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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2019

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: 000-55781

AirXpanders, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**20-2555438**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

3047 Orchard Parkway
San Jose, CA, 95134
(650) 390-3000
(Address of principal executive offices) (Zip Code)
(Registrant's telephone number, including area code)

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T 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. (Check one):

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 ☒

Securities registered pursuant to Section 12(b) of the Act: NONE

As of April 30, 2019, there were 186,153,283 shares of the registrant's common stock outstanding.

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements concerning our operating performance and events or developments that we expect or anticipate will occur in the future that are based on management's beliefs, assumptions and expectations and on information currently available to management. Any statements contained in this Quarterly Report on Form 10-Q that are not of historical facts may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "should," "could," "plan," "believes," "estimates," 'expects," "intends," or the negative of these words or other similar terms or expressions that involve risks and uncertainties which have not been based solely on historical facts but on our beliefs, assumptions and expectations about our future operating performance, events and results. The forward-looking statements are contained principally in the sections entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." Forward-looking statements include, but are not limited to, statements about:

- our ability to continue as a going concern;
- our ability to comply with covenants and obligations under our loan agreement;
- the U.S. commercial market acceptance and U.S. sales of our product;
- our ability or the ability of third-party contract manufacturer to build our product in sufficient quantities or at required quality standards to satisfy anticipated demand;
- our ability to manufacture our product at a lower cost in order to generate positive gross margins;
- our ability to identify appropriate facilities to meet our future manufacturing needs;
- our ability to obtain or maintain reimbursement for our current or new products; and
- our expectations with respect to the integrity or capabilities of our intellectual property positions.

Management believes that these forward-looking statements are reasonable as and when made. These forward-looking statements are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this Quarterly Report on Form 10-Q may turn out to be inaccurate. We have included important factors in the cautionary statements included in this Quarterly Report on Form 10-Q, particularly in the "Risk Factors" section, that could cause actual results or events to differ materially from the forward-looking statements that we make.

You are cautioned not to place undue reliance on the forward-looking statements because they speak only as of the date when made. Unless required by law, we do not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. We may not actually achieve the plans, projections or expectations disclosed in our forward-looking statements, and actual results, developments or events could differ materially from those disclosed in the forward-looking statements we make.

AirXpanders, Inc.
Quarterly Report on Form 10-Q
As of and For the Three Months Ended March 31, 2019

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PART I. – FINANCIAL INFORMATION

ITEM 1. Financial Statements

AirXpanders, Inc.
Condensed Consolidated Balance Sheets
(In thousands, except share and per share amounts)
(unaudited)

	March 31, 2019	December 31, 2018
ASSETS		
Current assets		
Cash and cash equivalents	$ 4,399	$ 9,375
Accounts receivable, net	799	765
Inventory	8,475	8,781
Prepaid expenses and other current assets	1,284	1,313
Total current assets	14,957	20,234
Property and equipment, net	3,374	3,638
Other assets	132	132
Total assets	**$ 18,463**	**$ 24,004**
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current liabilities		
Current portion of long-term debt, net of discount	$ 15,043	$ —
Accounts payable	2,549	1,800
Accrued expenses	2,178	2,771
Total current liabilities	19,770	4,571
Long-term debt, less current portion, net of discount	—	14,907
Total liabilities	19,770	19,478
Commitments and Contingencies (Note 8)		
Stockholders' (deficit) equity		
Preferred stock, $0.001 par value; 10,000,000 authorized; no shares issued and outstanding at March 31, 2019 and December 31, 2018	—	—
Class A common stock, $0.001 par value; 600,000,000 authorized; 186,153,283 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	186	186
Additional paid-in capital	126,549	126,372
Accumulated deficit	(128,042)	(122,032)
Total stockholders' (deficit) equity	(1,307)	4,526
Total liabilities and stockholders' (deficit) equity	**$ 18,463**	**$ 24,004**

See accompanying notes to condensed consolidated financial statements.

AirXpanders, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except per share amounts)
(unaudited)

	Three Months Ended March 31,	
	2019	**2018**
Net revenue	$ 1,657	$ 1,754
Cost of goods sold	2,861	2,356
Gross loss	(1,204)	(602)
Operating expenses:		
Research and development	1,084	1,450
Selling, general and administrative	3,255	3,983
Total operating expenses	4,339	5,433
Operating loss	(5,543)	(6,035)
Other expense (income):		
Interest expense	502	460
Other income, net	(35)	(52)
Total other expense (income), net	467	408
Operating loss before income tax provision	(6,010)	(6,443)
Provision for income taxes	—	—
Net loss	(6,010)	(6,443)
Net loss per common share: basic and diluted	$ (0.03)	$ (0.07)
Weighted-average number of common shares used in computing net loss per common share: basic and diluted	186,153	95,943
Comprehensive Loss:		
Net loss	$ (6,010)	$ (6,443)
Unrealized loss on investments	—	7
Total comprehensive loss	$ (6,010)	$ (6,450)

See accompanying notes to condensed consolidated financial statements.

AirXpanders, Inc.
Condensed Consolidated Statements of Stockholders' Equity (Deficit)
(In thousands, except share and per share amounts)
(unaudited)

	Class A Common Stock					
	Issued and Outstanding Shares	Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
Balance, December 31, 2017	95,943,409	$ 96	$ 112,045	$ 6	$ (95,311)	$ 16,836
Stock-based compensation	—	—	210	—	—	210
Unrealized loss on investments	—	—	—	(7)	—	(7)
Net loss	—	—	—	—	(6,443)	(6,443)
Balance, March 31, 2018	95,943,409	$ 96	$ 112,255	$ (1)	$ (101,754)	$ 10,596

	Class A Common Stock				
	Issued and Outstanding Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
Balance, December 31, 2018	186,153,283	$ 186	$ 126,372	$ (122,032)	$ 4,526
Stock-based compensation	—	—	177	—	177
Net loss	—	—	—	(6,010)	(6,010)
Balance, March 31, 2019	186,153,283	$ 186	$ 126,549	$ (128,042)	$ (1,307)

See accompanying notes to condensed consolidated financial statements.

AirXpanders, Inc.
Condensed Consolidated Statements of Cash Flows
(In thousands)
(unaudited)

	For the Three Months Ended March 31,	
	2019	**2018**
Cash flows from operating activities		
Net loss	$ (6,010)	$ (6,443)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	315	304
Amortization of debt discount and deferred issuance cost	136	124
Inventory write-down and reserves	81	698
Sales return reserve	17	(6)
Stock-based compensation	177	210
Changes in operating assets and liabilities:		
Accounts receivable	(51)	(90)
Inventory	225	(3,456)
Prepaid expenses and other assets	30	(119)
Accounts payable	749	982
Accrued expenses	(594)	(621)
Net cash used in operating activities	(4,925)	(8,417)
Cash flows from investing activities		
Maturities of short-term investments	-	5,987
Purchases of property and equipment	(51)	(550)
Net cash (used in) provided by investing activities	(51)	5,437
Net decrease in cash and cash equivalents	(4,976)	(2,980)
Cash and cash equivalents — beginning of period	9,375	4,162
Cash and cash equivalents — end of period	$ 4,399	$ 1,182
Supplemental disclosure:		
Cash paid for interest	$ 366	$ 318

See accompanying notes to condensed consolidated financial statements.

NOTE 1 – DESCRIPTION OF BUSINESS

AirXpanders, Inc. and its Australian branch ("AirXpanders" or the "Company") is a Delaware corporation formed on March 17, 2005, and is headquartered in San Jose, California. The Company's principal business is to design, manufacture, sell and distribute medical devices used in two-stage breast reconstruction procedures following mastectomy. AirXpanders' AeroForm Tissue Expander System (AeroForm) is a needle-free, patient-controlled tissue expander used in patients undergoing two-stage breast reconstruction following mastectomy prior to the insertion of a breast implant. AeroForm was granted its first CE mark in Europe in October 2012, was approved by Australia's Therapeutic Goods Administration in October 2013, commenced its initial marketing release of AeroForm in Australia in January 2015, and was granted its U.S. Food and Drug Administration, or FDA, de novo marketing authorization in December 2016 (as a Class II medical device). To date, the Company has been primarily engaged in developing and launching its initial product technology, completing clinical trials, building the manufacturing infrastructure to support commercialization efforts, recruiting key personnel and raising capital.

NOTE 2 – LIQUIDITY AND GOING CONCERN

The accompanying condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business for the foreseeable future. The Company has incurred net losses and cash flow deficits from operations since its inception and has an accumulated deficit of $128.0 million at March 31, 2019. To date, the Company's products have been approved for marketing and sales in the United States, Australia and Europe, and the Company started selling its product in Australia in 2015, and in the United States in 2017. Management expects operating losses and cash flow deficits to continue for the foreseeable future. The Company's ability to achieve profitability is dependent primarily on its ability to gain market share in the U.S, build and maintain manufacturing capacity to support commercial launch in the U.S. and obtain a more profitable per unit manufacturing cost for its products. These conditions raise substantial doubt about the Company's ability to continue as a going concern for at least a year after the issuance date of the accompanying condensed consolidated financial statements. The Company plans to address these conditions by raising capital through equity or debt financings, or a combination of both, from outside current and new investors and institutions, or through other strategic alternatives, including a potential sale of the Company. There is no assurance, however, that the Company will be successful in raising the needed capital or selling the Company, and, in the event of a capital raising, that it will be available on terms acceptable to the Company.

In addition, the loan and security agreement currently outstanding (see Note 7) is subject to a variety of affirmative and negative covenants. These covenants include minimum revenue results, minimum cash and accounts receivable balances, required financial reporting, providing an unqualified auditor's opinion together with our annual financial statements within 120 days of the end of our fiscal year (the unqualified audit opinion covenant), limitations on certain dispositions and licensing of assets, limitations on the incurrence of additional debt, and achievement of certain financial milestones. To secure our performance of our obligations under this loan and security agreement, as amended, the Company granted a security interest in all of our assets, including our intellectual property. If the Company fails to comply with the terms of the loan and security agreement, including the unqualified audit opinion covenant, the occurrence of a material adverse change in its business, operations or condition (financial or otherwise) or prospects, the material impairment in its prospect of repayment, a material impairment in the perfection or priority of the lender's lien on our assets or the value of their collateral, failure to achieve agreed financial milestones, or the occurrence of certain other specified events could result in an event of default that, if not cured or waived, could result in the acceleration of all or a substantial portion of our loan, coupled with prepayment penalties, potential foreclosure on our assets, and other adverse results. For the quarter ended March 31, 2019 and the three months ended April 30, 2019, the Company failed to meet the minimum revenue level required under the loan and security agreement. Together with the Company's need to raise capital as described above, these conditions further raise substantial doubt about the Company's ability to continue as a going concern. Additionally, based on the ability of the lender to declare an event of default, the Company believes classification of the debt as short term is appropriate as of March 31, 2019.

The Company's ability to continue as a going concern, and correspondingly to execute on its business plan and strategy, is dependent upon the Company's ability to accomplish one or more of the following: raise additional capital in the very near term to fund its ongoing operations or engage in a strategic alternative, including a potential sale of the Company. If the Company is unable to accomplish one or more of these alternatives, the lender could declare an event of default under the loan and security agreement. In addition, the Company may have to pursue or otherwise accelerate strategic alternatives, including the possibility of seeking bankruptcy protection to protect stakeholder value in the event other options are not reasonably executable.

The accompanying condensed consolidated financial statements do not include any adjustments that may be needed if the Company were unable to continue as a going concern.

NOTE 3 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP). The condensed consolidated financial statements include the accounts of AirXpanders, Inc. and its Australian branch office. Intercompany transactions and balances have been eliminated in consolidation.

The accompanying condensed consolidated financial statements have been prepared in accordance with U.S. GAAP and applicable rules and regulations of the Securities and Exchange Commission (SEC) regarding interim financial reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by U.S. GAAP have been condensed or omitted, and accordingly the balance sheet as of December 31, 2018 has been derived from audited consolidated financial statements at that date but does not include all of the information required by U.S. GAAP for complete financial statements. These unaudited interim condensed consolidated financial statements have been prepared on the same basis as our annual financial statements and, in the opinion of management, reflect all adjustments (consisting only of normal recurring adjustments) that are necessary for a fair presentation of the Company's financial information. The results of operations for the three months ended March 31, 2019 are not necessarily indicative of the results to be expected for the year ending December 31, 2019 or for any other interim period or for any other future year. The condensed consolidated financial statements include the accounts of AirXpanders, Inc. and its Australian branch. Intercompany transactions and balances have been eliminated in consolidation.

