreements and, in such event, we may not continue to have rights to the products relating to such transaction or arrangement or may need to purchase such rights at a premium. If we enter into in-bound intellectual property license agreements, we may not be able to fully protect the licensed intellectual property rights or maintain those licenses. Future licensors could retain the right to prosecute and defend the intellectual property rights licensed to us, in which case we would depend on the ability of our licensors to obtain, maintain and enforce intellectual property protection for the licensed intellectual property. These licensors may determine not to pursue litigation against other companies or may pursue such litigation less aggressively than we would. Further, entering into such license agreements could impose various diligence, commercialization, royalty or other obligations on us. Future licensors may allege that we have breached our license agreement with them, and accordingly seek to terminate our license, which could adversely affect our competitive business position and harm our business prospects.

Unfavorable global economic conditions, including as a result of geopolitical conflict, could negatively affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. A severe or prolonged economic downturn, such as the global financial crisis of 2008, could result in a variety of risks to our business, including weakened demand for our solution, and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy, including due to the impact of inflationary pressures, could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. Any of the foregoing will negatively affect our business, financial condition and results of operations and we cannot anticipate all of the ways in which the economic climate and financial market conditions could negatively affect our business, financial condition and results of operations.

We may acquire other companies or technologies, which could divert our management's attention, result in additional dilution to our stockholders and otherwise negatively affect our business, financial condition and results of operations.

We may in the future seek to acquire or invest in businesses, applications or technologies that we believe could complement or expand our current business, enhance our technical capabilities or otherwise offer growth opportunities. Accordingly, although we have no current commitments with respect to any acquisition or investment, we may in the future pursue the acquisition of, or joint ventures relating to, complementary businesses, applications or technologies instead of developing them ourselves. The pursuit of potential acquisitions may divert the attention of management and cause us to incur various costs and expenses in identifying, investigating and pursuing suitable acquisitions, whether or not they are consummated. We may not be able to identify desirable acquisition targets or

be successful in entering into an agreement with any particular target or obtain the expected benefits of any acquisition or investment.

We may not be able to successfully integrate acquired personnel, operations and technologies, or effectively manage the combined business following an acquisition. Acquisitions could also result in dilutive issuances of equity securities, the use of our available cash, or the incurrence of debt, which will harm our operating results. In addition, if an acquired business fails to meet our expectations, it will negatively affect our business, financial condition and results of operations.

Consolidation in the healthcare industry or group purchasing organizations could lead to demands for price concessions, which may affect our ability to sell our products at prices necessary to support our current business strategies.

The commercial payor industry is undergoing significant consolidation. When payors combine their operations, the combined company may elect to reimburse our products at the lowest rate paid by any of the participants in the consolidation or use its increased size to negotiate reduced rates. If one of the payors participating in the consolidation does not reimburse for the Zephyr Valve and our solution at all, the combined company may elect not to reimburse for the same, which would adversely impact our operating results.

Our long-term growth depends on our ability to enhance our solution, expand our indications and develop and commercialize additional products. If we fail to identify, acquire and develop other products, we may be unable to grow our business.

It is important to our business that we continue to enhance the Zephyr Valve, Chartis System and StratX Platform and develop and introduce new products. Developing products is expensive and time-consuming and could divert management's attention away from our core business. The success of any new product offering or product enhancements to our solution will depend on several factors, including our ability to:

- assemble sufficient resources to acquire or discover additional products;
- properly identify and anticipate physician and patient needs;
- develop and introduce new products and product enhancements in a timely manner;
- avoid infringing upon the intellectual property rights of third parties;
- demonstrate, if required, the safety and efficacy of new products with data from pre-clinical studies and clinical trials;
- obtain the necessary regulatory clearances or approvals for expanded indications, new products or product modifications;
- be fully compliant with FDA and comparable foreign regulatory authorities' requirements relating to the marketing of new devices or modified products;
- produce new products in commercial quantities at an acceptable cost;
- provide adequate training to potential users of our products;
- receive adequate coverage and reimbursement for procedures performed with our products; and
- develop an effective and dedicated sales and marketing team.

If we are not successful in expanding our indications and developing and commercializing new products and product enhancements, our ability to increase our revenue may be impaired, which could have a material adverse effect on our business, financial condition and results of operations.

In addition, we may choose to focus our efforts and resources on a potential products or indication that ultimately prove to be unsuccessful, or to license or purchase a marketed product that does not meet our financial expectations. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other potential products or other diseases that may later prove to have greater commercial potential, or relinquish valuable rights to such potential products through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to retain sole development and commercialization rights, which could adversely impact our business, financial condition and results of operations.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs and products and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other products or product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to timely capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and products and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product or product candidate, we may relinquish valuable rights to that product or product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

We are subject to anti-bribery, anti-corruption, and anti-money laundering laws, including the U.S. Foreign Corrupt Practices Act, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures and legal expenses, which could negatively affect our business, financial condition and results of operations.

As we grow our international presence and global operations, we will be increasingly exposed to trade and economic sanctions and other restrictions imposed by the United States, the European Union and other governments and organizations. The U.S. Departments of Justice, Commerce, State and Treasury and other federal agencies and authorities have a broad range of civil and criminal penalties they may seek to impose against corporations and individuals for violations of economic sanctions laws, export control laws, the U.S. Foreign Corrupt Practices Act ("FCPA"), and other federal statutes and regulations, including those established by the Office of Foreign Assets Control ("OFAC"). In addition, the U.K. Bribery Act of 2010 ("Bribery Act") prohibits both domestic and international bribery, as well as bribery across both private and public sectors. An organization that fails to prevent bribery by anyone associated with the organization can be charged under the Bribery Act unless the organization can establish the defense of having implemented adequate procedures to prevent bribery. Under these laws and regulations, as well as other anti-corruption laws, anti-money laundering laws, export control laws, customs laws, sanctions laws and other laws governing our operations, various government agencies may require export licenses, may seek to impose modifications to business practices, including cessation of business activities in sanctioned countries or with sanctioned persons or entities and modifications to compliance programs, which may increase compliance costs, and may subject us to fines, penalties and other sanctions. A violation of these laws or regulations would negatively affect our business, financial condition and results of operations.

We are in the process of enhancing policies and procedures designed to ensure compliance by us and our directors, officers, employees, representatives, consultants and agents with the FCPA, OFAC restrictions, the Bribery Act and other export control, anti-corruption, anti-money-laundering and anti-terrorism laws and regulations. We cannot

assure you, however, that our policies and procedures are or will be sufficient or that directors, officers, employees, representatives, consultants and agents have not engaged and will not engage in conduct for which we may be held responsible, nor can we assure you that our business partners have not engaged and will not engage in conduct that could materially affect their ability to perform their contractual obligations to us or even result in our being held liable for such conduct. Violations of the FCPA, OFAC restrictions, the Bribery Act or other export control, anti-corruption, anti-money laundering and anti-terrorism laws or regulations may result in severe criminal or civil sanctions, and we may be subject to other liabilities, which could negatively affect our business, financial condition and results of operations.

Our results may be impacted by changes in foreign currency exchange rates.

A significant proportion of our sales are outside of the United States, and a majority of those are denominated in foreign currencies, which exposes us to foreign currency risks, including changes in currency exchange rates. Foreign currency exchange fluctuations have negatively impacted, and may continue to negatively impact, our revenue from international markets. We do not currently engage in any hedging transactions. If we are unable to address these risks and challenges effectively, our international operations may not be successful, and our business could be harmed.

Our ability to utilize our net operating loss carryforwards and research and development credit may be limited.

In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended ("Code"), a corporation that undergoes an ownership change, generally defined as a greater than 50% change by value in its equity ownership over a three-year period, is subject to limitations on its ability to utilize its pre-change net operating losses ("NOLs") and its research and development credit carryforwards to offset future taxable income. Our existing NOLs and research and development credit carryforwards may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change, our ability to utilize NOLs and research and development credit carryforwards could be further limited by Sections 382 and 383 of the Code. In addition, our ability to deduct net interest expense may be limited if we have insufficient taxable income for the year during which the interest is incurred, and any carryovers of such disallowed interest would be subject to the limitation rules similar to those applicable to NOLs and other attributes. Future changes in our stock ownership, some of which might be beyond our control, could result in an ownership change under Section 382 of the Code. For these reasons, in the event we experience a change of control, we may not be able to utilize a material portion of the NOLs, research and development credit carryforwards or disallowed interest expense carryovers, even if we attain profitability.

We may not be able to achieve or maintain satisfactory pricing and margins for our products.

Manufacturers of medical devices have a history of price competition, and we can give no assurance that we will be able to achieve satisfactory prices for our solution or maintain prices at the levels we have historically achieved. Any decline in the amount that payors reimburse our customers for the Zephyr Valve and related products could make it difficult for customers to continue using, or to adopt, our solution and could create additional pricing pressure for us. If we are forced to lower the price we charge for our solution, our gross margins will decrease, which will adversely affect our ability to invest in and grow our business. If we are unable to maintain our prices, or if our costs increase and we are unable to offset such increase with an increase in our prices, our margins could erode. We will continue to be subject to significant pricing pressure, which will negatively affect our business, financial condition and results of operations.

Governmental export or import controls could limit our ability to compete in foreign markets and subject us to liability if we violate them.

Our products may be subject to U.S. export controls. Governmental regulation of the import or export of our products, or our failure to obtain any required import or export authorization for our products, when applicable, will harm our international sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets

or, in some cases, prevent the export of our products to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments and persons targeted by U.S. sanctions. If we fail to comply with export and import regulations and such economic sanctions, we may be fined or other penalties could be imposed, including a denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons or technologies targeted by such regulations, could result in decreased use of our products by, or in our decreased ability to export our products to existing or potential customers with international operations. Any decreased use of our products or limitation on our ability to export or sell access to our products would likely negatively affect our business, financial condition and results of operations.

Public health crises, such as the COVID-19 pandemic, have in the past and may in the future have a material adverse impact on our business, financial condition and results of operations.

Public health crises, such as the COVID-19 pandemic, and other events beyond our control, have in the past and may in the future have a material adverse impact on our business, financial condition and results of operations. For example, the COVID-19 pandemic and related governmental and societal responses to mitigate its impact had a material adverse impact on our business, financial condition and results of operations by decreasing and delaying procedures performed using our products due to healthcare organizations prioritizing the treatment of patients with COVID-19 and altering their operations to respond to the pandemic.

