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Appendix 4D
Half-Yearly Report
Six Months Ended June 30, 2017
Provided Pursuant to ASX Listing Rule 4.2A

PALO ALTO, CA, United States — AirXpanders Inc. (ASX: AXP) (AirXpanders or **Company**) is pleased to provide its Half-Yearly Report for the six months ended June 30, 2017 (the "Half-Yearly Report"). The Half-Yearly Report contains the information required by ASX Listing Rules for Appendix 4D.

The Half-Yearly Report does not include all of the commentary, notes and information that are typically found in an annual financial report. Accordingly, this Half-Yearly Report should be read in conjunction with AirXpanders' annual report for the year ended December 31, 2016 and any public announcements made by the Company during the subsequent interim period in accordance with the continuous disclosure requirements of the ASX Listing Rules.

Results for Announcement to the Market

Important information concerning financial results for the half-year ended June 30, 2017

AirXpanders lodges its half-year financial results in the form of United States Securities and Exchange Commission ("SEC") Quarterly Report on Form 10-Q, which includes financial results for the three and six months ended 30 June 2017. The Form 10-Q for the three and six months ended 30 June 2017 is attached, has been prepared in accordance with United States Generally Accepted Accounting Principles ("US GAAP") and was filed with the SEC on August 9, 2017 (U.S. time). All amounts in the Form 10-Q and this Half-Yearly Report are denominated in United States dollars unless otherwise indicated.

Operating Results for the half-year ended 30 June 2017
Net Tangible Assets per share and per CDI as of 30 June 2017

(All comparisons to six months ended 30 June 2016)
(All amounts in thousands)

	$USD	up/down	% movement
Revenue from ordinary activities	$957	up	341%
Loss after tax from ordinary activities attributable to members	($15,318)	up	73%
Net loss after tax attributable to members	($15,320)	up	73%

Dividend information	Amount per security	Franked amount per security	Tax rate for franking

	$USD	$USD	credit
Interim dividend	Nil	Nil	N/A
Previous corresponding dividend	Nil	Nil	N/A

Net tangible asset backing	30 June 2017 $USD	30 June 2016 $USD
Net tangible asset per share of Class A Common Stock (Share) of the Company	$0.37	$0.33
Net tangible asset per CDI assuming all Shares held as CDIs	$0.12	$0.11

- **Independent Audit Review:** This report is based on the consolidated 2016 Half-Year Financial Statements which have been reviewed by SingerLewak, LLP with the Independent Auditor's Review Report provided.
- **Changes in control over entities:** There were no entities over which control has been gained or lost during the period.
- **Details of dividends and dividend reinvestment plans:** No dividends have been declared or proposed.
- **Details of associates or joint ventures:** Not applicable.
- **Set of accounting standards used in compiling the report:** The unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the U.S. (US GAAP) and are denominated in U.S. dollars.
- **Details of audit disputes or audit qualification:** None.

Commentary to the Operating Results

The Company reported revenues of $1.0 million, increased from $0.2 million for the previous corresponding period, reflecting the commencement of commercial operations in the United States in the first quarter of 2017. Of the reported revenues $0.6 million was generated from sales in the US. Revenue from the Australian market also increased, due to continued growth in unit sales.

"Our revenue has grown rapidly, in line with our entry into the US market contributing to an overall growth of unit sales of 145% in the past quarter. We have also invested in the sales personnel and scale up of manufacturing to ensure the business is ready to meet the demand for AeroForm, as we advance to full commercial launch in the United States once our manufacturing transfer to Costa Rica is complete," said Scott Dodson, President and CEO of AirXpanders.

Cost of goods sold of $4.7 million increased from $1.9 million for the corresponding period, reflecting the increase in revenue, in addition to inventory write-down and other reserves of $2.4 million relative to approximately $0.4 million in the corresponding period in 2016, primarily related to lower of cost or market, or LCM, adjustments. LCM adjustments are noncash adjustments to inventory balances and are required under US GAAP to record inventory at the lower of cost or market.

Total operating expenses increased to $11.6 million from $7.1 million for the previous corresponding period, reflecting increased investment in sales, marketing and general administrative expenses in preparation for commercial launch in the United States, as well as increased spending on the scale up of manufacturing capability.

The net loss for the six months ended 30 June 2017, increased to $15.3 million compared to $8.8 million for the previous corresponding period.