Foreign Currency

The Company transacts business in Australia. The functional currency of its Australian branch is the U.S. dollar. Monetary assets and liabilities are translated at the year-end exchange rate and non-monetary assets and liabilities are translated at historical rates and items in the statement of operations are translated at average rates with gains and losses from remeasurement being recorded in other expense (income), net in the accompanying condensed consolidated statements of operations and comprehensive loss. Foreign currency translation and remeasurement gains or losses included in other expense (income), net in the accompanying condensed consolidated statements of operations and comprehensive loss was a de minimis loss during the three months ended March 31, 2019, and a loss of $0.1 million during the three months ended March 31, 2018.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reporting period. Actual results could differ materially from those estimates. The Company's most significant estimates relate to valuation of stock options, estimate of sales returns and valuation of its inventory at the lower of cost or market.

Certain Significant Risks and Uncertainties

The Company operates in a dynamic, highly competitive industry and believes that changes in any of the following areas could have a material adverse effect on the Company's future financial position, results of operations, or cash flows: ability to obtain future financing; advances and trends in new technologies and industry standards; regulatory approval and market acceptance of the Company's products; development of sales channels; certain supplier relationships; reliance on sole suppliers or a limited number of suppliers for certain components, subassemblies and services; litigation or claims against the Company based on intellectual property, patent, product, regulatory, or other factors including the Company's ability to attract and retain employees necessary to support its growth.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to credit risk consist primarily of cash and cash equivalents. The Company maintains all of its U.S. cash balances at one financial institution, which at times may exceed the Federal Deposit Insurance Corporation (FDIC) limits of $250,000 for interest-bearing accounts. At March 31, 2019 and December 31, 2018, the Company had unrestricted cash balances of approximately $4.1 million and $8.9 million, respectively, that were in excess of the FDIC limits. The Company currently maintains its Australian cash balances at one financial institution, which, at times, may exceed the Australian government guaranteed limit of USD $0.2 million (AU$250,000). At March 31, 2019 and December 31, 2018, the Company had no cash balances that were in excess of the Australian guaranteed limit. At March 31, 2019 and December 31, 2018, the Company maintained cash and investment balances of $4.4 million and $9.4 million, respectively, with one U.S. financial institution.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less, when purchased, to be cash equivalents.

Inventory

Inventory is valued at the lower of cost or market value, with cost determined by the first-in, first-out method. When needed, the Company provides reserves for excess or obsolete inventory.

Property and Equipment

Property and equipment are stated at cost, net of accumulated depreciation and amortization. Depreciation and amortization is computed using the straight-line method over the following estimated useful lives of the assets:

Machinery and equipment	5 years
Computer equipment	3 years
Furniture and fixtures	5 years
Software licenses	1 - 3 years
Office equipment	3 years

Leasehold improvements and property and equipment under capital leases are amortized over the shorter of the estimated useful lives of the assets or the lease terms. Construction in process assets are stated at cost and will be depreciated over their estimated useful lives once placed in service.

Expenditures for repairs and maintenance are charged to expense as incurred. Upon disposition of an asset, the cost and related accumulated depreciation are removed from the accounts and the resulting gain or loss is reflected in the condensed consolidated statement of operations.

Impairment of Long-Lived Assets

The Company's long-lived assets and other assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. Recoverability of an asset to be held and used is measured by a comparison of the carrying amount of an asset to the future undiscounted cash flows expected to be generated by the asset. If such asset is considered to be impaired, the impairment to be recognized is measured as the amount by which the carrying amount of the asset exceeds its fair value. Through March 31, 2019, the Company had not experienced impairment losses on its long-lived assets.

Fair Value of Financial Instruments

The Company follows Financial Accounting Standards Board ("FASB") Accounting Standards Codification Topic No. 820, Fair Value Measurement ("ASC 820"), which clarifies fair value as an exit price, establishes a hierarchal disclosure framework for measuring fair value, and requires extended disclosures about fair value measurements. The provisions of ASC 820 apply to all financial assets and liabilities measured at fair value.

As defined in ASC 820, fair value represents the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As a result, fair value is a market-based approach that should be determined based on assumptions that market participants would use in pricing an asset or a liability. As a basis for considering these assumptions, ASC 820 defines a three-tier value hierarchy that prioritizes the inputs used in the valuation methodologies in measuring fair value.

Level 1 – Quoted prices in active markets for identical assets or liabilities.

Level 2 – Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities, quoted prices 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 assets or liabilities.

Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value.

The following table sets forth by level, within the fair value hierarchy, the Company's assets measured at fair value on a recurring basis in the balance sheet as of the following dates (in thousands):

	March 31, 2019			
	Fair Value Measurements Using Input Types			
	Level 1	Level 2	Level 3	Total
Cash and cash equivalents	$ 4,399	$ —	$ —	$ 4,399
Total assets at fair value	$ 4,399	$ —	$ —	$ 4,399

	December 31, 2018			
	Fair Value Measurements Using Input Types			
	Level 1	Level 2	Level 3	Total
Cash and cash equivalents	$ 9,375	$ —	$ —	$ 9,375
Total assets at fair value	$ 9,375	$ —	$ —	$ 9,375

Long-term debt is valued at carrying value which is considered to be representative of its fair value based on current market rates available to the Company for comparable borrowing facilities as well as due to its short time of maturity (Level 2 measurement).

Revenue Recognition

The Company adopted Accounting Standards Codification ("ASC") 606, *Revenue from Contracts with Customers*, effective January 1, 2019 using the modified retrospective method. Results for reporting periods beginning after January 1, 2019 are presented under ASC 606, while prior period amounts are not adjusted and continue to be reported in accordance with our historic accounting under ASC 605, *Revenue Recognition*. The adoption of this standard did not have a cumulative effect on opening accumulated deficit as of January 1, 2019, as the timing and measurement of revenue recognition is materially the same under ASC 606 as it was under the prior guidance.

Under ASC 605, the Company recognized revenue from product sales when the following four criteria were met: delivery had occurred, there was persuasive evidence of an arrangement, the fee was fixed or determinable, and collectability of the related receivable was reasonably assured. The Company recognized revenue when title to the product and risk of loss transferred to customers, provided there was no remaining performance obligations required of the Company or any written matters requiring customer acceptance. Revenue recognition generally occurred upon either shipment or implantation of the device.

Under ASC 606, the Company recognizes revenue from product sales when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. For sales of our devices to customers and distributors, control is transferred upon delivery to customers, or, in some cases, upon implantation of the device.

In the United States, the Company offers a thirty day return policy and recognizes revenue net of sales returns and allowances. Appropriate reserves are established for anticipated sales returns based on historical experience, recent gross sales and any notification of pending returns. Actual sales returns in any future period are inherently uncertain and thus may differ from the estimates. If actual sales returns differ significantly from the estimates, an adjustment to revenue in the current or subsequent period would be recorded.

The Company has established an allowance for sales returns of $0.1 million as of March 31, 2019 and December 31, 2018, respectively, recorded net against accounts receivable in the balance sheet.

Shipping and Handling Costs

Shipping and handling costs, net of amounts charged to customers, are included as a component of cost of goods sold.

Accounts Receivable and Allowance for Doubtful Accounts

Accounts receivable are stated at cost, net of allowance for doubtful accounts. Credit is extended to customers based on an evaluation of their financial condition and other factors. The Company does not charge interest on past due balances. The Company generally does not require collateral or other security to support accounts receivable. The Company performs ongoing credit evaluations of its customers and maintains an allowance for doubtful accounts.

The Company estimates its allowance for doubtful accounts by evaluating specific accounts where information indicates that customers may have an inability to meet their financial obligations and receivable amounts are outstanding for an extended period beyond the invoice terms. In these cases, the Company uses assumptions and judgment, based on the best available facts and circumstances, to either record a specific allowance against these customer balances or to write the balances off. The accounts receivable aging is reviewed on a regular basis and write-offs are recorded on a case-by-case basis net of any amounts that may be collected. Allowance charges are recorded as operating expenses. Based on the Company's customer analysis, it has established an allowance for doubtful accounts of $26,000 as of March 31, 2019 and December 31, 2018, respectively, recorded net against accounts receivable in the balance sheet.

Stock-Based Compensation

Stock-based compensation is measured at the grant date based on the fair value of the award. The fair value of the award that is ultimately expected to vest is recognized as expense on a straight-line basis over the requisite service period, which is generally the vesting period. The expense recognized for the portion of the award that is expected to vest has been reduced by an estimated forfeiture rate. The forfeiture rate is determined at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

The Company uses the Black-Scholes option-pricing model (the "Black-Scholes model") as the method for determining the estimated fair value of stock options.

Expected Term

The Company's expected term represents the period that the Company's stock-based awards are expected to be outstanding and is determined using the simplified method, which essentially equates to a weighted average of the vesting periods and total term of the award.

Expected Volatility

Expected volatility is estimated using the Company's own volatility history and comparable public company's volatility (both equally weighted) for similar terms as the Company does not have a long enough operating period as a public company to estimate its own volatility solely based upon the Company's stock price history.

Expected Dividend

The Black-Scholes model calls for a single expected dividend yield as an input. The Company has never paid dividends and has no current plans to pay dividends on its common stock.

Risk-Free Interest Rate

The risk-free interest rate used in the Black-Scholes model is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of the option.

The Company recognizes the fair value of stock options granted to nonemployees as stock-based compensation expense over the period in which the related services are received.

Research and Development

Costs incurred in research and development activities (including clinical trials) are expensed as incurred. Research and development costs include, but are not limited to, payroll and personnel expenses, laboratory supplies, consulting costs, travel, parts and materials, equipment expenses, and equipment depreciation.

Income Taxes

The Company accounts for income taxes using the asset and liability method. Under this method, deferred income tax assets and liabilities are recorded based on the estimated future tax effects of differences between the financial statement and income tax basis of assets and liabilities. In addition, deferred tax assets are recorded for the future benefit of utilizing net operating loss and tax credit carryovers. Deferred tax assets and liabilities are measured using the enacted tax rates applied to taxable income. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is provided against the Company's deferred income tax assets when it is more likely than not that the asset will not be realized.

Significant judgment is required in determining any valuation allowance recorded against deferred tax assets. In assessing the need for a valuation allowance, the Company considers all available evidence, including past operating results, estimates of future taxable income and the feasibility of tax planning strategies. In the event that the Company changes its determination as to the amount of deferred tax assets that are more likely than not to be realized, the Company will adjust its valuation allowance with a corresponding impact to the provision for income taxes in the period in which such determination is made.

The Company follows authoritative guidance regarding uncertain tax positions. This guidance requires that realization of an uncertain income tax position must be more likely than not (i.e. greater than 50% likelihood of receiving a benefit) before it can be recognized in the financial statements. The guidance further prescribes the benefit to be realized assumes a review by tax authorities having all relevant information and applying current conventions. The interpretation also clarifies the financial statement classification of tax related penalties and interest and sets forth disclosures regarding unrecognized tax benefits. The Company recognizes potential accrued interest and penalties related to unrecognized tax benefits as income tax expense.

Segments

The Company has determined the chief executive officer is the chief operating decision maker. The Company's chief executive officer reviews financial information presented for purposes of assessing performance and making decisions on how to allocate resources. The Company has determined that it operates in a single reporting segment.

Basic and Diluted Net Loss Per Share

Basic net loss per share is computed by dividing the net loss by the weighted-average number of shares of common stock outstanding during the period. Diluted net loss per share is computed by giving effect to all potential shares of common stock, resulting from the conversion or exercise of stock options, stock warrants, convertible debt and convertible preferred stock to the extent dilutive. For the periods presented, all such common stock equivalents have been excluded from diluted net loss per share as the effect to net loss per share would be anti-dilutive.

Following is a table summarizing the potentially dilutive common shares that were excluded from diluted weighted-average common shares outstanding for the three months ended March 31, 2019 and 2018, respectively, as there effects would be antidilutive (in thousands):

	2019	2018
Shares of common stock issuable upon exercise of warrants	1,706	615
Shares of common stock issuable upon exercise of stock options	15,488	8,153
Potential common shares excluded from diluted net loss per share	17,194	8,768

Recent Accounting Pronouncements

The Company assesses the adoption impact of recently issued accounting standards by the Financial Accounting Standards Board on our financial statements. The above describes the impact of newly issued standards as well as material updates to our previous assessments, if any, from our audited financial statements included in our annual report on Form 10-K, filed with the SEC on February 27, 2019.