A public health crisis could significantly disrupt economic activity globally and have a material adverse impact our ability to access capital and on our business, financial condition and results of operations as a result of hospitals reducing capital and overall spend and other potential changes in healthcare organizations' prioritizing of patient treatment, significant job losses and unemployment, including the inability of patients to obtain or maintain health insurance policies, inflation, and reductions in disposable income. Additionally, if a public health crisis or other event beyond our control were to emerge, there may be limited provider capacity due to labor shortages, or for other reasons, which could limit the ability of patients to receive treatment with Zephyr Valves. This limited provider and hospital capacity could have a material adverse effect on our business, financial condition and results of operations, and it may have the effect of heightening other risks described in this "Risk Factors" section.

Risks Related to Government Regulation and Our Industry

Our products and operations are subject to extensive government regulation and oversight both in the United States and abroad. If we fail to obtain and maintain necessary regulatory approvals for the Zephyr Valve and related products, or if approvals for future products and indications are delayed or not issued, it will negatively affect our business, financial condition and results of operations.

The Zephyr Valve is subject to extensive regulation by the FDA in the United States and comparable foreign regulatory authorities abroad. Regulations specific to medical devices are wide ranging and govern, among other things:

- product design, development, manufacture, and release;
- laboratory, pre-clinical and clinical testing, labeling, packaging, storage and distribution;
- product safety and efficacy;
- premarketing clearance or approval;
- service operations;
- record keeping;
- product marketing, promotion and advertising, sales and distribution;

- post-marketing surveillance, including reporting of deaths or serious injuries and recalls and correction and removals;
- post-market approval studies; and
- product import and export.

The 510(k) or PMA and foreign equivalents process can be expensive, lengthy and unpredictable. We may not be able to obtain any necessary clearances, certification or approval or may be unduly delayed in doing so, which will negatively affect our business, financial condition and results of operations. Furthermore, even if we are granted regulatory clearances, certification or approvals, they may include significant limitations on the indicated uses for the product, which may limit the market for the product. Although we have obtained PMA approval and CE marked our product after obtaining related CE Certificates of Conformity to market the Zephyr Valve, our approval can be revoked if safety or efficacy problems develop.

The FDA, comparable foreign regulatory authorities and Notified Bodies can delay, limit or deny clearance, certification or approval of a device for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA, the applicable regulatory authority or Notified Body that our products are safe or effective for their intended uses;
- the disagreement of the FDA or the applicable foreign regulatory authority or Notified Body with the design or implementation of our clinical trials or the interpretation of data from pre-clinical studies or clinical trials;
- serious and unexpected adverse device effects experienced by participants in our clinical trials;
- the data from our pre-clinical studies and clinical trials may be insufficient to support clearance, certification or approval, where required;
- our inability to demonstrate that the clinical and other benefits of the device outweigh the risks;
- the manufacturing process or facilities we use may not meet applicable requirements; and
- the potential for approval policies or regulations of the FDA or applicable foreign regulatory authorities to change significantly in a manner rendering our clinical data or regulatory filings insufficient for clearance, certification or approval.

If we fail to remain in compliance with applicable European Union laws, we would be unable to continue to affix the CE mark to our products, which would prevent us from selling them within the European Economic Area ("EEA") and other European countries in which we rely on the CE mark.

The FDA and state and international authorities including EU Member States have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by any such agency and authority, which may include any of the following sanctions:

- adverse publicity, warning letters, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, refunds, recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- denial of our requests for regulatory clearance, certification or premarket approval of new products or services, new intended uses or modifications to existing products or services;

- withdrawal of regulatory clearance, certification or premarket approvals that have already been granted; or
- criminal prosecution.

If any of these events were to occur, it will negatively affect our business, financial condition and results of operations.

Changes in the regulatory environment may constrain or require us to restructure our operations, which may harm our revenue and operating results.

Healthcare laws and regulations change frequently and may change significantly in the future. We may not be able to adapt our operations to address every new regulation, and new regulations may negatively affect our business, financial condition and results of operations. We cannot assure you that a review of our business by courts or regulatory authorities would not result in a determination that adversely affects our revenue and operating results, or that the healthcare regulatory environment will not change in a way that restricts our operations. In addition, there is risk that the U.S. Congress may implement changes in laws and regulations governing healthcare service providers, including measures to control costs, or reductions in reimbursement levels, which may negatively affect our business, financial condition and results of operations.

The federal government is considering ways to change, and has changed, the manner in which healthcare services are paid for in the United States. CMS establishes Medicare payment levels for hospitals and physicians on an annual basis, which can increase or decrease payment to such entities. CMS, as well as insurers, have increased their efforts to control the cost, utilization and delivery of healthcare services. From time to time, the U.S. Congress has considered and implemented changes in the CMS fee schedules in conjunction with budgetary legislation. Further reductions of reimbursement by CMS for services or changes in policy regarding coverage of tests or other services provided or other requirements for payment, such as prior authorization or a physician's or qualified practitioner's signature on test/service requisitions, may be implemented from time to time. Individual states may also enact legislation that impacts Medicaid payments to hospitals and physicians. Reductions in the reimbursement rates and changes in payment policies of other third-party payors may occur as well. Similar changes in the past have resulted in reduced payments as well as added costs and have added more complex regulatory and administrative requirements. Further changes in federal, state, local and third-party payor regulations or policies may negatively affect our business, financial condition and results of operations. Actions by agencies regulating insurance or changes in other laws, regulations, or policies may also negatively affect our business, financial condition and results of operations.

In addition to changes to the regulatory environment in the United States, there have been changes to the regulatory environment in certain foreign jurisdiction in which we operate. For example, the European Union Medical Device Regulation (Regulation (EU) 2017/745) ("MDR") became applicable in 2021 and includes transitional provisions. We are currently placing our medical devices on the market in accordance with the stringent requirements of the transitional provisions of the MDR, the requirements of the European Union Medical Devices Directive (Council Directive 93/42/EEC) ("MDD") and the guidance of the European Commission's Medical Devices Coordination Group. We intend to complete conformity assessment procedures for our medical devices in accordance with the MDR prior to the expiration of our existing CE Certificate(s) of Conformity issued by our Notified Body, BSI, on the basis of the MDD, and the expiration of the transitional provisions of the MDR. The changes to the regulatory system implemented in the EU by the MDR include stricter requirements for clinical evidence and pre-market assessment of safety and performance, new classifications to indicate risk levels, requirements for third party testing by Notified Bodies, tightened and streamlined quality management system assessment procedures and additional requirements for the quality management system, additional requirements for traceability of products and transparency as well a refined responsibility of economic operators. We are also required to provide clinical data in the form of a clinical evaluation report. Fulfilment of the obligations imposed by the MDR may cause us to incur substantial costs. We may be unable to fulfil these obligations for medical devices we intend to place on the EU market, or our Notified Body, where they are involved, may consider that we have not adequately demonstrated compliance with our related obligations to merit a CE Certificate of Conformity on the basis of the MDR. We must obtain the appropriate CE Certificate(s) of Conformity in accordance with the MDR to continue to place our

products on the EU market, or other countries that relate their medical device regulations to a CE mark, once we can no longer benefit from the transitional provisions of the MDR. The modifications of the MDR may have an effect on the way we conduct our business in the EEA. Additional regulatory changes may negatively affect our business, financial condition and results of operations.

Changes in funding for, or disruptions caused by global health concerns impacting, the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed, cleared or approved or commercialized in a timely manner, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, statutory, regulatory, and policy changes and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new devices to be reviewed and/or approved or cleared by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting business as usual or conducting inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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

The FDA and similar foreign regulatory authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA's authority to require a recall must be based on an FDA finding that there is reasonable probability that the device would cause serious injury or death. 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. The FDA requires that certain classifications of recalls be reported to the FDA within ten working days after the recall is initiated. A government-mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing errors, design or labeling defects or other deficiencies and issues. Similar regulatory authorities in other countries have similar authority to recall devices because of material deficiencies or defects in design or manufacture that could endanger health. Any recall would divert management attention and financial resources and could cause the price of our stock to decline, expose us to product liability or other claims and harm our reputation with customers. A future recall announcement will harm our reputation with customers and negatively affect our sales. In addition, the FDA or a foreign regulatory authority could take enforcement action for failing to report the recalls when they were conducted.

In addition, under the FDA's medical device reporting regulations ("MDRs"), we are required to report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. Repeated product malfunctions may result in a voluntary or involuntary product recall. We are also required to follow detailed recordkeeping requirements for all firm-initiated medical device corrections and removals, and to report such corrective and removal actions to FDA if they are carried out in response to a risk to health and have not otherwise been reported under the MDRs. Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new approvals, or

clearances for the device before we may market or distribute the corrected device. Seeking such approvals or clearances may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties, or civil or criminal fines. We may also be required to bear other costs or take other actions that may have a negative impact on our sales as well as face significant adverse publicity or regulatory consequences, which will negatively affect our business, financial condition and results of operations, including our ability to market our products in the future. Comparable requirements and related consequences are applicable in foreign countries.

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

We are subject to certain federal, state and foreign fraud and abuse laws, health information privacy and security laws and transparency laws, which, if violated, could subject us to substantial penalties and negatively affect our business, financial condition and results of operations.