The Company had cash, cash equivalents and short-term investments of $27.2 million at 30 June 2017. On 7 August 2017, the Company announced it had borrowed $15 million, before issuance costs, under a loan and security agreement.

A detailed discussion of the operating results and liquidity can be found in "*Management's Discussion and Analysis of Financial Condition and Results of Operations"* in the attached SEC Quarterly Report on Form 10-Q.

Compliance Statement

The attached SEC Quarterly Report on Form 10-Q is not subject to audit dispute or qualification. This Half-Yearly Report is based on the attached SEC Quarterly Report on Form 10-Q and has been subject to review procedures as required by the SEC. A Report of Independent Registered Public Account Form provided by SingerLewak, LLP, has been included.

Please find attached the Company's SEC Quarterly Report on Form 10-Q for the three and six months ended June 30, 2017, and the auditor review report.

-ENDS-

Company	***Investor Relations***
Scott Dodson President & CEO Tel: +1 (650)-390-9008 Email: sdodson@airxpanders.com	Kyahn Williamson WE Buchan Tel: +61 (3) 9866 4722 / + 61 (0)401018828 Email: kwilliamson@buchanwe.com.au

About AirXpanders

Founded in 2005, AirXpanders, Inc. (www.airxpanders.com) designs, manufactures and markets innovative medical devices to improve breast reconstruction. The Company's AeroForm Tissue Expander System, is used in patients undergoing two-stage breast reconstruction following mastectomy. Headquartered in Palo Alto, California, AirXpanders' vision is to be the global leader in reconstructive surgery products and to become the standard of care in two-stage breast reconstruction. AirXpanders is a publically listed Company on the Australian Securities Exchange under the symbol "AXP." AeroForm was granted U.S. FDA *de novo* marketing authorization in 2016, first CE mark in Europe in 2012 and is currently licensed for sale in Australia.

Forward-Looking Statements

This announcement contains or may contain forward-looking statements that are based on management's beliefs, assumptions and expectations and on information currently available to management.

All statements that address operating performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements. These include, without limitation, our cash sufficiency forecast; U.S.

commercial market acceptance and U.S. sales of our product as well as, our expectations with respect to our ability to complete the transfer of manufacturing to our third-party contract manufacturer on a timely basis; our ability to become the global leader in reconstructive surgery products and to become the standard of care in two-stage breast reconstruction.

Management believes that these forward-looking statements are reasonable when made. You should not place undue reliance on forward-looking statements because they speak only as of the date when made. AirXpanders may not actually achieve the plans, projections or expectations disclosed in forward-looking statements. Actual results, developments or events could differ materially from those disclosed in the forward-looking statements. For additional information and considerations regarding the risks faced by AirXpanders that could cause actual results to differ materially, see its registration statement, as amended, on Form 10, as filed with the Securities and Exchange Commission on July 17, 2017 including under the caption "Risk Factors," as well as other periodic reports filed with the SEC from time to time. AirXpanders disclaims any obligation to update information contained in any forward-looking statement, except as required by law.

For more information, refer to the Company's website at www.airxpanders.com.

Foreign Ownership Restriction:

AirXpanders' CHESS Depositary Interests (CDIs) are issued in reliance on the exemption from registration contained in Regulation S of the US Securities Act of 1933 (Securities Act) for offers or sales which are made outside the US. Accordingly, the CDIs have not been, and will not be, registered under the Securities Act or the laws of any state or other jurisdiction in the US. The holders of AirXpanders' CDIs are unable to sell the CDIs into the US or to a US person unless the re-sale of the CDIs is registered under the Securities Act or an exemption is available. Hedging transactions with regard to the CDIs may only be conducted in accordance with the Securities Act.

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2017

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.)**

1047 Elwell Court
Palo Alto, California 94303
(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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☐
Emerging growth company	☒		

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

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

As of August 3, 2017, there were 95,901,588 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," "could," "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:

- the U.S. commercial market acceptance and U.S. sales of our product;
- sufficiency of our cash needs and estimates;
- 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 expectations with respect to our ability to further commercialize our product in other markets;
- our ability to develop and commercialize new products including our ability to obtain or maintain reimbursement for our current or new products;
- our expectations with respect to our regulatory submissions and approvals; 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 and Six Months Ended June 30, 2017

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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)