NOTE 4 – INVENTORY

Inventory consisted of the following at (in thousands):

	March 31, 2019	December 31, 2018
Raw materials	$ 1,461	$ 1,759
Work in progress	4,055	4,793
Finished goods	2,959	2,229
Inventory	$ 8,475	$ 8,781

The Company had recorded inventory provisions and write-downs to inventory to market value by $0.1 million and $0.7 million for the three months ended March 31, 2019 and 2018, respectively.

NOTE 5 – PROPERTY AND EQUIPMENT

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

	March 31, 2019	December 31, 2018
Machinery and equipment	$ 3,630	$ 3,578
Computer equipment	327	327
Furniture and fixtures	239	239
Leasehold improvements	468	468
Software licenses	456	456
Construction in progress	637	637
Property and equipment, gross	5,757	5,705
Accumulated depreciation and amortization	(2,383)	(2,067)
Property and equipment, net	$ 3,374	$ 3,638

Depreciation and amortization expense amounted to $0.3 million and $0.3 million for the three months ended March 31, 2019 and 2018, respectively.

NOTE 6 – ACCRUED EXPENSES

Accrued expenses consisted of the following at (in thousands):

	March 31, 2019	December 31, 2018
Accrued compensation and benefits	$ 572	$ 1,093
Accrued rent payable	65	103
Accrued purchase commitments	31	56
Customer deposits	834	752
Accrued other	676	767
Total accrued expenses	$ 2,178	$ 2,771

NOTE 7 – DEBT FINANCING

In August 2017, the Company borrowed $15,000,000 under a loan and security agreement with a financial institution which matures in August 2022. Interest is paid monthly on the principal amount at a variable rate equal to the greater of (a) the thirty day LIBOR rate, or (b) 0.99%, plus 7.26% per annum. The loan is secured by substantially all of our assets, including intellectual property. Under the terms of the agreement, as amended on July 30, 2018, interest-only payments are due monthly through December 2019, with principal payments commencing in January 2020, due in 32 equal monthly installments. A final fee of $1,200,000 is due at maturity (or acceleration or prepayment), and is being accrued monthly as additional interest expense over the term of the loan. Subject to a prepayment fee equal to between 0.5% to 2.0% of the principal amount of the prepaid amount, we can prepay the entire loan amount by providing a written five-day notice prior to such prepayment and paying all outstanding principal, interest, final payment fees and prepayment fees plus any default fees and all other sums that shall have become due and payable.

Under the loan and security agreement, as amended in July 2018, the Company is required to maintain a certain minimum level of revenues, subject to quarterly measurement through 2018, and monthly thereafter, in addition to complying with certain other covenants, including minimum cash balances. The loan and security agreement also includes events of default, the occurrence and continuation of any of which provides the financial institution with the right to exercise remedies against us and the collateral securing the loans, including cash. These events of default include, among other things, the failure to pay amounts due under the credit facilities, insolvency, the occurrence of a material adverse event, which includes a material adverse change in our business, operations or properties (financial or otherwise) or a material impairment of the prospect of repayment of any portion of the obligations. A violation of any of these covenants or the occurrence of a material adverse change could result in a default under the loan and security, which would result in termination of all commitments and loans under the agreement and all amounts owing under the agreement to become immediately due and payable. As of September 30, 2017, March 31, 2018, June 30, 2018 and March 31, 2019, the Company was in violation of a covenant under the loan and security agreement. On November 9, 2017, the Company and the financial institution entered into a waiver and first amendment to the loan and security agreement, pursuant to which it received a waiver of the event of default for the September 30, 2017 noncompliance with a financial covenant,and modified certain financial covenants. On April 26, 2018, the Company and the financial institution entered into a further waiver and second amendment to the loan and security agreement, pursuant to which it received a waiver of the event of default for the March 31, 2018 noncompliance with a financial covenant. On July 30, 2018, the Company and the financial institution entered into a further waiver and fourth amendment to the loan and security agreement, pursuant to which it received a waiver of the event of default for the June 30, 2018 noncompliance with a financial covenant. The Company was not in compliance with the covenants as of March 31, 2019, and no waiver has been obtained as of the date of the issuance of these unaudited consolidated financial statements.

In connection with the loan and security agreement, the Company issued warrants to the financial institution for the purchase of 277,778 shares of its Class A common stock with an exercise price of $1.62 per share. The fair value of the warrants of $227,000 on the date of issuance was recorded as additional debt discount. In connection with the second amendment to the loan and security agreement, the Company issued warrants to the financial institution for the purchase of 277,778 shares of its Common Stock with an exercise price of $0.32 per share. The fair value of the warrants of $48,000 on the date of issuance was recorded as additional debt discount. In connection with the fourth amendment to the loan and security agreement, the Company issued warrants to the financial institution for the purchase of 937,500 shares of its Common Stock with an exercise price of $0.16 per share. The fair value of the warrants of $149,000 on the date of issuance was recorded as additional debt discount.

The Company recorded $0.1 million and $40,000 to interest expense related to amortization of the debt discount and issuance costs for the three months ended March 31, 2019 and 2018, respectively. As of March 31, 2019, the unamortized discount and issuance cost is $0.5 million.

The Company recorded $0.5 million and $0.4 million of interest expense on the loans for the three months ended March 31, 2019 and 2018, respectively. At March 31, 2019, $15.0 million was outstanding under this loan and security agreement.

As of March 31, 2019, the future principal payments, including the final fee, due under the loan and security agreement are (in thousands):

Year ending December 31,	
2019	-
2020	5,625
2021	5,625
2022	4,950
Total	$ 16,200

Debt Classification

The Company's debt outstanding under the August 2017 debt is currently classified as short-term. The loan and security agreement contains a subjective acceleration clause, which is a provision in a debt or financing agreement that allows the lender to accelerate the scheduled maturities of the debt or to cancel the financing agreement under conditions that are not objectively determinable, such as “if a material adverse change occurs” or for “failure to maintain satisfactory operations”. Under the terms of the loan and security agreement, if the lender were to determine that such an event occurs, the lender would be able to accelerate the amounts owed under the agreement, including outstanding principal, the final fee and any repayment penalty, and such amounts would become immediately due and payable. In addition, pursuant to the terms of the loan and security agreement, all of the Company's bank accounts are subject to a control agreement between the bank, the lender and the Company, whereby, upon proper notice to the bank of an event occurring under the subjective acceleration clause, the lender would be able to automatically withdrawal all funds in the Company's bank accounts, up to the amounts owed under the loan and security agreement. The Company believes classification of the debt as short term is appropriate as of March 31, 2019, due to the covenant violation requiring achievement of minimum revenue levels for the quarter ended March 31, 2019 and the three months ended April 30, 2019, the uncertainty of the Company's ability to meet future minimum revenue levels and minimum cash and receivable balances absent a capital raising, or adjustment of covenants. While the lender has not notified the Company of an event of default, the Company believes that the lender could consider these items as a material adverse change, which could give rise to an acceleration of any amounts outstanding under the loan and security agreement.

NOTE 8 – COMMITMENTS AND CONTINGENCIES

The Company signed a non-cancelable operating sublease for an approximate 24,000 square foot facility for office, research and development and manufacturing in San Jose, California. The sublease expires in August 2019. Additionally, the Company leases approximately 5,000 square feet for office and research and development in Palo Alto, California under a non-cancelable operating lease. The term of the lease expires in September 2019. This facility is currently under a non-cancelable sublease with a tenant through its expiration date. Previously, the Company maintained manufacturing space of approximately 9,000 square feet in Palo Alto, California. In August 2018 the Company negotiated the termination of the lease with the landlord. Previously, the Company maintained a sales office in Sydney, Australia under a non-cancelable lease that expired in April 2020. In August 2018 the Company negotiated with the landlord a transfer of the lease to a new tenant.

As of March 31, 2019, the future rental commitments due under the lease are (in thousands):

Year ending December 31,		
2019 (remaining 9 months)	$	273
Total	$	273

The Company maintains an inventory purchase agreements with its third-party contract manufacturer in Costa Rica. The Company's liability under this purchase commitment is generally restricted to a forecasted three month period. The Company estimates its open inventory purchase commitment as of March 31, 2019 was approximately $0.8 million. The Company recorded a $31,000 inventory write-down to market value related to this commitment, which is included in accrued expenses in the accompanying condensed consolidated balance sheet.

Indemnifications

The Company has agreed to indemnify its officers and directors for certain events or occurrences arising as a result of the officers or directors serving in such capacity. The Company has a directors and officers' liability insurance policy that limits its exposure and enables the Company to recover a portion of any future amounts paid resulting from the indemnification of its officers and directors. In addition, the Company enters into indemnification agreements with other parties in the ordinary course of business. The Company has not incurred material costs to defend lawsuits or settle claims related to these indemnification agreements. The Company's management believes the estimated fair value of these indemnification agreements is minimal and has not recorded a liability for these agreements as of March 31, 2019 and December 31, 2018.

Royalties

The Company uses AeroForm technology in the products it is developing. AeroForm embodies inventions that have been patented in certain key jurisdictions. Certain of those patents are held by Shalon Ventures (either alone or jointly with AirXpanders). Shalon Ventures and AirXpanders have entered into a License Agreement dated March 9, 2005 (as amended on March 9, 2009 and January 9, 2012) in relation to those inventions (Shalon Ventures License Agreement). Pursuant to the Shalon Ventures License Agreement, Shalon Ventures granted AirXpanders an exclusive license to develop, make, have made, use, offer for sale, sell, have sold, import and export products that, but for the license, would infringe one or more claims of the patents. The license covers all human uses of self-expanding tissue expanders anywhere in the world and includes the right to sublicense.

In consideration for the license, AirXpanders pays Shalon Ventures a running royalty of 3% of net sales of the licensed invention. If the amount of royalties paid in a calendar year is less than $10,000, then AirXpanders shall also pay Shalon Ventures' out of pocket costs for prosecuting and maintaining the relevant patents. Each party indemnifies the other for any liability arising out of its material breach of the license, or its gross negligence, intentional misconduct and illegal actions. AirXpanders also indemnifies Shalon Ventures for any liability arising out of the commercialization of products using the license. For the three months ended March 31, 2019 and 2018, respectively, the Company recorded approximately $51,000 and $51,000 in royalty fees, which is included in cost of goods sold in the accompanying condensed consolidated statements of operations. Mr. Teddy Shalon is the Chief Executive Officer and sole shareholder of Shalon Ventures. Mr. Shalon and Mr. Barry Cheskin are each party to an agreement with Shalon Ventures, under which Shalon Ventures has agreed to pay Mr. Shalon 58%, and Mr. Cheskin 8%, of any royalties due to Shalon Ventures from AirXpanders under the Shalon Ventures License Agreement. Mr. Shalon was a director of the Company through May 2017, and a current stockholder of the Company. Mr. Cheskin is a director and stockholder of the Company. Mr. Cheskin is also the co-founder and chairman of the board of the Company.

NOTE 9 – COMMON STOCK

The Company's Certificate of Incorporation, as amended, authorizes the Company to issue 600,000,000 shares of $0.001 par value Class A common stock. Common stockholders are entitled to dividends when and if declared by the Board of Directors. The holder of each share of common stock is entitled to one vote. At March 31, 2019 and December 31, 2018, no dividends had been declared for common stock. At March 31, 2019, 186,153,283 shares of Class A common stock were issued and outstanding.

NOTE 10 – CONVERTIBLE PREFERRED STOCK

The Company's Certificate of Incorporation, as amended, authorizes the Company to issue 10,000,000 authorized shares of preferred stock, with rights and privileges for preferred stock to be determined by Company's Board of Directors before issuing preferred shares. At March 31, 2019 and December 31, 2018, there were no outstanding shares of preferred stock.

NOTE 11 – STOCK-BASED COMPENSATION

The fair value of stock options is estimated on the grant date using the Black-Scholes valuation model and the assumptions noted in the following table.

	Three Months Ended March 31,	
	2019	2018
Expected terms (years)	6.25	6.0 - 6.5
Volatility	70%	32.1 - 33.7%
Risk-free rate	2.58%	2.6 - 2.7%
Dividend yield	—%	—%

Activity under the Plan is set forth below:

	Options Available for Grant	Number of Options Outstanding	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Life in Years
Balance — December 31, 2018	5,289,461	14,376,488	$ 0.21	9.4
Additional shares reserved	3,723,065	—		
Options granted	(1,260,000)	1,260,000	$ 0.09	
Options forfeited/cancelled/repurchase	148,164	(148,164)	$ 0.17	
Balance — March 31, 2019	7,900,690	15,488,324	$ 0.20	9.2
Vested or expected to vest at March 31, 2019		15,488,324	$ 0.20	9.2
Exercisable at March 31, 2019		1,746,388	$ 0.80	6.2

In connection with the grant of stock options to employees and non-employees, the Company recorded stock compensation expense as follows (in thousands):

	Three Months Ended March 31,	
	2019	2018
Cost of goods sold	$ 10	$ 27
Research and development	21	26
Selling, general and administrative	146	157
Total	$ 177	$ 210

NOTE 12 – SUBSEQUENT EVENT

On May 1, 2019, the Company notified approximately 45% of its workforce that their employment will be terminated. As a result of the workforce reduction, the Company recorded a restructuring charge in May 2019 for termination benefits of $0.2 million. The Company expects to complete the organizational restructuring by the end of the second quarter of 2019.