The products and services we offer are highly regulated, and there can be no assurance that the regulatory environment in which we operate will not change significantly and adversely in the future. Our arrangements with physicians, hospitals and clinics may expose us to broadly applicable fraud and abuse and other laws and regulations that may restrict the financial arrangements and relationships through which we market, sell and distribute our products and services. Federal and state healthcare laws and regulations that may affect our ability to conduct business, include, without limitation:

- federal and state laws and regulations regarding billing and claims payment applicable to our solution and regulatory agencies enforcing those laws and regulations;

- the federal Anti-Kickback Statute, which prohibits, among other things, any person or entity from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as Medicare and Medicaid;

- the federal false claims laws, including the FCA, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the federal government;

- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- the federal Physician Payments Sunshine Act, created under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "Affordable Care Act") and its implementing regulations, which requires certain manufacturers of drugs, medical devices, biologicals and medical supplies for which payment is available 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 (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other health care professionals (such as physician assistants and nurse practitioners) and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

- the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), as amended by the Health Information Technology for Economic and Clinical Health Act (“HITECH”), and its implementing regulations, which impose certain requirements relating to the privacy, security and transmission of individually identifiable health information on covered entities, including certain healthcare providers, health plans and healthcare clearinghouses, and their respective business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity as well as their covered subcontractors; HIPAA also created criminal liability for, among other things, knowingly and willfully falsifying or concealing a material fact or making a materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;

- the Federal Drug & Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;

- the federal physician self-referral prohibition, commonly known as the Stark Law, which prohibits, among other things, physicians who have a financial relationship, including an investment, ownership or compensation relationship with an entity, from referring Medicare and Medicaid patients to that entity for designated health services, which include clinical laboratory services, unless an exception applies. Similarly, entities may not bill Medicare, Medicaid or any other party for services furnished pursuant to a prohibited referral;

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and

- similar healthcare laws and regulations in the European Union, the UK and other jurisdictions, including national anti-bribery laws of European countries and national rules, regulations, industry self-regulation codes reporting requirements detailing interactions with and payments to healthcare providers and laws governing the privacy and security of certain protected information, such as personal data under the General Data Protection Regulation (“GDPR”).

The Affordable Care Act was enacted in 2010. The Affordable Care Act, among other things, amended the intent requirement of the federal Anti-Kickback Statute and criminal healthcare fraud statutes, including those created under HIPAA. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA.

To enforce compliance with the healthcare regulatory laws, certain enforcement bodies have continued their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time and resource-consuming and can divert management’s attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may have to agree to additional compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise negatively affect our business, financial condition and results of operations. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity and be costly to respond to.

In December 2022, we received a civil investigative demand (“CID”) from the U.S. Department of Justice, Civil Division in connection with an investigation under the Anti-Kickback Statute and False Claims Act (the “Investigation”). The CID requests information and documents regarding our relationships with certain health care providers, medical practices, and hospitals in connection with the sales and marketing of the Zephyr Valves and related products and services. We are fully cooperating with the Investigation. We are unable to express a view at

this time regarding the ultimate outcome of the Investigation or estimate an amount or range of reasonably possible loss. Depending on the outcome of the Investigation, there could be a material impact on our business, results of operations and financial condition.

Although we have adopted policies and procedures designed to comply with these laws and regulations and conduct internal reviews of our compliance with these laws, our activities, including those relating to the reporting of discount and rebate information and other information affecting federal, state and third-party reimbursement of our products (such as our patient reimbursement support program) and the sale and marketing of our products, may be subject to scrutiny under these laws. Because of the breadth of these laws and the narrowness of available statutory exceptions and regulatory safe harbors, it is possible that some of our activities could be subject to challenge under one or more such laws. The growth of our business and sales organization and our expansion outside of the United States may increase the potential of violating these laws or our internal policies and procedures. Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the federal, state and foreign laws described above or any other current or future fraud and abuse or other healthcare laws and regulations that apply to us, we may be subject to significant penalties, including significant criminal, civil, and administrative penalties, damages, fines, imprisonment for individuals, additional oversight and reporting obligations, exclusion from participation in government programs, such as Medicare and Medicaid, or comparable foreign programs, imprisonment, contractual damages, reputation harm and disgorgement and we could be required to curtail or cease our operations. Any of the foregoing consequences will negatively affect our business, financial condition and results of operations.

If we modify the Zephyr Valve, we may need to seek additional clearances, certification or approvals, which, if not granted, would prevent us from selling our modified products.

In the United States, the Zephyr Valve is marketed pursuant to a PMA order issued by the FDA. Any modifications to a PMA-approved device that could significantly affect its safety or effectiveness, including significant design and manufacturing changes, or that would constitute a major change in its intended use, manufacture, design, components, or technology requires approval of a new PMA application or PMA supplement. However, certain changes to a PMA-approved device do not require submission and approval of a new PMA or PMA supplement and may only require notice to FDA in a PMA 30-Day Notice, Special PMA Supplement—Changes Being Effected or PMA Annual Report. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer's decision. The FDA may not agree with our decisions regarding whether new approvals are necessary. If the FDA disagrees with our determination and requires us to seek new PMA approvals for modifications to our previously approved products for which we have concluded that new approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties. Furthermore, our products could be subject to recall if the FDA determines, for any reason, that our products are not safe or effective or that appropriate regulatory submissions were not made.

For those medical devices sold in the EU and for which we have obtained a CE Certificate of Conformity by a Notified Body, we must notify our Notified Body if significant changes are made to the devices or if there are substantial changes to our quality assurance systems affecting those products. In addition, if we make any substantial changes to medical devices for which we have obtained a CE Certificate of Conformity on the basis of the MDD and which we continue to place on the EU market on the basis of the transitional provisions of the MDR, we will no longer be able to benefit from the transitional provisions of the MDR. Substantial changes to such devices will trigger immediate compliance with the full regulatory framework of the MDR.

Delays in receipt or failure to receive approvals or certifications, the loss of previously received approvals or certifications, or the failure to comply with any other existing or future regulatory requirements, could reduce our sales, profitability and future growth prospects.

Failure to comply with post-marketing regulatory requirements could subject us to enforcement actions, including substantial penalties, and might require us to recall or withdraw a product from the market.

Even though we have obtained approval for the Zephyr Valve, we are subject to ongoing and pervasive regulatory requirements governing, among other things, the manufacture, marketing, advertising, medical device reporting, sale, promotion, registration, and listing of devices. For example, we must submit periodic reports to the FDA as a condition of PMA approval. These reports include safety and effectiveness information about the device after its approval. Failure to submit such reports, or failure to submit the reports in a timely manner, could result in enforcement action by the FDA. Following its review of the periodic reports, the FDA might ask for additional information or initiate further investigation.

In addition, the PMA approval for the Zephyr Valve was subject to several conditions of approval, including extended follow-up of the pre-market study cohort and post market study. Though we believe we have complied with these conditions to date, any failure to comply with the conditions of approval could result in the withdrawal of PMA approval and the inability to continue to market the device. Failure to conduct the required studies in accordance with Institutional Review Board ("IRB") and informed consent requirements, or adverse findings in these studies, could also be grounds for withdrawal of approval of the PMA. In the EU, the MDR also imposes strict post-market regulatory requirements which are also applicable to those devices for which we have obtained a CE Certificate of Conformity on the basis of the MDD and which we continue to place on the EU market on the basis of the transitional provisions of the MDR.

The regulations to which we are subject are complex and have become more stringent over time. Regulatory changes could result in restrictions on our ability to continue or expand our operations, higher than anticipated costs, or lower than anticipated sales. Even after we have obtained the proper regulatory approval or certification to market a device, we have ongoing responsibilities under FDA regulations and applicable foreign laws and regulations. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA, state or foreign regulatory authorities, which will negatively affect our business, financial condition and results of operations.

If treatment guidelines for severe emphysema or the standard of care evolves, we may need to redesign and seek new marketing authorization from the FDA or comparable foreign regulatory authorities, or certification from Notified Bodies, for one or more of our products.

If treatment guidelines for severe emphysema changes or the standard of care for this condition evolves, we may need to redesign the applicable product and seek new approvals from the FDA or comparable foreign regulatory authorities, or certification from Notified Bodies. Our PMA approvals from the FDA are based on current treatment guidelines. If treatment guidelines change so that different treatments become desirable, the clinical utility of one or more of our products could be diminished and will negatively affect our business, financial condition and results of operations.

If we or our suppliers fail to comply with the FDA's QSR or the European Union MDR, our manufacturing or distribution operations could be delayed or shut down and our revenue could suffer.

Our manufacturing and design processes and those of our third-party suppliers are required to comply with the FDA's QSR and the European Union MDR, including Quality Management System requirements, both of which cover procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of Zephyr Valves. We are also subject to similar state requirements and licenses, and comply with ongoing International Organization for Standardization ("ISO") in all operations, including design, manufacturing, and service, to maintain our CE Mark. In addition, we must engage in extensive recordkeeping and reporting and must make available our facilities and records for periodic unannounced inspections by governmental agencies, including the FDA, state authorities, competent authorities of EU Member States, European Union Notified Bodies and comparable authorities in other countries. If we fail a regulatory inspection, our operations could be disrupted and our manufacturing interrupted. Failure to take adequate corrective action in response to an adverse regulatory inspection could result in, among other things, a shutdown of our manufacturing or product

distribution operations, significant fines, suspension of marketing clearances, certification and approvals, seizures or recalls of our device, operating restrictions and criminal prosecutions, any of which would negatively affect our business, financial condition and results of operations. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with applicable regulatory requirements, which may result in manufacturing delays for our product and cause our revenue to decline.

We are registered with the FDA as a manufacturer. The FDA has broad post-market and regulatory enforcement powers. We are subject to unannounced inspections by the FDA and the Food and Drug Branch of the CDPH to determine our compliance with the QSR and other regulations at our manufacturing facility, and these inspections may include the manufacturing facilities of our suppliers. We believe that we are in compliance, in all material respects, with the QSR.

We also maintain a CE Certificate of Conformity for the design and manufacture of our products issued by BSI in the Netherlands, our European Notified Body, in accordance with the MDD and MDR, as applicable to our products. We believe that we are in compliance, in all material respects, with the MDD and MDR, as applicable to our products.

We can provide no assurance that we will continue to remain in compliance with the QSR, MDR, and MDD, as applicable to our products. If the FDA, CDPH, BSI or competent authorities of EU Member States inspect any of our facilities and discover compliance problems, we may have to cease manufacturing and product distribution until we can take the appropriate remedial steps to correct the audit findings. Taking corrective action may be expensive, time consuming and a distraction for management and if we experience a delay at our manufacturing facility, we may be unable to produce our solutions, which will negatively affect our business, financial condition and results of operations.

The misuse or off-label use of our solution will harm our image in the marketplace, result in injuries that lead to product liability suits or result in costly investigations and sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which will negatively affect our business, financial condition and results of operations.