	June 30, 2017	December 31, 2016
ASSETS		
Current assets		
Cash and cash equivalents	$ 2,215	$ 11,477
Short-term investments	24,938	—
Accounts receivable	501	118
Inventory	2,789	1,413
Prepaid expenses and other current assets	1,143	558
Total current assets	31,586	13,566
Property and equipment, net	3,620	1,879
Other assets	219	84
Total assets	**$ 35,425**	**$ 15,529**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Current portion of long-term debt, net of discount	$ 510	$ 1,195
Accounts payable	3,205	1,249
Accrued expenses	1,826	916
Total current liabilities	5,541	3,360
Commitments and Contingencies (Note 8)		
Stockholders' equity		
Preferred stock, $0.001 par value; 10,000,000 authorized; no shares issued and outstanding at June 30, 2017 and December 31, 2016	—	—
Class A common stock, $0.001 par value; 200,000,000 authorized; 95,896,120 and 79,241,708 shares issued and outstanding at June 30, 2017 and December 31, 2016	96	79
Class B common stock, $0.001 par value; 100,000,000 authorized; no shares issued and outstanding at June 30, 2017 and December 31, 2016	—	—
Additional paid-in capital	111,450	78,418
Accumulated other comprehensive loss	(14)	-
Accumulated deficit	(81,648)	(66,328)
Total stockholders' equity	29,884	12,169
Total liabilities and stockholders' equity	**$ 35,425**	**$ 15,529**

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 June 30,		Six Months Ended June 30,	
	2017	**2016**	**2017**	**2016**
Revenue	$ 701	$ 122	$ 957	$ 217
Cost of goods sold	2,696	878	4,725	1,909
Gross loss	(1,995)	(756)	(3,768)	(1,692)
Operating expenses:				
Research and development	2,319	2,015	4,377	3,318
Selling, general and administrative	3,724	2,005	7,215	3,750
Total operating expenses	6,043	4,020	11,592	7,068
Operating loss	(8,038)	(4,776)	(15,360)	(8,760)
Other expense (income):				
Interest expense	39	65	86	119
Other expense (income), net	(57)	75	(128)	(39)
Total other expense (income), net	(18)	140	(42)	80
Operating loss before income tax provision	(8,020)	(4,916)	(15,318)	(8,840)
Provision for income taxes	2	-	2	-
Net loss	(8,022)	(4,916)	(15,320)	(8,840)
Net loss per common share: basic and diluted	$ (0.08)	$ (0.07)	$ (0.17)	$ (0.12)
Weighted-average number of common shares used in computing net loss per common share: basic and diluted	95,890	71,670	91,685	71,202
Comprehensive Loss:				
Net loss	$ (8,022)	$ (4,916)	$ (15,320)	$ (8,840)
Unrealized loss on investments	(14)	—	(14)	—
Total comprehensive loss	$ (8,036)	$ (4,916)	$ (15,334)	$ (8,840)

See accompanying notes to condensed consolidated financial statements.

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

	Common Stock					
	Issued and Outstanding Shares	Amount	Additional Paid-In Capital	Accumulated other comprehensive loss	Accumulated Deficit	Total Stockholders' Equity
Balance, December 31, 2016	79,241,708	$ 79	$ 78,418	$ -	$ (66,328)	$ 12,169
Issuance of common stock for cash (net of issuance costs of $1,462)	16,304,348	16	32,633	—	—	32,649
Exercise of stock options, 374,549 shares net of 27,771 shares traded for exercise price	350,064	1	41	—	—	42
Stock-based compensation	—	—	358	—	—	358
Unrealized loss on investments	—	—	—	(14)	—	(14)
Net loss	—	—	—	—	(15,320)	(15,320)
Balance, June 30, 2017	95,896,120	$ 96	$ 111,450	$ (14)	$ (81,648)	$ 29,884

See accompanying notes to condensed consolidated financial statements.

AirXpanders, Inc.

Condensed Consolidated Statements of Cash Flows
(In thousands)
(unaudited)