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

The following discussion and analysis of our financial condition and results of operations should be read together with our condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto and management's discussion and analysis of financial condition and results of operations for the year ended December 31, 2018 included in our Annual Report on Form 10, filed with the Securities and Exchange Commission on February 27, 2019, or our Form 10-K. This discussion contains forward-looking statements that involve risks, uncertainties and assumptions. As a result of many factors, such as those set forth under "Risk Factors" in Item 1A of our Form 10-K which are incorporated herein by reference, our actual results may differ may differ materially from those described in or implied in these forward-looking statements.

Overview

AirXpanders is a U.S. based medical device company whose principal business is to design, manufacture, sell and distribute medical devices used in two-stage breast reconstruction procedures following mastectomy. Our AeroForm Tissue Expander System (AeroForm) is a needle-free, patient-controlled tissue expander used in patients undergoing two-stage breast reconstruction following mastectomy prior to the insertion of a breast implant. AeroForm was granted its first CE mark in Europe in October 2012, was approved by Australia's Therapeutic Goods Administration in October 2013, commenced its initial marketing release of AeroForm in Australia in January 2015, and was granted its U.S. Food and Drug Administration, or FDA, de novo marketing authorization in December 2016 (as a Class II medical device). To date, we have been primarily engaged in developing and launching our initial product technology, completing clinical trials, building the manufacturing infrastructure to support commercialization efforts, recruiting key personnel and raising capital.

We commenced commercial sales of AeroForm in 2015 and are focused on executing our strategy to become the standard of care for tissue expanders in breast reconstruction post mastectomy. Through 2017, our commercial activities were limited to Australia, where a number of our early clinical trials were performed. Commencing in 2018, the majority of our commercial effort will be focused on the U.S. Once sales are established in the U.S., we may extend our presence into Europe, where we have already obtained approval to market and sell AeroForm, and Asia, where we will need to obtain regulatory approvals.

We secured Australian reimbursement for AeroForm in November 2014. In December 2016, the FDA granted de novo marketing authorization for AeroForm as a Class II medical device, and we commenced commercial operations in January 2017. In the U.S. we believe we will benefit from existing reimbursement codes that provide broad reimbursement coverage for breast reconstruction procedures (including tools and devices used in those procedures, such as tissue expanders). In addition, due to the U.S. Women's Health and Cancer Rights Act of 1998, which federally mandates reimbursement of breast reconstruction procedures, private insurers that provide reimbursement for mastectomies (which we understand to be all major private insurers in the U.S.) are required to also provide reimbursement for procedures for breast reconstruction (inclusive of the use of tissue expanders such as AeroForm). Although rates of reimbursement for breast reconstruction procedures in the U.S. have been increasing in recent years, reimbursement rates are lower than our cost to produce AeroForm, and no assurance can be given that reimbursement amounts will continue to increase or that the amounts will be sufficient to enable us to sell AeroForm on a profitable basis in the U.S. Moreover, we cannot predict what changes may be made in the future to third party coverage and reimbursement in Australia or the U.S. and what impact any such changes may have on our ability to sell AeroForm.

AirXpanders was incorporated in Delaware in 2005 and is headquartered in San Jose, California. We have incurred net losses and cash flow deficits from operations since our inception. During the three months ended March 31, 2019, we had net revenues of approximately $1.7 million and a net loss of $6.0 million. Our accumulated deficit was approximately $128.0 million at March 31, 2019. To date, our products have been approved for marketing and sales in the United States, Australia and Europe.

In June 2015, we issued 29,629,654 shares of Common Stock in connection with an initial public offering (IPO) on the Australian Securities Exchange (ASX), a concurrent private placement under Regulation D of the Securities Act (or Concurrent Placement) and the conversion of convertible bridge notes payable and related accrued interest. We raised a total of approximately $30.1 million, net of issuance costs of approximately $2.9 million. Of this amount, $25.1 million were net cash proceeds directly from the IPO, and $5.0 million were cash proceeds from the Concurrent Placement and private placement of convertible bridge notes payable. In connection with the IPO, all of our existing shares of preferred stock were converted into Common Stock.

In June 2016, we issued 8,771,930 shares of Common Stock in connection with an equity offering on the ASX. Our cash proceeds were approximately $14.2 million, net of issuance costs of approximately $0.7 million.

In February 2017, we issued 16,304,348 shares of Common Stock in connection with an equity offering on the ASX. We raised a total of $32.6 million, net of issuance costs of approximately $1.5 million.

In August 2017, we borrowed $15.0 million under a loan and security agreement with a financial institution which matures in August 2022.

In August 2018, we issued 89,773,611 shares of Common Stock in connection with a rights offering of our CDIs in Australia and the 2018 Concurrent Private Placement. We raised a total of $13.4 million, net of issuance costs of approximately $1.3 million. In October 2018, we issued 299,060 shares of Common Stock for $50,000 in connection with the second closing of the 2018 Concurrent Private Placement.

In 2018, we completed multiple organizational restructurings which included reductions in workforce to reduce operating costs and better align our workforce with the needs of our business. In addition, in July 2018, we eliminated its direct sales force in Australia and commenced distributing its product through a third-party distributor in Australia.

In March 2019, we announced the voluntary suspension of trading of its securities on the ASX while we reviewed and finalized various matters pertaining to its operations, including resolving the debt covenant breach with our lender related to minimum revenue levels for the quarter ended March 31, 2019. In May 2019, we continued in suspension as we continue discussions with our lender with regards to the covenant breach and evaluated opportunities to raise additional capital.

As of March 31, 2019, we had cash and cash equivalents of $4.4 million. Therefore, substantial doubt exists as to our ability to continue as a going concern and if we are not able to raise capital within the second quarter of 2019, we will not be able to support our ongoing operations.

In an effort to address these liquidity concerns, on May 1, 2019, we commenced an internal restructuring and notified approximately 45% of our workforce that their employment would be terminated. We anticipate we will incur aggregate one-time restructuring charges of approximately $0.2 million in the second quarter of 2019. The aggregate expected restructuring charges to be incurred in connection with the reduction in workforce and the timing thereof are subject to a number of assumptions, and actual results may differ materially from those originally anticipated. We may also incur other material charges not currently contemplated due to events that may occur as a result of, or associated with, the restructuring. Our intent with this restructuring is to refocus activities, streamline operations and make more efficient use of remaining cash as we attempt to continue to develop the market. We cannot predict whether the restructuring will be an effective means of continuing our ongoing operations.

Our ability to continue as a going concern, and correspondingly to execute on our business plan and strategy, is dependent upon our ability to accomplish one or more of the following: raise additional capital in the very near term to fund our ongoing operations or engage in a strategic alternative, which includes the potential sale of the business. On May 2, 2019, we engaged a financial advisor to assist us in exploring financial and strategic opportunities to enhance stakeholder value. If we are unable to accomplish one or more of these alternatives in the near term, the lender could declare an event of default under the loan and security agreement and we may have to pursue or otherwise accelerate strategic alternatives, including the possibility of seeking bankruptcy protection to protect stakeholder value in the event other options are not reasonably executable. As a result, our primary goal in the near-term is to successfully complete the review of strategic alternatives and consummate a transaction or series of transactions to achieve the objectives as described above. Our ability to identify and complete such a strategic alternative is highly speculative.

Critical Accounting Policies and Estimates

The preparation of our financial statements conforms to accounting principles generally accepted in the United States of America, which requires management to make estimates and judgments in applying our accounting policies that have an important impact on our reported amounts of assets, liabilities, revenue, expenses and related disclosures at the date of our financial statements. On an ongoing basis, management evaluates its estimates including those related to sales returns and allowances, bad debts, inventory valuations, impairment and income taxes. Management bases its estimates and judgments on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from management's estimates.

There were no significant changes in our critical accounting policies during the three months ended March 31, 2019. Please refer to Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations," in our Form 10-K for a complete discussion of our critical accounting policies.

Going Concern

As we have limited commercialization of our product, we are generating a small amount of revenue and are not cash flow positive or profitable. Our net revenue from sales of AeroForm was $1.7 million for the three months ended March 31, 2019, and $7.8 million for the year ended December 31, 2018, and, as of March 31, 2019, we had cash and cash equivalents of approximately $4.4 million. We believe our current cash balances are insufficient to cover the Company's operating expenses through the end of the second quarter of 2019. These conditions raise substantial doubt about the Company's ability to continue as a going concern for at least a year after the issuance date of the accompanying condensed consolidated financial statements. The Company plans to address these conditions by raising capital through equity or debt financings, or a combination of both, from outside current and new investors and institutions, or through a sale of the Company. There is no assurance, however, that the Company will be successful in raising the needed capital or selling the Company, or, in the event of a capital raising, that it will be available on terms acceptable to the Company.

Our ability to continue as a going concern, and correspondingly to execute on our business plan and strategy, is dependent upon our ability to accomplish one or more of the following: raise additional capital in the very near term to fund our ongoing operations or engage in a strategic alternative, including a potential sale of the business. If we are unable to accomplish one or more of these alternatives the lender could declare an event of default under the loan and security agreement. If this occurs, we may have to pursue or otherwise accelerate strategic alternatives, including the possibility of seeking bankruptcy protection to protect stakeholder value in the event other options are not reasonably executable.

Debt Classification

Our debt outstanding under the August 2017 debt is currently classified as short-term. The loan and security agreement contains a subjective acceleration clause, which is a provision in a debt or financing agreement that allows the lender to accelerate the scheduled maturities of the debt or to cancel the financing agreement under conditions that are not objectively determinable, such as "if a material adverse change occurs" or for "failure to maintain satisfactory operations". Under the terms of the loan and security agreement, if the lender were to determine that such an event occurs, the lender would be able to accelerate the amounts owed under the agreement, including outstanding principal, the final fee and any repayment penalty, and such amounts would become immediately due and payable. In addition, pursuant to the terms of the loan and security agreement, all of our bank accounts are subject to a control agreement between the bank, the lender and us, whereby, upon proper notice to the bank of an event occurring under the subjective acceleration clause, the lender would be able to automatically withdrawal all funds in our bank accounts, up to the amounts owed under the loan and security agreement. We believe classification of the debt as short term is appropriate as of March 31, 2019, due to the covenant violation for the quarter ended March 31, 2019 of the requirement to achieve minimum revenue levels, the uncertainty of our ability to meet future minimum revenue levels and minimum cash and receivable balances absent a capital raising, or adjustment of covenants. While the lender has not notified us of an event of default, the Company believes that the lender could consider these items as a material adverse change, which could give rise to an acceleration of any amounts outstanding under the loan and security agreement.

Results of Operations

The following table sets forth significant components of our results of operations for the periods presented.

	Three Months Ended March 31,	
	2019	2018
	(in thousands)	
Net revenue	$ 1,657	$ 1,754
Cost of goods sold	2,861	2,356
Gross loss	(1,204)	(602)
Operating expenses:		
Research and development	1,084	1,450
Selling, general and administrative	3,255	3,983
Total operating expenses	4,339	5,433
Operating loss	(5,543)	(6,035)
Other expense (income), net:		
Interest expense	502	460
Other income, net	(35)	(52)
Total other expense (income), net	467	408
Operating loss before income tax provision	(6,010)	(6,443)
Provision for income taxes	—	—
Net loss	$ (6,010)	$ (6,443)

Three Months Ended March 31, 2019 compared to Three Months Ended March 31, 2018

Revenue and Cost of Goods Sold

	Three Months Ended March 31,	
	2019	2018
	(in thousands)	
Net revenue	$ 1,657	$ 1,754
Cost of goods sold	2,861	2,356
Gross loss	$ (1,204)	$ (602)

Net revenue. The decrease in revenue in the first quarter of 2019 relative to the comparable period in 2018 was the result of a decrease of $0.1 million in Australia revenues due to the Company's transition to a distributor in the third quarter of 2018, resulting in an overall decrease in average selling price. Worldwide unit sales remained relatively unchanged in the first quarter of 2019 relative to the comparable period in 2018.