Our solution has been approved by the FDA for specific indications. We train our marketing and direct sales force to not promote our products for uses outside of the FDA-approved indications for use, known as “off-label” uses. We cannot, however, prevent a physician from using our products off-label, when in the physician’s independent professional medical judgment, he or she deems it appropriate. There may be increased risk of injury to patients if physicians attempt to use our products off-label. Furthermore, the use of our products for indications other than those approved by the FDA or any foreign regulatory body, or for which we have CE marked our products, may not effectively treat such conditions, which will harm our reputation in the marketplace among physicians and patients.

Physicians may also misuse our products or use improper techniques if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If our products are misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. Product liability claims could divert management’s attention from our core business, be expensive to defend, and result in sizable damage awards against us that may not be covered by insurance. In addition, if the FDA or any foreign regulatory body determines that our promotional materials or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs, and the curtailment of our operations. Any of these events will negatively affect our business, financial condition and results of operations and cause our stock price to decline.

We may be subject to regulatory or enforcement actions if we engage in improper marketing or promotion of our products.

Our educational and promotional activities and training methods must comply with FDA and other applicable laws, including the prohibition of the promotion of a medical device for a use that has not been cleared or approved by the FDA, or for which we have CE marked our products. Use of a device outside of its cleared, approved, or CE marked indications is known as "off-label" use. Physicians may use our products off-label in their professional medical judgment, as the FDA and comparable foreign regulatory authorities do not restrict or regulate a physician's choice of treatment within the practice of medicine. However, if the FDA or comparable foreign regulatory authorities determine that our educational and promotional activities or training constitutes promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of warning letters, untitled letters, fines, penalties, injunctions, or seizures, which could have an adverse impact on our reputation and financial results. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our educational and promotional activities or training methods to constitute promotion of an off-label use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged, and adoption of the products could be impaired. Although our policy is to refrain from statements that could be considered off-label promotion of our products, the FDA or another regulatory authority could disagree and conclude that we have engaged in off-label promotion. It is also possible that other federal, state or foreign enforcement authorities might take action, such as federal prosecution under the FCA, if they consider our business activities constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil or administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations. In addition, the off-label use of our products may increase the risk of product liability claims. Product liability claims are expensive to defend and could divert our management's attention, result in substantial damage awards against us, and harm our reputation.

The clinical trial process required to obtain regulatory approvals and certification is lengthy and expensive with uncertain outcomes. If clinical studies of our future products do not produce results necessary to support regulatory clearance, certification or approval in the United States or, with respect to our current or future products, elsewhere, we will be unable to expand the indications for or commercialize these products and may incur additional costs or experience delays in completing, or ultimately be unable to complete, the commercialization of those products.

We have obtained PMA approval for the Zephyr Valve. In order to obtain PMA approval for a device, the sponsor must conduct well-controlled clinical trials designed to assess the safety and efficacy of the product candidate. Similar requirements may apply outside the U.S. Conducting clinical trials is a complex and expensive process, can take many years, and outcomes are inherently uncertain. We incur substantial expense for, and devote significant time to, clinical trials but cannot be certain that the trials will ever result in commercial revenue. We may experience significant setbacks in clinical trials, even after earlier clinical trials showed promising results, and failure can occur at any time during the clinical trial process. Any of our products may malfunction or may produce undesirable adverse effects that could cause us or regulatory authorities to interrupt, delay or halt clinical trials. We, the FDA, or another regulatory authority may suspend or terminate clinical trials at any time to avoid exposing trial participants to unacceptable health risks.

Successful results of pre-clinical studies are not necessarily indicative of future clinical trial results, and predecessor clinical trial results may not be replicated in subsequent clinical trials. Additionally, the FDA or comparable foreign regulatory authorities may disagree with our interpretation of the data from our pre-clinical studies and clinical trials, or may find the clinical trial design, conduct or results inadequate to prove safety or efficacy, and may require us to pursue additional pre-clinical studies or clinical trials, which could further delay the clearance, certification or approval of our products. The data we collect from our pre-clinical studies and clinical trials may not be sufficient to support FDA or comparable foreign regulatory authority clearance or approval, or certification, and if we are unable

to demonstrate the safety and efficacy of our future products in our clinical trials, we will be unable to obtain regulatory clearance, certification or approval to market our products.

In addition, we may estimate and publicly announce the anticipated timing of the accomplishment of various clinical, regulatory and other product development goals, which are often referred to as milestones. These milestones could include the obtainment of the right to affix the CE mark in the European Union; the submission to the FDA of an Investigational Device Exemption ("IDE") application to commence a pivotal clinical trial for a new product candidate; the enrollment of patients in clinical trials; the release of data from clinical trials; and other clinical and regulatory events. The actual timing of these milestones could vary dramatically compared to our estimates, in some cases for reasons beyond our control. We cannot assure you that we will meet our projected milestones and if we do not meet these milestones as publicly announced, the commercialization of our products may be delayed and, as a result, our stock price may decline.

Clinical trials are necessary to support PMA applications and may be necessary to support PMA supplements for modified versions of our marketed device products. Similar requirements may apply outside the U.S. This would require the enrollment of large numbers of suitable subjects, which may be difficult to identify, recruit and maintain as participants in the clinical trial. Adverse outcomes in the post-approval studies could also result in restrictions or withdrawal of approval of the PMA or comparable foreign approvals or certification. We will likely need to conduct additional clinical studies in the future to support new indications for our products or for approvals, certification or clearances of new product lines, or for the approval or certification of the use of our products in some foreign countries. Clinical testing is difficult to design and implement, can take many years, can be expensive and carries uncertain outcomes. The initiation and completion of any of these studies may be prevented, delayed, or halted for numerous reasons. We may experience a number of events that could adversely affect the costs, timing or successful completion of our clinical trials, including:

- we may be required to submit an IDE application to the FDA, or comparable foreign applications, which must become effective prior to commencing human clinical trials, and the FDA or comparable foreign regulatory authorities may reject our application and notify us that we may not begin investigational trials;
- regulators and other comparable foreign regulatory authorities may disagree as to the design or implementation of our clinical trials;
- regulators, IRBs, ethics committees or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site;
- we may not reach agreement on acceptable terms with prospective contract research organizations ("CROs") and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of subjects or patients required for clinical trials may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, and the number of clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors, including those manufacturing products or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend, vary or terminate clinical trials for various reasons, including a finding that the subjects are being exposed to unacceptable health risks;

- we may have to amend clinical trial protocols or conduct additional studies to reflect changes in regulatory requirements or guidance, which we may be required to submit to an IRB, ethics committee or regulatory authority for re-examination;

- regulators, IRBs, ethics committees, or other parties may require or recommend that we or our investigators suspend, vary or terminate clinical research for various reasons, including safety signals or noncompliance with regulatory requirements;

- the cost of clinical trials may be greater than we anticipate;

- clinical sites may not adhere to the clinical protocol or may drop out of a clinical trial;

- we may be unable to recruit a sufficient number of clinical trial sites;

- regulators, IRBs, ethics committees or other reviewing bodies may fail to approve or subsequently find fault with our manufacturing processes or facilities of third-party supplier with which we enter into agreement for clinical and commercial supplies, the supply of devices or other materials necessary to conduct clinical trials may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply;

- approval policies or regulations of the FDA or applicable foreign regulatory authorities may change in a manner rendering our clinical data insufficient for approval; and

- our current or future products may have undesirable side effects or other unexpected characteristics.

Patient enrollment in clinical trials and completion of patient follow-up depend on many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial, patient compliance, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the product being studied in relation to other available therapies, including any new treatments that may be approved for the indications we are investigating. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and efficacy of a product candidate, or they may be persuaded to participate in contemporaneous clinical trials of a competitor's product candidate or provider's competing clinical trial. In addition, patients participating in our clinical trials may drop out before completion of the trial or experience adverse medical events unrelated to our products. Delays in patient enrollment or failure of patients to continue to participate in any of our clinical trials may delay commencement or completion of the clinical trial, cause an increase in the costs of the clinical trial and delays, or result in the failure of the clinical trial.

Clinical trials must be conducted in accordance with the laws and regulations of the FDA and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental authorities and IRBs or ethics committees at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with supplies of our devices produced under current good manufacturing practice, requirements and other regulations. Furthermore, we may rely on CROs, and clinical trial sites to ensure the proper and timely conduct of our clinical trials and we may have limited influence over their actual performance. We depend on our collaborators and on medical institutions and CROs to conduct our clinical trials in compliance with good clinical practice ("GCP") requirements. To the extent our collaborators or the CROs fail to enroll participants for our clinical trials, fail to conduct the study to GCP standards or are delayed for a significant time in the execution of trials, including achieving full enrollment, we may be affected by increased costs, program delays or both. In addition, clinical trials that are conducted in countries outside the United States may subject us to further delays and expenses as a result of increased shipment costs, additional regulatory requirements and the engagement of non-U.S. CROs, as well as expose us to risks associated with clinical investigators who are unknown to the FDA, and different standards of diagnosis, screening and medical care.

Even if our future products are cleared or approved in the United States, commercialization of our products in foreign countries would require clearance, certification or approval by regulatory authorities in those countries. Clearance, certification or approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials. Any of these occurrences could have an adverse effect on our business, financial condition and results of operations.

Our products may cause or contribute to adverse medical events or be subject to failures or malfunctions that we are required to report to the FDA and comparable foreign regulatory authorities, and if we fail to do so, we would be subject to sanctions that could negatively affect our business, financial condition and results of operations.

We are required to file various reports with the FDA, national competent authorities of EU Member States and comparable foreign regulatory authorities, including reports required by the MDRs and the (EU) MDR that require that we report to the regulatory authorities if our solutions may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur and we have filed such reports in the past. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product. If these reports are not filed in a timely manner, regulators may impose sanctions and we may be subject to product liability or regulatory enforcement actions, all of which will negatively affect our business, financial condition and results of operations.

If we initiate a correction or removal for the Zephyr Valve to reduce a risk to health posed by it, we would be required to submit a publicly available correction and removal report to the FDA and, in many cases, similar reports to other regulatory authorities. This report could be classified by the FDA or comparable foreign regulatory authorities as a device recall which could lead to increased scrutiny by the FDA, other foreign regulatory authorities and our customers regarding the quality and safety of our solutions. Furthermore, the submission of these reports could be used by competitors against us and cause physicians to delay or cancel prescriptions, which will harm our reputation.