	For the Six Months Ended June 30,	
	2017	**2016**
Cash flows from operating activities		
Net loss	$ (15,320)	$ (8,840)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	193	154
Amortization of debt discount and deferred issuance cost	65	21
Inventory write-down and reserves	2,400	413
Stock-based compensation	358	178
Changes in operating assets and liabilities:		
Accounts receivable	(383)	(2)
Inventory	(3,776)	(570)
Prepaid expenses and other assets	(719)	(470)
Accounts payable	1,956	117
Accrued expenses	910	264
Net cash used in operating activities	(14,316)	(8,735)
Cash flows from investing activities		
Purchase of short-term investments	(24,953)	-
Purchase of property and equipment	(1,934)	(486)
Net cash used in investing activities	(26,887)	(486)
Cash flows from financing activities		
Principal payments on notes payable	(750)	(712)
Proceeds from issuance of common stock, net of issuance costs	32,649	14,159
Proceeds from exercise of stock options	42	-
Net cash provided by financing activities	31,941	13,447
Net (decrease) increase in cash and cash equivalents	(9,262)	4,226
Cash and cash equivalents — beginning of period	11,477	19,113
Cash and cash equivalents — end of period	$ 2,215	$ 23,339
Supplemental disclosure:		
Cash paid for interest	$ 26	$ 98
Cash paid for taxes	$ 2	$ 1

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 Palo Alto, California. The Company designs, manufactures and markets medical devices to improve breast reconstruction. The Company's AeroForm Tissue Expander System is used in patients undergoing two-stage breast reconstruction following mastectomy. AeroForm was granted U.S. FDA de novo marketing authorization in 2016, its first CE mark in Europe in 2012 and is currently licensed for sale in Australia. To date, the Company has been primarily engaged in developing and launching its initial product technology, building the manufacturing infrastructure to support commercialization efforts, recruiting key personnel and raising capital.

NOTE 2 – LIQUIDITY

The accompanying 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 $81.6 million at June 30, 2017. To date, the Company's products have been approved for marketing and sales in Europe, Australia and the United States, 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. The Company believes our current cash balances will be sufficient to meet our anticipated cash requirements to fund our commercial launch of AeroForm in the United States in 2017, and build our supporting manufacturing infrastructure and salesforce to support our commercialization efforts for at least the next twelve months. The accompanying 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 and related financial information are unaudited and should be read in conjunction with the audited financial statements and the related notes thereto for the year ended December 31, 2016 included in the Company's registration statement on Form 10, as amended, which was filed with the SEC on July 17, 2017.

The accompanying condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (US GAAP) and the 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, 2016 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 and six months ended June 30, 2017 are not necessarily indicative of the results to be expected for the year ending December 31, 2017 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. Certain amounts presented in prior periods have been reclassified to the current year presentation. Such changes had no effect on the previously reported net loss or accumulated deficit.

Foreign Currency

The Company transacts business in Australia. The functional currency of its branch office in Australia 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 loss of $6,000 and $67,000 during the three months ended June 30, 2017 and 2016, respectively, and a gain of $44,000 and $9,000 during the six months ended June 30, 2017 and 2016, respectively.

Use of Estimates

The preparation of the accompanying condensed consolidated financial statements in conformity with US 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 revenue recognition, the valuation of its common stock prior to the IPO, valuation of stock options and valuation of its inventory at the lower of cost or market.

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 June 30, 2017 and December 31, 2016, the Company had unrestricted cash balances of approximately $1.6 million and $10.8 million, respectively, that were in excess of the FDIC limits. The Company also maintains all of its Australian cash balance at one financial institution, which at times may exceed the Australian government guaranteed limit of approximately USD $195,000 (AU$ 250,000). At June 30, 2017 and December 31, 2016, the Company had cash balances of approximately $0.2 million and $0.8 million, respectively, that were in excess of the guaranteed limit.

Cash, Cash Equivalents and Short-Term Investments

The Company considers all highly liquid investments with an original maturity of three months or less, when purchased, to be cash equivalents. Short term investments are classified as "available-for-sale" and are reported at fair value with unrealized gains and losses reported in stockholders' equity as a component of other comprehensive income. As of June 30, 2017, the Company's investments consisted of U.S. Treasury Securities. The cost of securities sold is based on the specific identification method. The Company classifies its investments as current based on the nature of the investment and their availability for use in current operations. The Company reviews its investment portfolio quarterly to determine if any securities may be other-than-temporarily impaired due to increased credit risk, changes in industry or sector of a certain instrument or ratings downgrades. At June 30, 2017 and December 31, 2016, the Company maintained balances of $26.8 million and $10.5 million, respectively, with one U.S. financial institution and the US dollar equivalent of approximately $0.4 million and $1.0 million, respectively, with one Australian financial institution.