Cost of Goods Sold. The increase in cost of goods sold of $0.5 million in the first quarter of 2019 relative to the comparable period of 2018 was primarily related to unabsorbed production costs due to under-utilization of manufacturing capacity commensurate with a slow down in production activity. In addition, we recorded an inventory write-down and other inventory reserves of $0.1 million in the first quarter of 2019 relative to approximately $0.7 million in the comparable period in 2018, primarily related to lower of cost or market, or LCM, adjustments.

We expect to continue to experience gross losses in 2019 as we continue to manufacture our products at volumes not sufficient to reduce the cost to manufacture to allow positive gross profit given the current forecasted average selling prices in the U.S. and reimbursement rates (which determine pricing to hospitals) in Australia.

Total Operating Expenses

	Three Months Ended March 31,		QTD Change
	2019	**2018**	%
	(in thousands)		
Research and development	$ 1,084	$ 1,450	(25)
Selling, general and administrative	3,255	3,983	(18)
Total operating expenses	$ 4,339	$ 5,433	(20)

Research and Development Expense. Research and development expenses decreased by $0.4 million in the first quarter of 2019 relative to the comparable period of 2018, primarily due to a decrease in personnel expenses of $0.3 million.

Selling, General and Administrative Expense. Selling, general and administrative expense decreased by $0.7 million in the first quarter of 2019 relative to the comparable period of 2018, principally due a decrease in personnel expenses of $0.4 million and a decrease in marketing programs of $0.2 million.

Total Other Expense (Income), Net

	Three Months Ended March 31,	
	2019	**2018**
	(in thousands)	
Interest expense	$ 502	$ 460
Other expense (income), net	(35)	(52)
Total other expense (income), net	$ 467	$ 408

Interest Expense. The increase in interest expense in the three months ended March 31, 2019, and relative to the comparable period in 2018 was due to increase amortization of debt issuance costs.

Liquidity and Capital Resources

As of March 31, 2019, we have cash balances of $4.4 million. Based on our current operating plan, which includes a May 2019 reduction in workforce described in more detail elsewhere, this cash balance is insufficient to support our operating expenses beyond the second quarter of 2019.

We have incurred losses since our inception in 2005 including net losses after taxes of $6.0 million in the three months ended March 31, 2019, and $26.7 million, $29.0 million, and $19.4 million in 2018, 2017 and 2016, respectively, and as of March 31, 2019, we had an accumulated deficit of approximately $128.0 million. We have financed our operations from a combination of sales of equity securities and issuances of convertible term notes.

In 2015, we raised net proceeds of $30.1 million in connection with an IPO on the ASX, a Concurrent Placement and the issuance of convertible bridge notes, which were converted to Common Stock at the IPO. In connection with the IPO, all of our existing shares of preferred stock were converted into Common Stock. In June 2016, we received $14.2 million, net of issuance costs, in an equity offering. In February 2017, we received net proceeds of $32.6 million in an equity offering. In August and October 2018, we received net proceeds of $13.4 million in an equity rights offering and private placement.

In August 2017, we borrowed $15,000,000 under a loan and security agreement with Oxford which matures in August 2022. Interest is paid monthly on the principal amount at a variable rate equal to the greater of (a) the thirty day LIBOR rate, or (b) 0.99%, plus 7.26% per annum. The loan, as amended, is secured by substantially all of our assets, including intellectual property. Under the terms of the agreement, as amended, interest-only payments are due monthly through December 2019, with principal payments commencing in January 2020, due in 32 equal monthly installments. A final fee of $1,200,000 is due at maturity (or acceleration or prepayment). Subject to a prepayment fee equal to between 0.5% to 2.0% of the principal amount of the prepaid amount, we can prepay the entire loan amount by providing a written five-day notice prior to such prepayment and paying all outstanding principal, interest, final payment fees and prepayment fees plus any default fees and all other sums that shall have become due and payable.

Under the loan and security agreement, as amended, we are required to maintain a certain minimum level of monthly revenues, in addition to complying with certain other covenants, including minimum cash balances and accounts receivable balances. The loan and security agreement also includes events of default, the occurrence and continuation of any of which provides the financial institution with the right to exercise remedies against us and the collateral securing the loans, including cash. These events of default include, among other things, the failure to pay amounts due under the credit facilities, insolvency, the occurrence of a material adverse event, which includes a material adverse change in our business, operations or properties (financial or otherwise) or a material impairment of the prospect of repayment of any portion of the obligations. A violation of any of these covenants or the occurrence of a material adverse change could result in a default under the loan and security, which would result in termination of all commitments and loans under the agreement and all amounts owing under the agreement to become immediately due and payable. As of September 30, 2017, March 31, 2018, June 30, 2018 and March 31, 2019, we were in violation of a covenant under the loan and security agreement. On November 9, 2017, AirXpanders and the financial institution entered into a waiver and first amendment to the loan and security agreement, pursuant to which we received a waiver of the event of default for the September 30, 2017 noncompliance with a financial covenant and modified certain financial covenants. On April 26, 2018, AirXpanders and the financial institution entered into a further waiver and second amendment to the loan and security agreement, pursuant to which it received a waiver of the event of default for the March 31, 2018 noncompliance with a financial covenant. On July 30, 2018, the Company and the financial institution entered into a further waiver and fourth amendment to the loan and security agreement, pursuant to which it received a waiver of the event of default for the June 30, 2018 noncompliance with a financial covenant. The Company was not in compliance with all covenants as of March 31, 2019, and the lender has not provided a waiver as of the date of issuance of the accompanying condensed consolidated financial statements.

In 2018 and the second quarter of 2019, we completed a number of organizational restructurings which included reductions in workforce to reduce operating costs and better align our workforce with the needs of our business.

Our independent registered accountants report on our December 31, 2018 consolidated financial statements contains an emphasis of a matter regarding substantial doubt about our ability to continue as a going concern. The condensed consolidated financial statements have been prepared assuming we will continue as a going concern and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets, or the amounts and classification of liabilities that may result if we do not continue as a going concern.

Our ability to continue as a going concern, and correspondingly to execute on our business plan and strategy, is dependent upon our ability to accomplish one or more of the following: raise additional capital in the very near term to fund our ongoing operations or engage in a strategic alternative, which includes the potential sale of the business. On May 2, 2019, we engaged a financial advisor to assist us in exploring financial and strategic opportunities to enhance stakeholder value. If we are unable to accomplish one or more of these alternatives in the near term, the lender could declare an event of default under the loan and security agreement and we may have to pursue or otherwise accelerate strategic alternatives, including the possibility of seeking bankruptcy protection to protect stakeholder value in the event other options are not reasonably executable. As a result, our primary goal in the near-term is to successfully complete the review of strategic alternatives and consummate a transaction or series of transactions to achieve the objectives as described above. Our ability to identify and complete such a strategic alternative is highly speculative.

The following table sets forth the major sources and uses of cash for each of the periods set forth below:

	Three Months Ended March 31,	
	2019	2018
	(in thousands)	
Net cash used in operating activities	$ (4,925)	$ (8,417)
Net cash (used in) provided by investing activities	(51)	5,437
Net decrease in cash and cash equivalents	$ (4,976)	$ (2,980)

Cash Flows from Operating Activities

For the three months ended March 31, 2019, cash used in operating activities of $4.9 million resulted primarily from a net loss of $6.0 million, reduced by noncash adjustments, primarily depreciation and amortization of $0.3 million and stock based compensation of $0.2 million. Cash used was favorably impacted by $0.4 million to due improved working capital.

For the three months ended March 31, 2018, cash used in operating activities of $8.4 million resulted primarily from a net loss of $6.4 million, reduced by noncash adjustments, primarily depreciation and amortization of $0.3 million and stock based compensation of $0.2 million. Additional operating cash requirements consisted of $2.8 million for inventory purchases.

Cash Flows from Investing Activities

For the three months ended March 31, 2019, cash used by investing activities consisted of capital expenditures.

For the three months ended March 31, 2018, cash provided by investing activities consisted of $5.9 million of maturities of short-term investments, and $0.5 million for capital expenditures.

Cash Flows from Financing Activities

There were no activities from financing activities in the three months ended March 31, 2019 and 2018.

Funding Considerations

Based on our current operating plan, we do not have sufficient capital to continue our operations beyond the second quarter of 2019. We plan to raise additional capital in the future to support our operations. However, we currently have no committed sources of capital funding and there is no assurance that additional funding will be available to us in the future or be secured on acceptable terms. These factors raise substantial doubt about our ability to continue as a going concern within one year from the date the consolidated financial statements are issued. If adequate funding is not available, we may no longer be a going concern and may be forced to curtail operations, including our commercial activities and research and development programs, or cease operations altogether, file for bankruptcy, or undertake any combination of the foregoing. In such event, our stockholders may lose their entire investment in our company.

In addition, if we do not meet our payment obligations to third parties as they become due, we may be subject to litigation claims and our creditworthiness would be adversely affected. Even if we are successful in defending against these claims, litigation could result in substantial costs and would be a distraction to management, and may have other unfavorable results that could further adversely impact our financial condition.

Our forecast of the period of time through which our financial resources will be adequate to support our operations and further expand the commercialization of our product, and our expectations about raising additional funds, are forward-looking statements and involve risks and uncertainties, and actual results could vary materially and negatively as a result of a number of factors, including the factors discussed in the "Risk Factors" section of this Quarterly Report on Form 10-Q. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect.

Due to the numerous risks and uncertainties associated with the development and commercialization of AeroForm, we are unable to estimate precisely the amounts of capital and operating expenditures necessary to complete the development of, and to obtain full commercial scale launch in the U.S. Our funding requirements will depend on many factors, including, but not limited to, the following:

- the rate of progress and cost of our commercialization activities;
- the expenses we incur in marketing and selling AeroForm;
- the revenue generated by sales of AeroForm;
- the success of our investment in our manufacturing and supply chain infrastructure;
- the time and costs involved in obtaining regulatory approvals for AeroForm in new markets;
- the success of our research and development efforts;
- the emergence of competing or complementary developments; and
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

We will continue to manage our capital structure and to consider all financing opportunities, whenever they may occur, that could strengthen our long-term liquidity profile. Any such capital transactions may or may not be similar to transactions in which we have engaged in the past. There can be no assurance that any such financing opportunities will also be available on acceptable terms, if at all.

Off–Balance Sheet Arrangements

We do not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, that would have been established for the purpose of facilitating off-balance sheet arrangements (as that term is defined in Item 303(a)(4)(ii) of Regulation S-K) or other contractually narrow or limited purposes. As such, we are not exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in those types of relationships. We enter into guarantees in the ordinary course of business related to the guarantee of our own performance and the performance of our branch office in Australia.

Contractual Obligations and Commitments

During the three months ended March 31, 2019, there have been no material changes to the contractual obligations previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2018.

Recent Accounting Pronouncements

For a discussion of recent accounting pronouncements please refer to Note 3, "Summary of Significant Accounting Policies", to our consolidated financial statements included in our Annual Report on Form 10-K.

ITEM 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, prior to the filing of this quarterly report. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, as of the end of the period covered by this quarterly report, our disclosure controls and procedures were effective.

Changes in Internal Control

There were no changes in our internal control over financial reporting during the period covered by this Quarterly Report on Form 10-Q that have materially affected, or were reasonably likely to materially affect, our internal control over financial reporting.

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating disclosure controls and procedures, our management recognizes that any system of controls, however well designed and operated, can provide only reasonable assurance, and not absolute assurance, that the desired control objectives of the system are met. In addition, the design of any control system is based in part upon certain assumptions about the likelihood of future events. Because of these and other inherent limitations of control systems, there can be no assurance that any design will succeed in achieving its stated goals in all future circumstances. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met and, as set forth above, our Chief Executive Officer and our Chief Financial Officer have concluded, based on their evaluation as of the end of the period covered by this quarterly report, that our disclosure controls and procedures were effective to provide reasonable assurance that the objectives of our disclosure control system were met.

PART II. – OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may be involved in litigation relating to claims arising out of our operations. We are not currently involved in any material legal proceedings, and our management believes there are currently no claims or actions pending against us, the ultimate disposition of which could have a material adverse effect on our operations, financial condition, or cash flows. We may, however, be involved in material legal proceedings in the future. Such matters are subject to uncertainty and there can be no assurance that such legal proceedings will not have a material adverse effect on our business, results of operations, financial position or cash flows.