If we assess a potential quality issue or complaint as not requiring either field action or notification, respectively, regulators may review documentation of that decision during a subsequent audit. If regulators disagree with our decision, or take issue with either our investigation process or the resulting documentation, regulatory agencies may impose sanctions and we may be subject to regulatory enforcement actions, including warning letters, all of which will negatively affect our business, financial condition and results of operations.

If we do not obtain and maintain international regulatory registrations, certification or approvals for our products, we will be unable to market and sell our products outside of the United States.

Sales of our products outside of the United States are subject to foreign regulatory requirements that vary widely from country to country. In addition, the FDA regulates exports of medical devices from the United States. While the regulations of some countries may not impose barriers to marketing and selling our products or only require notification, others require that we obtain the approval of a specified regulatory body. Complying with foreign regulatory requirements, including obtaining registrations, certification or approvals, can be expensive and time-consuming, and we may not receive regulatory approvals or certification in each country in which we plan to market our products, or we may be unable to do so on a timely basis. The time required to obtain registrations, certification or approvals, if required by other countries, may be longer than that required for FDA approval, and requirements for such registrations, clearances, certification or approvals may significantly differ from FDA requirements. If we modify our products, we may need to apply for additional regulatory approvals or certification before we are permitted to sell the modified product. In addition, we may not continue to meet the quality and safety standards required to maintain the authorizations or certification that we have received. If we are unable to maintain our authorizations or certification in a particular country, we will no longer be able to sell the applicable product in that country.

Regulatory approval by the FDA does not ensure registration, clearance, certification or approval by regulatory authorities in other countries, and registration, clearance, certification or approval by one or more foreign regulatory authorities does not ensure registration, clearance or approval by regulatory authorities in other foreign countries or by the FDA. However, a failure or delay in obtaining registration, certification or regulatory clearance or approval in one country may have a negative effect on the regulatory process in others.

Healthcare reform measures could hinder or prevent the commercial success of our solutions.

In the United States, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system in ways that will harm our future revenues and profitability and the demand for our solutions. Federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. Current and future legislative proposals to further reform healthcare or reduce healthcare costs may limit coverage of or lower reimbursement for the procedures associated with the use of our products. The cost containment measures that payors and providers are instituting and the effect of any healthcare reform initiative implemented in the future could impact our revenue from the sale of our products. For example, the Affordable Care Act contains a number of provisions that continue to impact the healthcare industry.

There have been executive, judicial and congressional challenges to certain aspects of the Affordable Care Act. For example, on June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 ("IRA") into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program. It is possible that the Affordable Care Act will be subject to judicial or congressional challenges in the future, including congressional legislation to modify or replace the Affordable Care Act or elements of the Affordable Care Act. It is unclear how any such challenges and the healthcare reform measures of the Biden administration will impact the Affordable Care Act and our business, financial condition and results of operations.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, the Budget Control Act of 2011, among other things, included reductions to CMS payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect until 2032 unless additional congressional action is taken. Additionally, the American Taxpayer Relief Act of 2012, among other things, reduced CMS payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

The Biden administration and Congress may pursue significant changes to the current healthcare laws. The impact of those changes on us and potential effect on the medical device industry as a whole is currently unknown. Any changes to the Affordable Care Act are likely to have an impact on our results of operations, and may negatively affect our business, financial condition and 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 negatively affect our business, financial condition and results of operations.

The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare will harm:

- our ability to set a price that we believe is fair for the Zephyr Valve;
- our ability to generate revenue and achieve or maintain profitability; and
- the availability of capital.

Changes in healthcare policy could increase our costs and subject us to additional regulatory requirements that may interrupt commercialization of our current and future solutions. In addition, changes in healthcare policy could increase our costs, decrease our revenue and impact sales of and reimbursement for our current and future products.

We are subject to stringent and evolving obligations related to data privacy and information security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; a disruption of our business operations; reputational harm; loss of revenue or profits; and other adverse business impacts.

In the ordinary course of business, we or the third parties upon whom we rely, may collect, store, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, share or otherwise process proprietary, confidential, and sensitive data (including but not limited to intellectual property, proprietary business information and personal data).

We are subject to diverse laws and regulations relating to data privacy and information security. Our data processing activities may also subject us to numerous other data privacy and information security obligations, such as external and internal privacy and security policies, contracts, and other obligations that govern the processing of personal data by us and on our behalf. In addition, privacy advocates and industry groups have proposed, and may propose in the future, standards by which we are legally or contractually bound to comply.

New data privacy and information security laws are being enacted in the United States and globally, and existing ones are being updated and strengthened. For example, the California Consumer Privacy Act ("CCPA") went into effect on January 1, 2020 and requires companies that process personal data on California residents to make new disclosures to consumers about their data collection, use and sharing practices, and allow consumers to opt out of certain data sharing with third parties. The CCPA also provides for civil penalties for violations (up to $7,500 per violation), as well as a private right of action for certain data breaches that is expected to increase data breach litigation. In addition, the California Privacy Rights Act of 2020 ("CPRA"), which became effective on January 1, 2023, expands the compliance requirements and rights available to consumers under the CCPA. The CPRA also establishes a new California Privacy Protection Agency to implement and enforce the CCPA (as amended), which could increase the risk of an enforcement action. As such, the CPRA may require additional compliance investment and potential business process changes in the meantime. Other states, such as Virginia, Colorado, Utah and Connecticut, have also passed comprehensive data privacy laws, and similar laws are being considered in several other states. While these states, like the CCPA, also exempt some data processed in the context of clinical trials, these developments further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely. Complying with these numerous, complex and often changing regulations is expensive and difficult, and failure to comply with any data privacy and information security laws or any security incident or breach involving the misappropriation, loss or other unauthorized use or disclosure of sensitive data, such as personal data, confidential patient or consumer information, whether by us, one of our business associates or another third-party, could negatively affect our business, financial condition and results of operations, including but not limited to: investigation costs, material fines and penalties; compensatory, special, punitive and statutory damages; litigation; consent orders regarding our privacy and security practices; requirements that we provide notices, credit monitoring services or credit restoration services or other relevant services to impacted individuals; adverse actions against our licenses to do business; and injunctive relief.

Outside the United States, an increasing number of laws, regulations, and industry standards govern data privacy and security. For example, the GDPR governs the processing (which can include any action, such as collection, use, storage adaptation or alteration, disclosure or transfer) of personal data relating to individuals located in Europe (including the UK). Among other things, the GDPR sets out extensive compliance requirements, including providing detailed disclosures about how personal data is collected and processed, demonstrating that an appropriate legal basis is in place to justify data processing activities; granting various rights for data subjects in regard to their personal data, such as the right to delete certain personal data, as well as enhancing pre-existing rights (e.g., data subject access requests); introducing the obligation to notify data protection regulators or supervisory authorities (and in certain cases, affected individuals) of significant data breaches; imposing limitations on retention of personal data; maintaining a record of data processing; complying with the principle of accountability and the obligation to

demonstrate compliance through policies, procedures, training and audit; and expanding the definition of personal data to include coded data and requiring changes to informed consent practices, as well as more detailed notices for clinical trial subjects and investigators. The GDPR imposes substantial fines for breaches and violations (up to the greater of €20 million, £17.5 million, or, in each case, 4% of our global turnover, whichever is greater). The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies and obtain compensation for damages resulting from violations of the GDPR.

In the ordinary course of business, we may transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the EEA and the UK have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA and UK's standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States.

If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

We cannot assure you that our third-party service providers with access to our or our customers', suppliers', trial patients' and employees' personal data and other sensitive or confidential information in relation to which we are responsible will not breach contractual obligations imposed by us, or that they will not experience data security breaches or attempts thereof, which could have a corresponding effect on our business, including putting us in breach of our obligations under privacy and information security laws and regulations, which could in turn adversely affect our business, results of operations and financial condition. We cannot assure you that our contractual measures and our own privacy and information security-related safeguards will protect us from the risks associated with the third-party processing, storage, and transmission of such information. We publish privacy policies, marketing materials and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and information security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Moreover, complying with the various data privacy and information security laws that are applicable to us could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. In addition, these obligations may require us to change our business model. Any failure (or perceived failure) to comply could result in government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend, could result in adverse publicity and could have a material adverse effect on our business, financial condition, and results of operations.

Our employees and personnel use generative AI technologies to perform their work, and the disclosure and use of personal data in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages.

Several jurisdictions around the globe, including Europe and certain U.S. states, have proposed or enacted laws governing AI/machine learning ("ML"). For example, European regulators have proposed a stringent AI regulation, and we expect other jurisdictions will adopt similar laws. Additionally, certain privacy laws extend rights to consumers (such as the right to delete certain personal data) and regulate automated decision making, which may be incompatible with our use of AI/ML. These obligations may make it harder for us to conduct our business using AI/ML, lead to regulatory fines or penalties, require us to change our business practices, retrain our AI/ML, or prevent or limit our use of AI/ML. For example, the FTC has required other companies to turn over (or disgorge) valuable insights or trainings generated through the use of AI/ML where they allege the company has violated privacy and consumer protection laws. If we cannot use AI/ML or that use is restricted, our business may be less efficient, or we may be at a competitive disadvantage.

We face potential liability related to the privacy of health information we obtain.

Most healthcare providers, including hospitals from which we obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA, as amended by the HITECH. We are not currently classified as a covered entity or business associate under HIPAA and thus are not subject to its requirements or penalties. However, any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information. In addition, we may maintain sensitive personally identifiable information, including health information, that we receive throughout the clinical trial process, in the course of our research collaborations, and directly from individuals (or their healthcare providers) who enroll in our patient reimbursement support programs. As such, we may be subject to state laws requiring notification of affected individuals and state regulators in the event of a breach of personal data, which is a broader class of information than the health information protected by HIPAA. Our clinical trial programs outside the United States may implicate international data protection laws, including the GDPR and national legislation of European Union Member States or the UK.

Our activities outside the United States impose additional compliance requirements and generate additional risks of enforcement for noncompliance. Failure by third-party contractors to comply with the strict rules on the transfer of personal data outside of the European Union into the United States may result in the imposition of criminal and administrative sanctions on such collaborators, which could adversely affect our business. Furthermore, certain health privacy laws, data breach notification laws, consumer protection laws and genetic testing laws may apply directly to our operations or those of our collaborators and may impose restrictions on our collection, use and dissemination of individuals' health information.