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 estimated useful lives of the assets, generally three to five 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 (generally three to five years, or in the case of leasehold improvements, over the shorter of the estimated useful life of the asset or the lease term) 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 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. As of June 30, 2017 and December 31, 2016, 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):

	June 30, 2017			
	Fair Value Measurements Using Input Types			
	Level 1	Level 2	Level 3	Total
Cash and cash equivalents	$ 2,215	$ —	$ —	$ 2,215
Short-term investments[1]	24,938	—	—	24,938
Total assets at fair value	$ 27,153	$ -	$ —	$ 27,153

	December 31, 2016			
	Fair Value Measurements Using Input Types			
	Level 1	Level 2	Level 3	Total
Cash and cash equivalents	$ 11,477	$ —	$ —	$ 11,477
Total assets at fair value	$ 11,477	$ —	$ —	$ 11,477

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 recognizes revenue from sales of its products in accordance with the Revenue Recognition Topic ASC 605. The Company recognizes revenue from product sales when the following four criteria are met: delivery has occurred, there is persuasive evidence of an arrangement, the fee is fixed or determinable, and collectability of the related receivable is reasonably assured. Revenue recognition generally occurs after a device has been implanted in a patient and a purchase order has been received from the customer.

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 did not have an allowance for doubtful accounts at June 30, 2017 and December 31, 2016.

Concentration

Four customers contributed 28% and 64%, respectively, of the Company's revenue for the three months ended June 30, 2017 and 2016. Four customers contributed 29% and 64%, respectively, of the Company's revenue for the six months ended June 30, 2017 and 2016. Five customers accounted for 42% of the accounts receivable balance at June 30, 2017. Four customers accounted for 70% of the accounts receivable balance at June 30, 2016. U.S. product sales are to hospitals and accounted for 61% and 68% of total revenues in the three and six months ended June 30, 2017, respectively, with the remainder to hospitals in Australia. All product sales during the three and six months ended June 30, 2016 were to hospitals in Australia.

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 comparable public company's volatility for similar terms as the Company does not have a long enough operating period as a public company to estimate its own volatility. Over time as the Company develops its own volatility history it will begin to incorporate that history into its expected volatility estimates.

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 as there effects would be antidilutive as of (in thousands):

	2017	2016
Shares of common stock issuable upon exercise of warrants	337	337
Shares of common stock options	6,357	5,239
Potential common shares excluded from diluted net loss per share	6,694	5,576

Recent Accounting Pronouncements

In May 2017, the FASB issued Accounting Standards Update 2017-09, "Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting," that provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. The new standard is effective for the Company in the first quarter of fiscal 2018. Early adoption is permitted. The new guidance must be applied on a prospective basis. The Company does not anticipate that the adoption of this standard will have a significant impact on our consolidated financial statements or the related disclosures.

NOTE 4 – INVENTORY

Inventory consisted of the following at (in thousands):

	June 30, 2017	December 31, 2016
Raw materials	$ 607	$ 760
Work in progress	1,763	439
Finished goods	419	214
Inventory	$ 2,789	$ 1,413

The Company had recorded inventory provisions and write-downs to inventory to market value by $2.4 million and $0.4 million for the six months ended June 30, 2017 and 2016, respectively.

NOTE 5 – PROPERTY AND EQUIPMENT

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

	June 30, 2017	December 31, 2016
Machinery and equipment	$ 1,194	$ 1,084
Computer equipment	233	161
Furniture and fixtures	161	84
Leasehold improvements	180	170
Software licenses	277	189
Office equipment	21	11
Construction in progress	2,440	872
Property and equipment, gross	4,506	2,571
Accumulated depreciation and amortization	(886)	(692)
Property and equipment, net	$ 3,620	$ 1,879

Depreciation and amortization expense amounted to $0.2 million and $0.2 million for the six months ended June 30, 2017 and 2016, respectively.

NOTE 6 – ACCRUED EXPENSES

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

	June 30, 2017	December 31, 2016
Accrued compensation and benefits	$ 820	$ 425
Accrued rent payable	120	69
Accrued clinical trials services	50	177
Accrued inventory supplies	-	93
Accrued other	836	152
Total accrued expenses	1,826	$ 916

NOTE 7 – DEBT FINANCING

In January 2014, the Company borrowed $3,500,000 under a loan and security agreement with a financial institution which matures in July 2017. Interest is paid monthly on the principal amount at 7.34% per annum. The loan is secured by substantially all of the Company's assets, excluding intellectual property. Under the terms of the agreement, interest-only payments were made monthly through March 2015, with principal payments commencing in April 2015, due in 28 equal monthly installments. A fee of $271,250 is due at maturity, which is being accrued over the term of the loan. The Company can prepay the entire loan amount by providing a written five-day notice prior to such prepayment and pay all outstanding principal, interest and prepayment fees plus any default fees and all other sums that shall have become due and payable.