Item 1A. Risk Factors

Our business is subject to various risks and uncertainties that may have a material adverse effect on our business, financial condition or results of operations. You should carefully consider the risks and uncertainties described below, together with all of the other information included in this Quarterly Report on Form 10-Q and in our most recent Annual Report on Form 10-K for the year ended December 31, 2018, or the Form 10-K. Our business faces significant risks and uncertainties, and those described below may not be the only risks and uncertainties we face. Additional risks and uncertainties not presently known to us or that we currently believe are immaterial may also significantly impair our business, financial condition or results of operations. If any of these risks or uncertainties occur, our business, financial condition or results of operations could suffer, the market price of our common stock could decline and you could lose all or part of your investment in our common stock. We have marked with an asterisk (*) those risks described below that reflect substantive changes from, or additions to, the risks described under Part I, Item 1A, "Risk Factors" included in the Form 10-K.

Risks Related to Our Business

We will need additional funding and may be unable to raise capital when needed, which could force us to delay, reduce, or eliminate planned activities or may result in our inability to operate as a going concern.*

As we have limited commercialization of our product, we are generating a small amount of revenue and are not cash flow positive or profitable. Our net revenue from sales of AeroForm was approximately $1.7 million for the three months ended March 31, 2019, and $7.8 million and $3.9 million for the years ended December 31, 2018 and 2017, respectively, and, as of March 31, 2019, we had cash and cash equivalents of approximately $4.4 million. We believe our current cash balances will not cover operating expenses beyond the second quarter of 2019. Our existing capital may be insufficient to meet our operating requirements. These requirements include, but not limited to, funding our continued commercial launch of AeroForm in the United States, or U.S., building our supporting manufacturing infrastructure and building inventory, continuing to build a dependable partnership with our current and other contract manufacturers, building our salesforce to support our commercialization efforts, repaying our outstanding debt obligations and covering any losses. Consequently, we may need to raise additional funds through financings or borrowings beyond this rights offering in order to accomplish our planned objectives. Failure to raise additional funds could delay, reduce, or halt our commercialization and would impact our ability to continue as a going concern. Additionally, we might be required to consider the sale of our business or assets on unfavorable business terms.

We have no committed sources of capital funding and there is no assurance that additional funding, if required, will be available to us in the future or be secured on acceptable terms. If adequate funding is not available, we may no longer be a going concern and may be forced to curtail operations, including our commercial activities and research and development programs, or cease operations altogether, file for bankruptcy, or undertake any combination of the foregoing. In such event, our stockholders may lose their entire investment in our company.

In addition, if we do not meet our payment obligations to third parties as they become due, we may be subject to litigation claims and our creditworthiness would be adversely affected. Even if we are successful in defending against these claims, litigation could result in substantial costs and would be a distraction to management, and may have other unfavorable results that could further adversely impact our financial condition.

There is substantial doubt about our ability to continue as a going concern.

Our independent registered accountants report on our December 31, 2018 consolidated financial statements contains an emphasis of a matter regarding substantial doubt about our ability to continue as a going concern. The consolidated financial statements have been prepared assuming we will continue as a going concern and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets, or the amounts and classification of liabilities that may result if we do not continue as a going concern. Based on our current operating plan, we do not have sufficient capital to continue our operations beyond June 30, 2019 without capital raising and material operational changes. You should not rely on our consolidated balance sheet as an indication of the amount of proceeds that would be available to satisfy claims of creditors, and potentially be available for distribution to shareholders, in the event of liquidation.

We have engaged a financial advisor to explore financial and strategic alternatives, which could include dilutive financings, strategic partnerships, sale of the company or bankruptcy.*

We engaged a financial advisor to identify and evaluate possible financial and strategic alternatives and their implications for the Company. No assurance can be given as to whether any particular recommended financial or strategic alternative will be undertaken, and if so, upon what terms or conditions. We may not have enough available cash to purse a strategic restructuring, refinancing, or other transaction, and may have to file for bankruptcy. Bankruptcy, whether Chapter 11 or Chapter 7, could result in significant decrease in value for all stakeholders. In addition, if we file for bankruptcy, it may cause disruption in supply from critical vendors required to continue operations, negatively impact sales and collections from customers and negatively impact employee relations.

We have a history of net losses and we may never achieve or maintain profitability.

We are a U.S. based medical device company with a limited history of operations and have limited commercial experience with our product. Medical device product development is a speculative undertaking and involves a substantial degree of risk. To date, we have focused on developing our sole product, AeroForm, and currently have no other products in development. We have incurred net losses since our inception, including net losses of approximately $6.0 million in the three months ended March 31, 2019, and $26.7 million in 2018, $29.0 million in 2017, and $19.4 million in 2016. As of March 31, 2019, our accumulated deficit was approximately $128.0 million. Although we have started to generate revenues from sales in Australia and the United States, we expect to continue to incur significant operating losses for the near future as we incur costs, including those associated with commercializing our products, building our supporting manufacturing infrastructure, building a dependable partnership with our current and other contract manufacturers, as well as the increased costs associated with being a public company in the U.S. with equity securities listed on the ASX.

Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to achieve sustained profitability would depress the value of our company and could impair our ability to raise capital, expand our business, diversify our research and development pipeline, market AeroForm or any other products we may identify and pursue, if approved, or continue our operations. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital. We cannot predict the extent of our future operating losses and accumulated deficit and we may never generate sufficient revenues to achieve or sustain profitability.

If we fail to comply with the covenants and other obligations under our security and loan agreement, the lender may be able to accelerate amounts owed under the facility and may foreclose upon the assets securing our obligations.*

In August 2017, we entered into a loan and security agreement with Oxford Finance LLC, or Oxford, pursuant to which we borrowed $15 million from Oxford. Under the Oxford loan agreement, we are subject to a variety of affirmative and negative covenants. These covenants include required financial reporting, providing an unqualified auditor's opinion together with our annual financial statements within 120 days of the end of our fiscal year (the unqualified audit opinion covenant), limitations on certain dispositions and licensing of assets, limitations on the incurrence of additional debt, and achievement of certain financial milestones. To secure our performance of our obligations under this loan and security agreement, as amended, we granted Oxford a security interest in all of our assets, including our intellectual property. Our failure to comply with the terms of the loan and security agreement, including the unqualified audit opinion covenant, the occurrence of a material adverse change in our business, operations or condition (financial or otherwise) or prospects, the material impairment in our prospect of repayment, a material impairment in the perfection or priority of the Oxford's lien on our assets or the value of Oxford's collateral, failure to achieve agreed financial milestones, or the occurrence of certain other specified events could result in an event of default that, if not cured or waived, could result in the acceleration of all or a substantial portion of our loan, coupled with prepayment penalties, potential foreclosure on our assets, and other adverse results.

Oxford has already granted us three waivers in connection with covenant breaches under the loan and security agreement, and we believe they may grant us a waiver for the most recent covenant breaches related to the revenue shortfall for the quarter ended March 31, 2019 and the three month period ended April 30, 2019, but there is no certainty that Oxford will grant us a further waiver if we do not comply with any covenants in the future. There is no guarantee that future covenant violations (if any) will similarly be waived. We are currently evaluating our prospects of meeting the covenants in the coming months.

If Oxford were to declare an event of default, it would have the option, among other things, of accelerating the debt under our loan and security agreement and foreclosing on the Company's assets pledged as collateral for the term loan. Any declaration of an event of default would result in a requirement that we repay indebtedness, which could severely affect our liquidity and significantly harm our business.

Due to our current cash flow position, the substantial doubt about our ability to continue as a going concern, and Oxford's ability to declare an event of default, we reclassified the long-term portion of the loan to current. We will continue to evaluate the debt classification on a quarterly basis and evaluate for reclassification in the future should our financial condition improve.

Additionally, the existing collateral pledged under the loan and security agreement, and the covenants to which we are bound may prevent us from being able to secure additional debt or equity financing on favorable terms, or at all, or to pursue business opportunities, including potential acquisitions, heighten our vulnerability to downturns in our business or our industry or the general economy, limit our ability to adjust to changing market conditions and place us at a competitive disadvantage compared to our competitors who have greater capital resources.

Our results of operations could be negatively impacted if we are unable to collect our accounts receivable or if we experience a large number of product returns.*

We are currently selling our product primarily to hospitals in the United States. In connection with each sale, we typically provide credit to customers on a short-term basis with payment typically due within 30 days of invoicing. In the past we have experienced and may continue to experience the need to write off accounts receivable due to the inability to collect outstanding customer balances. The restructuring announced in May 2019 which included the elimination of approximately half of the field sales force could have a negative impact on our customers' perception and negatively impact our ability to collect amounts due from customers. The inability to collect accounts receivable may continue to have a negative impact on our results of operations.

We reserve for sales returns as a reduction to revenue based on our historical experience with return rates and the specific circumstances which lead us to believe a customer may return product. If we experience a large number of product returns or an unexpected increase to product return rates, it would have a negative impact on our revenue and results of operations.

If we are unable to identify a new manufacturing facility, our ability to manufacture and sell our product and to pursue our research and development efforts may be jeopardized.*

We currently manufacture key subassemblies and product components of the AeroForm system in our single facility in San Jose, California. Our products consist of components sourced from a variety of contract manufacturers and suppliers, with final packaging completed at our facility. Our current sublease on the San Jose, California, facility expires at the end of August 2019. If we are unable to identify and secure a new facility, it may be difficult or impossible for us to manufacture products for an extended period of time. If a facility is unavailable for even a short period of time, the inability to manufacture our current products, and the interruption in research and development of any future products, may result in harm to our reputation, increased costs, lower revenues and the loss of customers. Furthermore, once identified and secured, it could be costly and time-consuming to move our operations to the new facility, particularly as the use of a new facility would require FDA review and approval of a PMA supplement.

We must attract and retained skilled staff to pursue our business model.

Our long term growth and performance is dependent on attracting and retaining highly skilled staff. The medical device industry, and the San Francisco Bay area where we maintain our headquarters, has strong competition for highly skilled workers (including senior researchers, clinical staff, and management) due to the limited number of people with the appropriate skill set.

We currently employ, or engage as consultants, a number of key management and scientific personnel. There is a risk that we will be unable to attract and retain the necessary staff to pursue our business model. In April 2018, Mr. Scott Dodson, our former President and CEO, resigned. In June 2018, Mr. Frank Grillo was hired as our President and CEO. While we were able to attract and hire a replacement, there is no guarantee we can retain Mr. Grillo, or other key management and scientific personnel. This may affect how efficiently we operate our business and our future financial performance could be impacted.

We have structured incentive programs for our key personnel, including an equity incentive plan. Despite these measures, there is no guarantee that we will be able to attract and retain suitable qualified personnel, which could negatively affect our ability to reach our goals.

Efforts to restructure our operations and align our resources with market opportunities could disrupt our business and affect our results of operations.*

In 2018 and in May 2019, we completed a number of reductions in force and internal reorganizations to reduce the size and cost of our operations and to better match our resources with our market opportunities. We may take similar steps in the future to improve efficiency and match our resources with market opportunities. These changes may not be successful in adequately reducing the cost of our operations. In addition, any such changes could be disruptive to our business.

Our business model will depend solely on the success of AeroForm for breast reconstruction procedures.

We expect to derive all of our revenue in the foreseeable future from sales of AeroForm for breast reconstruction procedures. We have no other commercial products or products in active development at this time. Acceptance of our product in the marketplace is uncertain, and our failure to achieve sufficient market acceptance will significantly limit our ability to generate revenue and be profitable. If we are unable to successfully launch and achieve meaningful market penetration with AeroForm, our commercial strategy will be unattainable and our business operations, financial results and growth prospects will be materially and adversely affected.

We are dependent on the acceptance, promotion and safe usage of AeroForm by surgeons and their patients.

Regulatory approval and clearance of AeroForm, including in Australia and the U.S., will not guarantee market adoption. In order to achieve commercial success, we are dependent on the acceptance and promotion of AeroForm by patients and surgeons. Reasons that patients and surgeons may be slow to adopt AeroForm include, but are not limited to:

- preference of the products of competitors due to familiarity with those products or for various other reasons;
- concern that radiotherapy treatments may be affected by the presense of AeroForm;
- pricing of AeroForm as compared to traditional saline expanders;
- limited clinical data illustrating the benefits of AeroForm to patients and surgeons;
- concern over potential liability risks involved in using a new product; and
- any delay in the qualification of AeroForm for reimbursement from relevant health care funding bodies in jurisdictions where approved reimbursement codes and reimbursement status for similar products does not already exist.

While we already have early good relationships with a number of leading surgeons in Australia and the U.S., this in and of itself does not ensure the widespread support of AeroForm among surgeons. If a significant number of surgeons in our key markets do not adopt or recommend AeroForm, or continue to promote and use the products of competitors, this would adversely impact or delay our ability to generate revenue and achieve profitability.