Moreover, patients about whom we or our collaborators obtain health information, as well as the providers who share this information with us, may have statutory or contractual rights that limit our ability to use and disclose the information. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend and could result in adverse publicity that could negatively affect our business, financial condition and results of operations. If we or third-party contractors or consultants fail to comply with applicable federal, state or local regulatory requirements, we could be subject to a range of regulatory actions that could affect our or our contractors' ability to develop and commercialize our product candidates and could harm or prevent sales of any affected products that we are able to commercialize, or could substantially increase the costs and expenses of developing, commercializing and marketing our products. Any threatened or actual government enforcement action could also

generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business.

Our employees, consultants, and other commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk that our employees, consultants, and other commercial partners and business associates may engage in fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or other unauthorized activities that violate the regulations of the FDA and non-U.S. regulators, including those laws requiring the reporting of true, complete and accurate information to such regulators, manufacturing standards, healthcare fraud and abuse laws and regulations in the United States and internationally or laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry, including the sale of medical devices, are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. It is not always possible to identify and deter misconduct by our employees, consultants and other 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 comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, or comparable foreign programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of operations, any of which could adversely affect our ability to operate our business and our results of operations. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees and reputational harm, and divert the attention of management in defending ourselves against any of these claims or investigations.

Compliance with environmental laws and regulations could be expensive, and the failure to comply with these laws and regulations could subject us to significant liability.

Our research, development and manufacturing operations involve the use of hazardous substances, and we are subject to a variety of federal, state, local and foreign environmental laws and regulations relating to the storage, use, handling, generation, manufacture, treatment, discharge and disposal of hazardous substances. Our products may also contain hazardous substances, and they are subject to laws and regulations relating to labeling requirements and to their sale, collection, recycling, treatment, storage and disposal. Compliance with these laws and regulations may be expensive and noncompliance could result in substantial fines and penalties. Environmental laws and regulations also impose liability for the remediation of releases of hazardous substances into the environment and for personal injuries resulting from exposure to hazardous substances, and they can give rise to substantial remediation costs and to third-party claims, including for property damage and personal injury. Liability under environmental laws and regulations can be joint and several and without regard to fault or negligence, and they tend to become more stringent over time, imposing greater compliance costs and increased risks and penalties associated with violations. We cannot assure you that violations of these laws and regulations, or releases of or exposure to hazardous substances, will not occur in the future or have not occurred in the past, including as a result of human error, accidents, equipment failure or other causes. The costs of complying with environmental laws and regulations, and liabilities that may be imposed for violating them, or for remediation obligations or responding to third-party claims, could negatively affect our business, financial condition and results of operations.

Risks Related to Our Intellectual Property

We may become a party to intellectual property litigation or administrative proceedings that could be costly and could interfere with our ability to sell and market our products.

The medical device industry has been characterized by extensive litigation regarding patents, trademarks, trade secrets, and other intellectual property rights, and companies in the industry have used intellectual property litigation to gain a competitive advantage. It is possible that U.S. and foreign patents and pending patent applications or trademarks controlled by third parties may be alleged to cover our products, or that we may be accused of misappropriating third parties' trade secrets. Additionally, our products include components that we purchase from vendors, and may include design components that are outside of our direct control. Our competitors, many of which have substantially greater resources and have made substantial investments in patent portfolios, trade secrets, trademarks, and competing technologies, may have applied for or obtained, or may in the future apply for or obtain, patents or trademarks that will prevent, limit or otherwise interfere with our ability to make, use, sell or export our products or to use our technologies or product names. Moreover, in recent years, individuals and groups that are non-practicing entities, commonly referred to as patent trolls, have purchased patents and other intellectual property assets for the purpose of making claims of infringement in order to extract settlements. From time to time, we may receive threatening letters, notices or invitations to license, or may be the subject of claims that our products and business operations infringe or violate the intellectual property rights of others. The defense of these matters can be time consuming, costly to defend in litigation, divert management's attention and resources, damage our reputation and brand and cause us to incur significant expenses or make substantial payments. Vendors from whom we purchase hardware or software may not indemnify us in the event that such hardware or software is accused of infringing a third-party's patent or trademark or of misappropriating a third-party's trade secret.

Since patent applications are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our products. Competitors may also contest our patents, if issued, by showing the patent examiner that the invention was not original, was not novel or was obvious. In litigation, a competitor could claim that our patents, if issued, are not valid for a number of reasons. If a court agrees, we would lose our rights to those challenged patents. Because we have not conducted a formal freedom to operate analysis for patents related to our products, we may not be aware of issued patents that a third party might assert are infringed by one of our current products or future product candidates, which could materially impair our ability to commercialize our products or product candidates. Even if we diligently search third-party patents for potential infringement by our products or product candidates, we may not successfully find patents that our products or product candidates may infringe. If we are unable to secure and maintain freedom to operate, others could preclude us from commercializing our products or product candidates.

In addition, we may in the future be subject to claims by our former employees or consultants asserting an ownership right in our patents, patent applications or other intellectual property, as a result of the work they performed on our behalf. Although we generally require all of our employees and consultants and any other partners or collaborators who have access to our proprietary know-how, information or technology to assign or grant similar rights to their inventions to us, we cannot be certain that we have executed such agreements with all parties who may have contributed to our intellectual property, nor can we be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy.

Any lawsuits relating to intellectual property rights could subject us to significant liability for damages and invalidate our proprietary rights. Any potential intellectual property litigation also could force us to do one or more of the following:

- stop making, selling or using products or technologies that allegedly infringe the asserted intellectual property;
- lose the opportunity to license our intellectual property to others or to collect royalty payments based upon successful protection and assertion of our intellectual property rights against others; incur significant legal expenses;
- pay substantial damages or royalties to the party whose intellectual property rights we may be found to be infringing;

- pay the attorney's fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing;
- redesign those products or technologies that contain the allegedly infringing intellectual property, which could be costly, disruptive and infeasible; and
- attempt to obtain a license to the relevant intellectual property from third parties, which may not be available on reasonable terms or at all, or from third parties who may attempt to license rights that they do not have.

In addition, if we are found to willfully infringe third-party patents or trademarks or to have misappropriated trade secrets, we could be required to pay treble damages in addition to other penalties. Although patent, trademark, trade secret, and other intellectual property disputes in the medical device area have often been settled through licensing or similar arrangements, costs associated with such arrangements may be substantial and could include ongoing royalties. We may be unable to obtain necessary licenses on satisfactory terms, if at all. If we do not obtain necessary licenses, we may not be able to redesign our products to avoid infringement.

Any litigation or claim against us, even those without merit and even those where we prevail, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation. If we are found to infringe the intellectual property rights of third parties, we could be required to pay substantial damages (which may be increased up to three times of awarded damages) or substantial royalties and could be prevented from selling our products unless we obtain a license or are able to redesign our products to avoid infringement. Any such license may not be available on reasonable terms, if at all, and there can be no assurance that we would be able to redesign our products in a way that would not infringe the intellectual property rights of others. We could encounter delays in product introductions while we attempt to develop alternative methods or products. If we fail to obtain any required licenses or make any necessary changes to our products or technologies, we may have to withdraw existing products from the market or may be unable to commercialize one or more of our products.

In addition, we generally indemnify our customers with respect to infringement by our products of the proprietary rights of third parties. Third parties may assert infringement claims against our customers. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers, regardless of the merits of these claims. If any of these claims succeed or settle, we may be forced to pay damages or settlement payments on behalf of our customers or may be required to obtain licenses for the products they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products.

Similarly, interference or derivation proceedings provoked by third parties or brought by the U.S. Patent and Trademark Office ("USPTO") may be necessary to determine priority with respect to our patents, patent applications, trademarks or trademark applications. We may also become involved in other proceedings, such as reexamination, inter parties review, derivation or opposition proceedings before the USPTO or other jurisdictional body relating to our intellectual property rights or the intellectual property rights of others. Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing our products or using product names, which would have a significant adverse impact on our business, financial condition and results of operations.

Additionally, we may file lawsuits or initiate other proceedings to protect or enforce our patents or other intellectual property rights, which could be expensive, time consuming and unsuccessful. Competitors may infringe our issued patents or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property. In addition, in a patent or other intellectual property infringement proceeding, a court may decide that a patent or other intellectual property of ours is invalid or unenforceable, in whole or in part, construe the patent's claims or other intellectual property narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents or other intellectual property do not cover the technology in question. Furthermore, even

if our patents or other intellectual property are found to be valid and infringed, a court may refuse to grant injunctive relief against the infringer and instead grant us monetary damages or ongoing royalties. Such monetary compensation may be insufficient to adequately offset the damage to our business caused by the infringer's competition in the market. An adverse result in any litigation proceeding could put one or more of our patents or other intellectual property at risk of being invalidated or interpreted narrowly, which could adversely affect our competitive business position, financial condition and results of operations.

Our success will depend on our, and any of our current and future licensors', ability to obtain, maintain and protect our intellectual property rights.

In order to remain competitive, we must develop, maintain and protect the proprietary aspects of our brands, technologies and data. We rely on a combination of contractual provisions, confidentiality procedures and patent, copyright, trademark, trade secret and other intellectual property laws to protect the proprietary aspects of our brands, technologies and data. These legal measures afford only limited protection, and competitors or others may gain access to or use our intellectual property and proprietary information. Our success will depend, in part, on preserving our trade secrets, maintaining the security of our data and know-how and obtaining and maintaining other intellectual property rights by us and our current and future licensors. We, and our current and future licensors, may not be able to obtain or maintain intellectual property or other proprietary rights necessary to our business or in a form that provides us with a competitive advantage.

In addition, our trade secrets, data and know-how could be subject to unauthorized use, misappropriation, or disclosure to unauthorized parties, despite our efforts to enter into confidentiality agreements with our employees, consultants, clients and other vendors who have access to such information, and could otherwise become known or be independently discovered by third parties. Our intellectual property, including trademarks, could be challenged, invalidated, infringed, and circumvented by third parties, and our trademarks could also be diluted, declared generic or found to be infringing on other marks. If any of the foregoing occurs, we could be forced to re-brand our products, resulting in loss of brand recognition and requiring us to devote resources to advertising and marketing new brands, and suffer other competitive harm. Third parties may also adopt trademarks similar to ours, which could harm our brand identity and lead to market confusion. Failure to obtain and maintain intellectual property rights necessary to our business and failure to protect, monitor and control the use of our intellectual property rights could negatively impact our ability to compete and cause us to incur significant expenses. The intellectual property laws and other statutory and contractual arrangements in the United States and other jurisdictions we depend upon may not provide sufficient protection in the future to prevent the infringement, use, violation or misappropriation of our trademarks, data, technology and other intellectual property and services, and may not provide an adequate remedy if our intellectual property rights are infringed, misappropriated or otherwise violated.