In March 2015, the Company amended the loan and security agreement to extend the interest-only period from March 2015 to April 2015, with principal payments commencing in May 2015, due in 27 equal monthly installments. The Company had the option to borrow an additional $3,500,000 under the agreement, with the same terms, if certain conditions were met. This option expired unexercised in June 2015.

In connection with the loan agreement and security agreement, the Company granted a warrant to the financial institution for the purchase of 52,500 shares of Series E convertible preferred stock ("Series E") at $1.00 per share. As a result of the Company's IPO in June 2015 and conversion of all outstanding preferred stock into common stock, the warrants were converted into warrants for 52,500 shares of common stock at an exercise price of $1.00 per share. The fair value of the warrant of $32,000 on the date of issuance was recorded as a debt discount.

The Company recorded $13,000 and $11,000 to interest expense related to amortization of the debt discount and issuance costs for the three months ended June 30, 2017 and 2016, respectively, and $27,000 and $21,000 to interest expense related to amortization of the debt discount and issuance costs for the six months ended June 30, 2017 and 2016, respectively. As of June 30, 2017 and December 31, 2016, the unamortized discount and issuance cost is $4,000 and $31,000, respectively.

The Company recorded $26,000 and $54,000 of interest expense on the loans for the three months ended June 30, 2017 and 2016, respectively, and $59,000 and $0.1 million of interest expense on the loans for the six months ended June 30, 2017 and 2016, respectively. At June 30, 2017 and December 31, 2016, $0.5 million and $1.2 million, respectively, was outstanding under this loan and security agreement.

NOTE 8 – COMMITMENTS AND CONTINGENCIES

As of June 30, 2017, the future rental commitments due under the lease are (in thousands):

Year ending December 31,		
2017 (remaining 6 months)	$	294
2018		835
2019		681
2020		18
2021 and beyond		-
Total	$	1,828

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 June 30, 2017 and December 31, 2016.

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 June 30, 2017 and 2016, respectively, the Company recorded approximately $21,000 and $2,000 in royalty fees, which is included in cost of goods sold in the accompanying condensed consolidated statements of operations. For the six months ended June 30, 2017 and 2016, respectively, the Company recorded approximately $29,000 and $7,000 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, authorize the Company to issue 300,000,000 shares of $0.001 par value common stock consisting of 200,000,000 shares of common stock Class A and 100,000,000 shares of common stock Class B. Class A common stockholders are entitled to dividends when and if declared by the Board of Directors, Class B common stockholders are not entitled to any dividends. The holder of each share of Class A common stock is entitled to one vote and holders of Class B common stock are not entitled to vote. At June 30, 2017 and December 31, 2016, no dividends had been declared for common stock. At June 30, 2017, 95,896,120 shares of common stock Class A and no shares of common stock Class B, respectively, were issued and outstanding.

In February 2017, the Company issued 16,304,348 shares of common stock in connection with an equity offering on the ASX. The Company raised a total of $32,648,406, net of issuance costs of $1,461,659.

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 June 30, 2017 and December 31, 2016, 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.

	Six Months Ended June 30,	
	2017	2016
Expected terms (years)	5.28 - 10.0	5.54 - 6.08
Volatility	31.9 - 40.8%	34.11 - 34.88%
Risk-free rate	1.8 - 2.4%	1.18 - 1.43%
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, 2016	1,600,878	5,355,702	$ 0.92	6.6
Additional shares reserved (net of released)	1,584,834	—		
Options granted	(1,473,517)	1,473,517	$ 1.93	
Options exercised	—	(374,549)	$ 0.26	
Shares traded for option exercises	27,771	—		
Options forfeited/cancelled/repurchase	97,758	(97,758)	$ 0.53	
Balance — June 30, 2017	1,837,724	6,356,912	$ 1.18	7.2
Vested or expected to vest at June 30, 2017		6,209,730	$ 1.16	7.2
Exercisable at June 30, 2017		3,851,899	$ 0.59	5.8

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 June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Cost of goods sold	$ 25	$ 19	$ 44	$ 24
Research and development	14	17	25	21
Selling, general and administrative	196	115	289	133
Total	$ 235	$ 151	$ 358	$ 178

NOTE 12 – SUBSEQUENT EVENTS

In July 2017, on the maturity date, the Company repaid the entire outstanding principal and all accrued interest, along with the fee of $271,250 which was due at maturity, under the January 2014 loan and security agreement.