There have been reports of anaplastic large cell lymphoma linked to textured breast implants. While not directly linked to textured tissue expanders, some have questioned if there is a similar link. These events may lead to a reduction in the demand for textured tissue expanders and could adversely affect our business.*

Breast implants have been associated with higher rates of anaplastic large cell lymphoma, or ALCL, a rare type of cancer affecting cells of the immune system. In January 2011, the FDA indicated that there was a possible association between saline and silicone gel-filled breast implants and higher rates of ALCL, with the causal links not yet understood. In March 2015, France's National Cancer Institute, or NCI, noted that there is a clearly established link between ALCL and breast implants, which is referred to as breast implant-associated ALCL, or BIA-ALCL. The NCI noted in that report that most of the reported cases occurred in women with textured implants. In response, the Agence Nationale de Sécurité du Médicament et des Produits de Santé or ANSM, the regulatory authority in France, has required manufacturers marketing breast implants in France to submit biocompatibility data for review, and this review is ongoing. In the fourth quarter of 2018, following the non-renewal of its textured breast implant CE Mark licenses in Europe, Allergan plc suspended sales of textured breast implants and tissue expanders in Europe and withdrew its remaining textured breast implants and tissue expanders then on the market in Europe. In the second quarter of 2019, ANSM banned the sale of macro-textured and polyurethane implants, Health Canada advised Allergan of its intent to suspend its licenses for certain textured breast implants, and the Netherlands temporarily suspended the sale of macro-textured and polyurethane implants. While the Company does not commercialize in these markets, it is possible that as the BIA-ALCL risk becomes highly publicized, this could negatively, and significantly, impact demand for textured tissue expanders, including Aeroform. Additionally, in the fourth quarter of 2018, despite no known linkage between ALCL and textured tissue expanders, the Therapeutic Goods Administration in Australia, the regulatory body responsible for our products, after consultation with us, required that additional patient warnings be added to our labeling to disclose the risk of ALCL.

Future clinical studies or clinical experience may more strongly indicate that textured breast implants expose patients to greater risks of ALCL, which may reduce demand for textured tissue expanders generally, expose us to product liability claims, as well as to class actions and other lawsuits. These impacts may occur in the absence of any specific linkage with our products. Moreover, if cases of ALCL or other complications are discovered in the future and/or are reported in patients with AeroForm, we could be subject to mandatory product recalls, suspension or withdrawal of our regulatory licensure for sale in one or more countries, and significant legal liability. Any of these may have an adverse effect on our business or operating results, or a negative impact on our share price.

We may be unable to compete successfully with current tissue expanders in the market for breast reconstruction.

The market for traditional tissue expander products in breast reconstruction procedures is well established and dominated by two large pharmaceutical and medical device companies, Allergan, Inc. and Mentor Worldwide LLC, a division of Johnson & Johnson, which have been market leaders for a number of years. Our AeroForm will compete against the traditional saline expanders which have been used for many years, are supported by clinical data, have a lower average selling price and have significantly greater brand recognition. Furthermore, the resources and scale of the two dominant players in the tissue expander market provides them with significant advantages in terms of financing, research and development, manufacturing and marketing resources and this may restrict out ability to secure market share for AeroForm. Additionally, these companies offer their customers access to a suite of products, including breast implants, which may allow them to offer favorable pricing on volume purchases or bundled purchases.

We have limited sales, marketing and distribution resources.

We currently have limited marketing resources and will need to commit significant resources to developing sales, distribution and marketing capabilities. We currently utilize a direct sales force in the U.S. but most other markets will likely entail the use of a distributor. We will need to ensure compliance with all legal and regulatory requirements for sales, marketing and distribution in each relevant market. There is a risk that we will be unable to develop sufficient sales, marketing and distribution capacity to effectively commercialize AeroForm.

We rely on key suppliers for product components.

Our contracts with key suppliers are generally standard in nature, in the form of purchase order arrangements that are common to medical device firms in the early stages of commercialization, with no minimum orders required. As we move further into our commercialization phase, we will increasingly rely on key suppliers for AeroForm components. A disruption at a key supplier could cause a substantial delay in the availability of AeroForm, leading to a potential loss of sales. Development of key manufacturing processes along with process validation testing, device verification testing, and regulatory approvals required for a manufacturing change could take up to six months to complete. However, we believe that alternative suppliers could ultimately be located, qualified and approved for all critical system components with the six month timeframe.

We rely on a third party in Costa Rica to manufacture AeroForm.

Our main manufacturing of AeroForm is managed by a contract manufacturer located in Costa Rica. While we also plan to retain the ability to manufacture AeroForm at our California location, there are inherent risks in relying on outsourced contract manufacturers particularly where the contract manufacturer is located outside of the U.S. These risks include risks of economic change, recession, labor strikes or disruptions, political turmoil, changes in tariffs or trade barriers, and lack of contract enforceability.

Should the manufacturer's operations be disrupted for any reason or production halted, we may not be able to have enough AeroForm devices manufactured in a timely manner to satisfy product demand. While an alternative manufacturer could be appointed, it would take a significant amount of time to transfer the manufacturing process, which would include installation and validation of equipment, process and product qualifications and regulatory approvals. If such a disruption were to occur, it would adversely impact our ability to sell AeroForm and customers might instead purchase competing tissue expander products. There may also be an ongoing sales impact in the form of a reduction of goodwill as a result of our inability to supply hospitals and surgeons in a timely manner.

Third party payers, including government authorities and private health insurers, may not provide sufficient levels of reimbursement or any form of reimbursement for AeroForm.

Purchasers of tissue expanders for breast reconstruction procedures generally rely on third party payers, particularly government health administration authorities, including Medicare and Medicaid in the U.S., and private health insurers, to subsidize the cost of the products. We have to date secured reimbursement for AeroForm in Australia and believe that AeroForm benefits from existing reimbursement codes for breast reconstruction procedures in the U.S. Although rates of reimbursement for breast reconstruction procedures in the U.S. have been increasing in recent years, no assurance can be given that reimbursement amounts will continue to increase or that the amounts will be sufficient to enable us to sell AeroForm in the U.S. Moreover, we cannot predict what changes may be made in the future to third party coverage and reimbursement in Australia or the U.S. and what impact any such changes may have on our ability to sell AeroForm.

Reimbursement and healthcare payment systems in international markets vary significantly by country. Outside Australia and the U.S., we may not obtain international coverage and reimbursement approvals in a timely manner or at all.

In Australia, the report of the Competition Policy Review released on March 31, 2015 (commonly known as the Harper Report) stated that the regulation of prostheses should be further examined to see if pricing and supply can be made more competitive. However, it is not known whether any further review of prostheses regulation will occur and if it does occur, how resulting regulatory changes, if any, will affect the future reimbursement of AeroForm in Australia.

We may not be able to pass through the regulatory hurdles and gain the necessary approvals and clearances to sell AeroForm in certain other countries.

In the U.S., we received de novo clearance from the FDA, allowing us to commence sales to the U.S. market. We have received TGA and CE Mark approval for AeroForm, allowing us to commence sales to the Australian and European markets, respectively.

In other jurisdictions, AeroForm is still at various pre-commercialization phases. We cannot guarantee that we will receive all necessary regulatory approvals, nor can we accurately predict the product approval timelines, or other requirements that may be imposed by regulators (for example, further clinical trials or other requirements proving safety and effectiveness of AeroForm). Furthermore, there may be changes to regulatory standards, which could delay or prevent us from obtaining the necessary regulatory approvals. In addition, any future changes to AeroForm may require separate clearance or approval.

Any delays or barriers to our obtaining necessary regulatory clearances would limit the size of the market opportunity until such time, if any, that we will be able to obtain such clearances for AeroForm.

We are dependent on the protection and enforcement of our intellectual property rights.

The protection of the intellectual property we rely on is critical to our business and commercial success. If we are unable to protect or enforce the intellectual property rights embodied in AeroForm, there is a risk that other companies will incorporate the intellectual property into their technology, which could adversely affect our ability to compete in the market for tissue expanders.

As of December 31, 2018, our patent portfolio consisted of four issued and three pending U.S. patents, and 26 issued and 12 pending foreign patents. Our issued foreign patents were granted in Australia, Hong Kong, Japan and several of the major countries in the European Union.

In addition, some of the key patents related to AeroForm are co-owned by us and Shalon Ventures (includes U.S. patents) or licensed to us exclusively by Shalon Ventures (non-U.S. patents only). Although the license agreement between us and Shalon Ventures may only be terminated by a party in limited circumstances, if Shalon Ventures was to terminate the license agreement it could affect our ability to produce and sell AeroForm outside the U.S.

We may be subject to future third party intellectual property rights disputes.

We do not believe that our activities infringe any third party's intellectual property rights. To date, no third party has asserted this to be the case. However, in the future we may be subjected to infringement claims or litigation arising out of patents and pending applications of our competitors, or additional proceedings initiated by third parties or intellectual property authorities to re-examine the patentability of licensed or owned patents. The defense and prosecution of intellectual property claims and litigation, and related legal and administrative proceedings are costly and time-consuming to pursue, and their outcome is uncertain. If we infringe the rights of third parties, we could be prevented from selling AeroForm or any future products and be forced to defend against litigation and to pay damages.

We have a limited operating history and may face difficulties encountered by companies early in their commercialization.

We have a limited operating history upon which to evaluate our business and forecast future net sales and operating results. In assessing our business prospects, you should consider the various risks and difficulties frequently encountered by companies early in their commercialization in competitive markets, particularly companies that develop and sell medical devices. These risks include our ability to:

- implement and execute our business strategy;
- expand and improve the productivity of our sales force and marketing programs;
- increase awareness of our brand and build loyalty among surgeons;
- manage expanding operations;
- respond effectively to competitive pressures and developments; and
- successfully implement design changes to refine AeroForm over time and obtain any updates to regulatory approvals related to the changes.

Ongoing regulation of our products may limit how we manufacture and market our product candidates, which could materially impair our ability to generate revenue.

Once regulatory approval has been granted, an approved product and its manufacturer are subject to ongoing review and regulation. Any approved or cleared product may only be promoted for its approved or cleared uses consistent with the products labeling. In addition, product labeling, packaging, QSR requirements, adverse event reporting, advertising and promotion, scientific and educational activities, and promotional activities involving the internet and social media will be subject to extensive regulatory requirements. To ensure compliance with regulatory requirements, medical device manufacturers are subject to market surveillance and periodic, pre-scheduled and unannounced inspections by the FDA, and these inspections may include the manufacturing facilities of our subcontractors.

Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, including various sanctions such as warning letters; fines, injunctions, and civil penalties; recall or seizure of our products; operating restrictions, partial suspension or total shutdown of production; refusal to grant 510(k) clearance or PMA approvals of new products; withdrawal of 510(k) clearance or PMA approvals; and criminal prosecution. Further, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

If we market products in a manner that violates fraud and abuse and other health care laws, we may be subject to significant enforcement and sanctions.

In addition to FDA restrictions on marketing of medical device products, several other types of state, federal and foreign health care laws, including those commonly referred to as "fraud and abuse" laws, have been applied to restrict certain marketing practices in the medical device industry. These laws include, among others, the following:

- The federal anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any good, facility, item or service reimbursable under a federal health care program, such as Medicare or Medicaid. This statute has been interpreted broadly to apply to arrangements between pharmaceutical manufacturers and prescribers, purchasers, and formulary managers, among others. There are statutory exceptions and regulatory safe harbors available to protect certain common activities from prosecution or other regulatory sanctions that must be strictly followed. Failure to meet all of the requirements of a particular statutory exception or regulatory safe harbor does not make the conduct per se illegal under the anti-kickback statute, but subjects the arrangement to a case-by-case basis review of its facts and circumstances. The Affordable Care Act amended the federal anti-kickback statute such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation and codified case law 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 federal False Claims Act.

- Federal false claims laws, including the civil False Claims Act, false statement laws and civil monetary penalty laws prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. The False Claims Act contains qui tam provisions, which allow a private individual, or relator, to bring a civil action on behalf of the federal government alleging that the defendant submitted a false claim to the federal government and to share in any monetary recovery. Certain marketing practices, including off-label promotion, may violate federal false claims laws.

- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created new federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any health care benefit program, including private third-party payers, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services. Like the federal anti-kickback statute, the Affordable Care Act amended the intent standard for certain health care fraud provisions under HIPAA such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their respective implementing regulations, imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information.