We rely, in part, on our ability to obtain, maintain, expand, enforce, and defend the scope of our intellectual property portfolio or other proprietary rights, including the amount and timing of any payments we may be required to make in connection with the licensing, filing, defense and enforcement of any patents or other intellectual property rights. The process of applying for and obtaining a patent is expensive, time consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost, in a timely manner, or in all jurisdictions where protection may be commercially advantageous, or we may not be able to protect our proprietary rights at all. Despite our efforts to protect our proprietary rights, unauthorized parties may be able to obtain and use information that we regard as proprietary. In addition, the issuance of a patent does not ensure that it is valid or enforceable, so even if we obtain patents, they may not be valid or enforceable against third parties. Our patent applications may not result in issued patents and our patents may not be sufficiently broad to protect our technology.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- any of our patents, or any of our pending patent applications, if issued, will include claims having a scope sufficient to protect our products;
- any of our pending patent applications will issue as patents;

- we will be able to successfully commercialize our products on a substantial scale, if approved, before our relevant patents we may have expire;
- we were the first to make the inventions covered by each of our patents and pending patent applications;
- we were the first to file patent applications for these inventions;
- others will not develop similar or alternative technologies that do not infringe our patents; any of our patents will be found to ultimately be valid and enforceable;
- any patents issued to us will provide a basis for an exclusive market for our commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties;
- we will develop additional proprietary technologies or products that are separately patentable; or
- our commercial activities or products will not infringe upon the patents of others.

Moreover, even if we are able to obtain patent protection, such patent protection may be of insufficient scope to achieve our business objectives. Issued patents may be challenged, narrowed, invalidated or circumvented. Decisions by courts and governmental patent agencies may introduce uncertainty in the enforceability or scope of patents owned by or licensed to us. Furthermore, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our own products and practicing our own technology. Alternatively, third parties may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend or assert our patents, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or agency with jurisdiction may find our patents invalid, unenforceable or not infringed; competitors may then be able to market products and use manufacturing and analytical processes that are substantially similar to ours. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

If we are unable to protect the confidentiality of our other proprietary information, our business and competitive position may be harmed.

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, and other proprietary information that is not patentable or that we elect not to patent. However, trade secrets can be difficult to protect, and some courts are less willing or unwilling to protect trade secrets. To maintain the confidentiality of our trade secrets and proprietary information, we rely heavily on confidentiality provisions that we have in contracts with our employees, consultants, collaborators and others upon the commencement of their relationship with us. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by such third parties, despite the existence generally of these confidentiality restrictions. These contracts may not provide meaningful protection for our trade secrets, know-how, or other proprietary information in the event of any unauthorized use, misappropriation, or disclosure of such trade secrets, know-how, or other proprietary information. There can be no assurance that such third parties will not breach their agreements with us, that we will have adequate remedies for any breach, or that our trade secrets will not otherwise become known or independently developed by competitors. Despite the protections we do place on our intellectual property or other proprietary rights, monitoring unauthorized use and disclosure of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property or other proprietary rights will be adequate. In addition, the laws of many foreign countries will not protect our intellectual property or other proprietary rights to the same extent as the laws of the United States. Consequently, we may be unable to prevent our proprietary technology from being exploited abroad, which could affect our ability to expand to international markets or require costly efforts to protect our technology.

We also license rights to use certain proprietary information and technology from third parties. The use of such proprietary information and technology is therefore subject to the obligations of the applicable license agreement between us and the owner. For example, the software we developed for the Chartis System includes the use of open source software that is subject to the terms and conditions of the applicable open source software licenses that grant us permission to use such software. The owner of any such proprietary information or technology also might not enforce or otherwise protect its rights in the proprietary information or technology with the same vigilance that we would, which would allow competitors to use such proprietary information and technology without having to adhere to a license agreement with the owner.

To the extent our intellectual property or other proprietary information protection is incomplete, we are exposed to a greater risk of direct competition. A third party could, without authorization, copy or otherwise obtain and use our products or technology, or develop similar technology. Our competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts or design around our protected technology. Our failure to secure, protect and enforce our intellectual property rights could substantially harm the value of our products, brand and business. The theft or unauthorized use or publication of our trade secrets and other confidential business information could reduce the differentiation of our products and harm our business, the value of our investment in development or business acquisitions could be reduced and third parties might make claims against us related to losses of their confidential or proprietary information. Any of the foregoing could materially and adversely affect our business, financial condition and results of operations.

Further, it is possible that others will independently develop the same or similar technology or product or otherwise obtain access to our unpatented technology, and in such cases, we could not assert any trade secret rights against such parties. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our trade secret rights and related confidentiality and nondisclosure provisions. If we fail to obtain or maintain trade secret protection, or if our competitors obtain our trade secrets or independently develop technology or products similar to ours or competing technologies or products, our competitive market position could be materially and adversely affected. In addition, some courts are less willing or unwilling to protect trade secrets and agreement terms that address non-competition are difficult to enforce in many jurisdictions and might not be enforceable in certain cases.

We also seek to preserve the integrity and confidentiality of our data and other confidential information by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached and detecting the disclosure or misappropriation of confidential information and enforcing a claim that a party illegally disclosed or misappropriated confidential information is difficult, expensive and time-consuming, and the outcome is unpredictable. Further, we may not be able to obtain adequate remedies for any breach.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. While an unintentional lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our products, we may not be able to stop a competitor from marketing products that are the same as or similar to our products, which would have a material adverse effect on our business.

We may not be able to protect our intellectual property rights throughout the world.

A company may attempt to commercialize competing products utilizing our proprietary design, trademarks or tradenames in foreign countries where we do not have any patents or patent applications and where legal recourse may be limited. This may have a significant commercial impact on our foreign business operations.

Filing, prosecuting and defending patents or trademarks on our current and future products in all countries throughout the world would be prohibitively expensive. The requirements for patentability and trademarking may differ in certain countries, particularly developing countries. The laws of some foreign countries do not protect intellectual property rights to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from utilizing our inventions and trademarks in all countries outside the United States. Competitors may use our technologies or trademarks in jurisdictions where we have not obtained patent or trademark protection to develop or market their own products and further, may export otherwise infringing products to territories where we have patent and trademark protection, but enforcement on infringing activities is inadequate. These products or trademarks may compete with our products or trademarks, and our patents, trademarks or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trademarks and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents and trademarks or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent and trademarks rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents and trademarks at risk of being invalidated or interpreted narrowly and our patent or trademark applications at risk, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, certain countries in Europe and certain developing countries, including India and China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we may have limited remedies if our patents are infringed or if we are compelled to grant a license to our patents to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license. Finally, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws.

We may be subject to claims that we or our employees have misappropriated the intellectual property of a third party, including trade secrets or know-how, or are in breach of non-competition or non-solicitation agreements with our competitors and third parties may claim an ownership interest in intellectual property we regard as our own.

Many of our employees and consultants were previously employed at or engaged by other medical device, biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants and contractors, may have executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may be subject to claims that we or these individuals have, inadvertently or otherwise, misappropriated the intellectual property or disclosed the alleged trade secrets or other proprietary information, of these former employers or competitors.

Additionally, we may be subject to claims from third parties challenging our ownership interest in intellectual property we regard as our own, based on claims that our employees or consultants have breached an obligation to assign inventions to another employer, to a former employer, or to another person or entity. Litigation may be necessary to defend against any other claims, and it may be necessary or we may desire to enter into a license to settle any such claim; however, there can be no assurance that we would be able to obtain a license on commercially

reasonable terms, if at all. If our defense to those claims fails, in addition to paying monetary damages, a court could prohibit us from using technologies or features that are essential to our products, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. An inability to incorporate technologies or features that are important or essential to our products could have a material adverse effect on our business, financial condition and results of operations, and may prevent us from selling our products. In addition, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. Any litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales personnel. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our products, which could have an adverse effect on our business, financial condition and results of operations.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our existing and future products.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. In 2011, the Leahy-Smith America Invents Act ("Leahy-Smith Act") was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and also may affect patent litigation. These also include provisions that switched the United States from a first-to-invent system to a first-to-file system, allow third-party submission of prior art to the USPTO during patent prosecution and set forth additional procedures to attack the validity of a patent by the USPTO administered post grant proceedings. Under a first-to-file system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective in 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition and results of operations.

In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement and defense of our patents and applications. Furthermore, the U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by U.S. and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain additional patent protection in the future.

The failure of third parties to meet their contractual, regulatory and other obligations could adversely affect our business.

We rely on suppliers, vendors, outsourcing partners, consultants, alliance partners and other third parties to research, develop, manufacture and commercialize our products and manage certain parts of our business. Using these third parties poses a number of risks, such as: (i) they may not perform to our standards or legal requirements; (ii) they may not produce reliable results; (iii) they may not perform in a timely manner; (iv) they may not maintain confidentiality of our proprietary information; (v) disputes may arise with respect to ownership of rights to technology developed with our partners; and (vi) disagreements could cause delays in, or termination of, the research, development or commercialization of our products or result in litigation or arbitration. Moreover, some third parties are located in markets subject to political and social risk, corruption, infrastructure problems and natural disasters, in addition to country-specific privacy and data security risk given current legal and regulatory

environments. Failure of third parties to meet their contractual, regulatory and other obligations may materially affect our business.

If our trademarks and tradenames are not adequately protected, then we may not be able to build name recognition in our markets and our business may be adversely affected.

We rely on trademarks, service marks, tradenames and brand names to distinguish our products from the products of our competitors and have registered or applied to register these trademarks. We have not yet registered certain of our trademarks, including "CHARITE" in Germany, and as a result we sell certain products using names that may not be protected or may be subject to third party challenges for infringement of such third party's trademarks. We cannot assure you that our trademark applications will be approved. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in proceedings before the USPTO and comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources towards advertising and marketing new brands. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. Certain of our current or future trademarks may become so well known by the public that their use becomes generic and they lose trademark protection. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business, financial condition and results of operations may be adversely affected.

Patent terms may not be able to protect our competitive position for an adequate period of time with respect to our current or future technologies.

Patents have a limited lifespan. In the United States, the standard patent term is typically 20 years after filing. Various extensions may be available. Even so, the life of a patent and the protection it affords are limited. As a result, our patent portfolio provides us with limited rights that may not last for a sufficient period of time to exclude others from commercializing products similar or identical to ours. For example, given the large amount of time required for the research, development, testing and regulatory review of implantable medical devices, patents protecting our products might expire before or shortly after they are commercialized.

Extensions of patent term may be available, but there is no guarantee that we would succeed in obtaining any particular extension-and no guarantee any such extension would confer patent term for a sufficient period of time to exclude others from commercializing products similar or identical to ours. In the United States, 35 U.S. Code § 156 Extension of patent term, permits a patent term extension of up to five years beyond the normal expiration of the patent, which is limited to the approved indication (or any additional indications approved during the period of extension). A patent term extension cannot extend the remaining term of a patent beyond 14 years from the date of product approval; only one patent may be extended; and extension is available for only those claims covering the approved device, a method for using it, or a method for manufacturing it. We have applied for such an extension however, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to any patents we obtain, or may grant more limited extensions than we request. An extension may not be granted or may be limited where there is, for example, a failure to exercise due diligence during the testing phase or regulatory review process, failure to apply within applicable deadlines, failure to apply before expiration of relevant patents, or some other failure to satisfy applicable requirements. If this occurs, our competitors may be able to launch their products earlier by taking advantage of our investment in development and clinical trials along with our clinical and pre-clinical data. This could have a material adverse effect on our business and ability to achieve profitability.

Risks Related to Ownership of Our Common Stock

Our stock price may be volatile and the value of our common stock may decline.

The market price of our common stock may be highly volatile and may fluctuate or decline substantially as a result of a variety of factors, some of which are beyond our control or are related in complex ways, including:

- actual or anticipated fluctuations in our financial condition and results of operations;
- variance in our financial performance from expectations of securities analysts or investors;
- the degree to which securities or industry analysts publish research or reports about our business;
    - changes in the pricing we offer our customers;
- changes in our projected operating and financial results;
- changes in laws or regulations applicable to our solution;
- announcements by us or our competitors of significant business developments, acquisitions, or new offerings;
- publicity associated with issues related to our solution;
- our involvement in litigation;
- future sales of our common stock or other securities, by us or our stockholders;
- changes in senior management or key personnel;
- the trading volume of our common stock;
- changes in the anticipated future size and growth rate of our market;
- general economic, regulatory, and market conditions, including inflation, rising interest rates, economic recessions or economic slowdowns;
- changes in the structure of healthcare payment systems; and
- developments or disputes concerning our intellectual property or other proprietary rights.

Broad market and industry fluctuations, as well as general economic, political, regulatory, and market conditions, may negatively impact the market price of our common stock. In addition, given the relatively small expected public float of shares of our common stock on the Nasdaq Global Select Market, the trading market for our shares may be subject to increased volatility. In the past, companies that have experienced volatility in the market price of their securities have been subject to securities class action litigation. We may be the target of this type of litigation in the future, which could result in substantial costs and divert our management's attention.

Future sales and issuances of our capital stock or rights to purchase capital stock could result in additional dilution of the percentage ownership of our stockholders and could cause the price of our common stock to decline.

Future sales and issuances of our capital stock or rights to purchase our capital stock could result in substantial dilution to our existing stockholders. We may sell common stock, convertible securities, and other equity securities

in one or more transactions at prices and in a manner as we may determine from time to time. If we sell any such securities in subsequent transactions, investors may be materially diluted. New investors in such subsequent transactions could gain rights, preferences, and privileges senior to those of holders of our common stock.

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

Sales of a substantial number of shares of our common stock by existing stockholders in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that such sales may have on the prevailing market price of our common stock.

We do not intend to pay dividends for the foreseeable future and, as a result, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.

We have never declared or paid any cash dividends on our capital stock, and we do not intend to pay any cash dividends in the foreseeable future. Any determination to pay dividends in the future will be at the discretion of our board of directors and may be restricted by the terms of any then-current credit facility. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investments.

We are currently a "smaller reporting company" and our compliance with the scaled reporting and disclosure requirements applicable to smaller reporting companies could make our common stock less attractive to investors.

We are a "smaller reporting company" as defined by Rule 12b-2 of the Exchange Act. As a result, we may take advantage of certain scaled disclosures available to smaller reporting companies, and we may take advantage of these scaled disclosures for so long as (i) our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

We have incurred, and will continue to incur, increased costs as a public company, and our management has devoted, and will continue to devote, substantial time to compliance with our public company responsibilities and corporate governance practices.

As a public company, we incur significant legal, accounting, and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global Select Market, and other applicable securities rules and regulations impose various requirements on public companies. Furthermore, the senior members of our management team do not have significant experience with operating a public company. As a result, our management and other personnel have devoted, and continue to devote, a substantial amount of time to compliance with these requirements. Moreover, compliance with these rules and regulations increase our legal and financial costs and make some activities more time-consuming and costly.

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

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws currently in effect 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, shares of undesignated preferred stock with terms, rights, and preferences determined by our board of directors that may be senior to our common stock;
- require that any action to be taken by our stockholders be effected at a duly called annual or special meeting and not by written consent;
- specify that special meetings of our stockholders can be called only by our board of directors, the chairperson of our board of directors, or our chief executive officer;
- establish an advance notice procedure for stockholder proposals to be brought before an annual meeting, including proposed nominations of persons for election to our board of directors;
- establish that our board of directors is divided into a number of classes, with each class serving staggered terms;
- prohibit cumulative voting in the election of directors;
- provide that our directors may be removed for cause only upon the vote of the holders of a majority of our outstanding shares of common stock;
- 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; and
- require the approval of our board of directors or the holders of at least a majority of our outstanding shares of common stock to amend our bylaws and certain provisions of our certificate of incorporation.

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 generally, subject to certain exceptions, prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder. Any delay or prevention of a change of control transaction or changes in our management could cause the market price of our common stock to decline.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and, to the extent enforceable, the federal district courts of the United States are the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) is the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a breach of fiduciary duty;
- any action asserting a claim against us arising under the Delaware General Corporation Law;
- our amended and restated certificate of incorporation or our amended and restated bylaws; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine.

These provisions do not apply to suits brought to enforce a duty or liability created by the Exchange Act or any claim for which the federal district courts of the United States have exclusive jurisdiction.

Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such actions under the Securities Act and an investor cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Accordingly, both state and federal courts have jurisdiction to entertain such claims and there is uncertainty as to whether a court would enforce such a forum selection provision as written in connection with claims arising under the Securities Act. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that the federal district courts of the United States are the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our amended and restated certificate of incorporation described above. While the Delaware courts have determined that such choice of forum provisions are facially valid and several state trial courts have enforced such provisions and required that suits asserting Securities Act claims be filed in federal court, there is no guarantee that courts of appeal will affirm the enforceability of such provisions and a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

These exclusive-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers, and other employees. If any court were to find either exclusive-forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business.

Item 2. Unregistered Sales of Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Insider Trading Arrangements

The following discussion includes trading arrangements adopted or terminated by our directors and officers during the three months ended June 30, 2024.

On June 10, 2024, Glendon French, a current member of our board of directors and former chief executive officer, adopted a new Rule 10b5-1 trading arrangement intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act for the sale of up to 300,000 shares of our common stock. The trading arrangement will expire on August 23, 2025, or earlier if all transactions under the trading arrangement are completed or if the trading arrangement is otherwise terminated according to its terms.

Item 6. Exhibits

		Incorporated by Reference				
Exhibit Number	**Description**	**Schedule Form**	**File Number**	**Exhibit**	**Filing Date**	**Filed Herewith**
10.1+	Offer Letter, dated March 19, 2024 by and between Mehul Joshi and Pulmonx Corporation	8-K	001-39562	10.1	April 2, 2024	
10.2	Third Amendment to Office Lease, by and between Pulmonx Corporation and HCP LS Redwood City, LLC, dated May 17, 2024.	8-K	001-39562	10.1	May 23, 2024	
10.3	Third Amendment to Sublease, by and between Pulmonx Corporation and Genomic Health, Inc., dated May 17, 2024.	8-K	001-39562	10.2	May 23, 2024	
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X

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	X
101.SCH	Inline XBRL Taxonomy Extension Schema with Embedded Linkbase Documents	X
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)	X

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+ Indicates management contract or compensatory plan.

* The certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Quarterly Report on Form 10-Q and will not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that section, nor shall they be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act, irrespective of any general incorporation language continued in such filing.

SIGNATURES

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

PULMONX CORPORATION

Date: August 2, 2024

By: /s/ Steven S. Williamson
Steven S. Williamson
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: August 2, 2024

By: /s/ Mehul Joshi
Mehul Joshi
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Steven S. Williamson, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Pulmonx Corporation;

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.

Date: August 2, 2024

By: /s/ Steven S. Williamson

Steven S. Williamson

President, Chief Executive Officer and Director

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Mehul Joshi, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Pulmonx Corporation;

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.

Date: August 2, 2024

By: /s/ Mehul Joshi

Mehul Joshi

Chief Financial Officer

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Pulmonx Corporation (the "Company") for the quarterly period ended June 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Steven S. Williamson, President and Chief Executive Officer of the Company, certify, pursuant to 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:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

Date: August 2, 2024

By: /s/ Steven S. Williamson
Steven S. Williamson
President, Chief Executive Officer and Director

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Pulmonx Corporation 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 the Form 10-Q), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

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

In connection with the Quarterly Report on Form 10-Q of Pulmonx Corporation (the "Company") for the quarterly period ended June 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Mehul Joshi, Chief Financial Officer of the Company, certify, pursuant to 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:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

Date: August 2, 2024

By: /s/ Mehul Joshi
Mehul Joshi
Chief Financial Officer

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Pulmonx Corporation 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 the Form 10-Q), irrespective of any general incorporation language contained in such filing.