- The federal Physician Payments Sunshine Act and its implementing regulations require that certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to annually report to the Centers for Medicare & Medicaid Services (CMS) information related to certain payments or other transfers of value made to physicians and teaching hospitals, and to report annually certain ownership and investment interests held by physicians and their immediate family members.

- The U.S. Foreign Corrupt Practices Act, the U.K Anti-Bribery Act, and similar anti-bribery laws that generally prohibit companies and their intermediaries from making improper payments to officials for the purpose of obtaining or retaining business.

- Analogous local, state and foreign laws, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving health care items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require medical device companies to comply with the device industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to health care providers and entities; state and foreign laws that require device manufacturers to report information related to payments and other transfers of value to health care professionals or entities; 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.

Efforts to ensure that our business arrangements with third parties will comply with applicable health care laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other health care laws.

Medical device and other health care companies have been prosecuted under these laws for a variety of promotional and marketing activities, such as providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; and engaging in off-label promotion. If our operations are found to be in violation of any of the health regulatory laws described above or any other laws that apply to us, we may be subject to significant sanctions, including criminal fines, civil monetary penalties, administrative penalties, disgorgement, individual imprisonment, exclusion from participation in federal health care programs, integrity obligations, contractual damages, injunctions, recall or seizure of products, total or partial suspension of production, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We are exposed to the risk of product liability and product recalls.

We are exposed to the risk of product liability claims as a company that sells products to the public. This is a particularly sensitive issue for health care companies, and the medical device market has a history of product recalls and litigation. We may be exposed to the risk of product liability claims, which are inherent in the design, manufacturing, marketing and use of medical devices. Furthermore, we must comply with medical device reporting and vigilance requirements in each jurisdiction in which AeroForm and any future products are marketed.

Any product liability claim, with or without merit, may cause damage to our reputation and business. We have sought to minimize this risk by taking out product liability insurance, but this may not be sufficient if a large damages claim is awarded. If we are called as a defendant in a product liability suit, this could be a costly activity that may also divert management focus away from key strategic initiatives of the business, potentially adversely impacting financial performance and damaging our reputation.

Off-label use of AeroForm may harm its image or lead to substantial penalties.

We are only permitted to market AeroForm for the uses indicated on the labeling cleared by the relevant regulatory bodies in each market. We cannot prevent a surgeon or other third party from using or recommending the use of AeroForm for purposes outside of its approved intended use. This may lead to the increased likelihood of an adverse event, or inadequate treatment of a patient's condition, which could harm our reputation in addition to potential claims for damages. If we were deemed to have marketed AeroForm for off-label use, we could be subject to civil or criminal sanctions, including fines, damages claims, injunctions or other penalties and our reputation within the industry may be damaged.

Risks Related to Our Industry

We may be adversely affected by health care reform legislation in the U.S. and other countries.

In recent years, there have been numerous initiatives at the U.S. federal and state levels for comprehensive reforms affecting the payment for, the availability of and reimbursement for healthcare services. Recent legislation and many of the proposed bills include funding to assess the comparative effectiveness of medical devices. It is unclear what impact the comparative effectiveness analysis will have on our products or financial performance. If significant reforms are made to the healthcare system in the U.S., or in other jurisdictions, those reforms could adversely affect our financial condition and operating results.

In March 2010, President Obama signed into law comprehensive healthcare reform legislation known as the *Affordable Care Act*, or the ACA, as modified by the Health Care and Education Reconciliation Act of 2010 (U.S.). The ACA was a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of health care spending, enhance remedies against health care fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers and impose additional health policy reforms. Substantial new provisions affecting compliance also were enacted, which may affect our business practices with health care practitioners. Complying with the ACA could significantly increase our costs.

Some of the provisions of the ACA have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Additionally, the continuing resolution on appropriations for fiscal year 2018, recently signed by President Trump, delays the implementation of certain PPACA-mandated fees, including the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". We continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business.

We expect that health care reform measures that have been and may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for our products. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other health care reforms may affect our ability to generate revenue and profits or commercialize our product candidates.

The manufacturing facilities of AeroForm must comply with stringent regulatory requirements.

Our products are classified as medical devices. Medical devices are subject to extensive regulation in the United States by the FDA and numerous other federal, state and foreign governmental authorities. FDA regulations specific to medical devices are wide-ranging and govern, among other things:

- design, development and manufacturing;
- testing;
- clinical trials in humans;
- electronic product safety;
- labeling;
- storage;
- marketing;
- premarket clearance or approval;
- record keeping procedures;
- advertising and promotion;
- post-market surveillance and reporting of deaths, serious injuries or malfunctions; and
- export.

Our manufacturing processes are required to comply with the FDA's Quality System Regulations, which cover the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our devices. The FDA enforces its Quality System Regulations through periodic unannounced inspections. If our manufacturing facility fails a Quality System inspection, our operations and manufacturing could be interrupted. Failure to take adequate and timely corrective action in response to an adverse Quality System inspection could force a shutdown of our manufacturing operations or a recall of our products. As we have outsourced a significant portion of our manufacturing to a contract manufacturer located in Costa Rica, we have limited direct control over the compliance of the facility which manufactures AeroForm. While we have implemented supplier and quality controls over the product being provided to us by the contract manufacturer, if the manufacturer does not comply with any relevant requirements, this may adversely affect our ability to manufacturer and sell AeroForm.

Compliance with these regulations can be complex, expensive and time-consuming. If we fail to comply with such regulations, we could be subject to the imposition of injunctions, suspensions or loss of regulatory approvals, product recalls, orders for repair, replacement or refund, customer notifications, termination of distribution, product seizures or civil penalties. In the most egregious cases, criminal sanctions or closure of our manufacturing facilities or those of our contract manufacturers or suppliers are possible. If we are required to shut down our manufacturing operations or recall any of our products, we may not be able to provide our customers with the quantity of products they require, and we could lose customers and suffer reduced revenue. If we are unable to obtain sufficient quantities of high quality products to meet customer demand on a timely basis, we could lose customers, our growth could be limited or halted and our business could be harmed. For example, in June 2018, we initiated a voluntary Class III recall of approximately 50 AeroForm Tissue Expander Systems. A Class III recall is a recall associated with distributed product in which use of, or exposure to, the product is not likely to cause adverse health consequences. Future recalls could divert management attention and financial resources and could harm our reputation with customers which in turn could have a material impact our financial results.

We are also subject to medical device reporting regulations that require us to report to the FDA if our products cause or contribute to a death or serious injury or if they malfunction. It is possible that claims could be made against us alleging that our products are defective or unsafe. Our failure to comply with applicable regulatory requirements could result in an enforcement action by the FDA. The identification of serious safety risks could result in product recalls or withdrawal of our clearance or approval. The imposition of any one or more of these penalties could have a negative effect on our business, product sales and profitability.

Furthermore, to maintain the CE Mark, The British Standards Institute, our Notified Body, will regularly audit our suppliers and manufacturers. Failure to comply with the applicable regulatory requirements can result in, among other things, temporary manufacturing shutdowns, product recalls, product shortages, bans on imports and exports and a damaged brand name.

Our third party contract manufacturer or component manufacturers may also be subject to the same sanctions and, as a result, may be unable to supply components for our products. Any failure to retain governmental clearances or approvals that we currently hold or to obtain additional similar clearances or approvals could prevent us from successfully marketing our products and technology and could harm our operating results. Furthermore, changes in the applicable governmental regulations could prevent further commercialization of our products and technologies and could harm our business.

Our presence in the international marketplace exposes us to foreign operational risks.

We sell AeroForm in Australia and the U.S. As a significant portion of the manufacturing of AeroForm is performed in Costa Rica, we are exposed to risks of foreign regulations in Costa Rica and national trade laws, including import and export laws as well as customs regulations and laws. There are potentially high compliance costs associated with these laws and failure to comply with any applicable law or regulatory obligations could result in penalties and/or enforcement action (for example, stoppages or delays in clearing our products through customs).

Risks Related to our CDIs and Common Stock

Our principal stockholders could collectively exert control over us and may not make decisions that in the best interests of all stockholders.

As of March 31, 2019, our principal stockholders beneficially owned a substantial percentage of our voting stock. If these significant stockholders were to act together, they would be able to exert a significant degree of influence over our management and affairs and over matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. Accordingly, there is a risk that these stockholders, although unrelated to each other, may make collective decisions that do not accord with, or are not in the best interests of, other stockholders and CDI holders. For example, the principal stockholders could, through their concentration of ownership, delay or prevent a change of control, even if a change of control is in the best interests of our other stockholders and CDI holders.

Provisions of our Certificate of Incorporation, our Bylaws and Delaware law could make an acquisition of us more difficult and may prevent attempts by stockholders to replace or remove current members of the Board.

Certain provisions of Delaware law, our Certificate of Incorporation and Bylaws could discourage, delay or prevent a change of control or deter tender offers for our common stock that stockholders and CDI holders may consider favorable, including transactions in which CDI holders might otherwise receive a premium for their CDIs.

Our Certificate of Incorporation authorizes us to issue up to 10,000,000 shares of preferred stock in one or more different series with terms to be fixed by our board of directors. Stockholder or CDI holder approval is not necessary to issue preferred stock in this manner. Issuance of these shares of preferred stock could have the effect of making it more difficult and more expensive for a person or group to acquire control of us, and could effectively be used as an anti-takeover device.

Our Bylaws provide for an advance notice procedure for stockholders or CDI holders to nominate director candidates for election or to bring business before an annual meeting of stockholders, including proposed nominations of persons for election to our board of directors, and require that special meetings of stockholders be called only by our chairman of the board, chief executive officer, president or the board pursuant to a resolution adopted by a majority of the board.

The anti-takeover provisions of Delaware law and provisions in our organizational documents may prevent our stockholders from receiving the benefit from any premium to the market price of our common stock offered by a bidder in a takeover context. Even in the absence of a takeover attempt, the existence of these provisions may adversely affect the prevailing market price of our common stock if they are viewed as discouraging takeover attempts in the future.

Being a public company is expensive and administratively burdensome.

We are subject to the periodic reporting requirements of the Securities Exchange Act of 1934, as amended (**Exchange Act**). Although we have been listed on the ASX since 2015 and have been required to file financial information and make certain other filings with the ASX, our status as a U.S. reporting company under the Exchange Act will cause us to incur additional legal, accounting and other expenses that we have not previously incurred. We expect these rules and regulations to increase our legal and financial compliance costs and to make some activities more time-consuming and costly. We also expect these rules and regulations may 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 approximately the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors (and the Audit and Risk Committee in particular) or as executive officers. We cannot predict or estimate the amount of additional costs we may incur or the timing of such costs.

The costs and management time involved in complying with Delaware laws, Australian laws and U.S. reporting requirements are likely to be significant.

As a Delaware company with an ASX listing and a registration as a foreign company in Australia, we will need to ensure continuous compliance with Delaware law and relevant Australian laws and regulations, including the ASX Listing Rules and certain provisions of the Corporations Act. To the extent of any inconsistency between Delaware law and Australian law and regulations, we may need to make changes to our business operations, structure or policies to resolve such inconsistency. If we are required to make such changes, this is likely to result in interruptions to our operations, additional demands on key employees and extra costs.

Item 2. Unregistered Sales of Equity Securities

None

Item 6. Exhibits

Exhibit No.	**Description of Document**
3.1*	Amended and Restated Certificate of Incorporation
3.2*	Certificate of Amendment to the Amended and Restated Certificate of Incorporation
3.3*	Amended and Restated By-Laws
31.1**	Certification of Chief Executive Officer pursuant to Rules 13a-14 or 15d-14 of the Exchange Act
31.2**	Certification of Chief Financial Officer pursuant to Rules 13a-14 or 15d-14 of the Exchange Act
32.1***	Certification of Chief Executive Officer pursuant to Rules 13a-14(b) or 15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350
32.1***	Certification of Chief Financial Officer pursuant to Rules 13a-14(b) or 15d-14(b) of the Exchange Act and 18 U.S.C. Section 1350
101.INS**	XBRL Instance Document
101.SCH**	XBRL Taxonomy Extension Schema Document
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB**	XBRL Taxonomy Extension Label Linkbase Database
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF**	XBRL Taxonomy Extension Definition Linkbase Document

* Previously filed as the similarly numbered exhibit to the Form 10 (File No. 000-55781), filed with the Securities and Exchange Commission on July 17, 2017, and incorporated by reference herein.

** Filed herewith

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

SIGNATURE

Pursuant to the requirements of Section 12 of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

AirXpanders, Inc.
(Registrant)

By: /s/ Scott Murcray
Name: Scott Murcray
Title: Chief Financial Officer and Chief Operating Officer

Date: May 15, 2019