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% (based on the current LIBOR rate, the note bears interest at 8.48%) per annum. The loan is secured by substantially all of the Company's assets, excluding intellectual property, which intellectual property is subject to a negative pledge in favor of the financial institution. Under the terms of the agreement, interest-only payments are due monthly through September 2019, with principal payments commencing in October 2019, due in 35 equal monthly installments. If the Company is in compliance with certain financial milestones, the interest-only payments can be extended by twelve months through September 2020, in which case the principal payments would commence in October 2020, due in 23 equal monthly installments. A final fee of $1,200,000 is due at maturity (or acceleration or prepayment), which will be accrued 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, the Company 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.

In connection with the loan and security agreement, the Company granted warrants to the financial institution for the purchase of 277,778 shares of common stock at $1.62 per share. The warrants are exercisable immediately and expire on August 4, 2027. The fair value of the warrants on the date of issuance will be recorded as a debt discount, and amortized over the life of the loan, along with the issuance costs.

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, 2016 included in our registration statement on Form 10, as amended, filed with the Securities and Exchange Commission on July 17, 2017, or our Form 10. 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 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 2016, our commercial activities were limited to Australia, where a number of our early clinical trials were performed. Commencing in 2017, 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 Palo Alto, California. We have incurred net losses and cash flow deficits from operations since our inception. During the six months ended June 30, 2017, we had revenues of approximately $1.0 million and a net loss of $15.3 million. Our accumulated deficit was approximately $81.6 million at June 30, 2017. To date, our products have been approved for marketing and sales in Europe, Australia and, most recently, in the U.S. We commenced the sale of our product in Australia in 2015, and in the U.S. in the first quarter of 2017.

On June 22, 2015, we issued 29,629,654 shares of Common Stock in connection with an initial public offering (IPO) on the Australian Securities Exchange, or the 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 $15,000,000 under a loan and security agreement with Oxford Finance LLC, or 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 is secured by substantially all of our assets, excluding intellectual property, which intellectual property is subject to a negative pledge in favor of Oxford. Under the terms of the agreement, interest-only payments are due monthly through September 2019, with principal payments commencing in October 2019, due in 35 equal monthly installments. If we are in compliance with certain financial milestones, the interest-only payments can be extended by twelve months through September 2020, in which case the principal payments would commence in October 2020, due in 23 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. In connection with the loan and security agreement, we granted warrants to Oxford for the purchase of 277,778 shares of common stock at $1.62 per share.

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 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 six months ended June 30, 2017. Please refer to Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations," in our Form 10 for a complete discussion of our critical accounting policies.

Liquidity and 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 $0.6 million for the year ended December 31, 2016 and, as of December 31, 2016, we had cash and cash equivalents of approximately $11.5 million. Our existing capital, which, since February 2017, includes $32.6 million in net proceeds raised from an equity offering on the ASX, and $15.0 million, net issuance costs, from borrowings under a loan and security agreement. We believe our current cash balances will be sufficient to meet our anticipated cash requirements to fund our initial and full commercial launch of AeroForm in the U.S. in 2017, and build our supporting manufacturing infrastructure and salesforce to support our commercialization efforts for at least the next twelve months.

Results of Operations

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
	(in thousands)			
Revenue	$ 701	$ 122	$ 957	$ 217
Cost of goods sold	2,696	878	4,725	1,909
Gross loss	(1,995)	(756)	(3,768)	(1,692)
Operating expenses:				
Research and development	2,319	2,015	4,377	3,318
Selling, general and administrative	3,724	2,005	7,215	3,750
Total operating expenses	6,043	4,020	11,592	7,068
Operating loss	(8,038)	(4,776)	(15,360)	(8,760)
Other expense (income):				
Interest expense	39	65	86	119
Other expense (income)	(57)	75	(128)	(39)
Total other expense (income), net	(18)	140	(42)	80
Operating loss before income tax provision	(8,020)	(4,916)	(15,318)	(8,840)
Provision for income taxes	2	-	2	—
Net loss and comprehensive loss	$ (8,022)	$ (4,916)	$ (15,320)	$ (8,840)

Three and Six Months Ended June 30, 2017 compared to Three and Six Months Ended June 30, 2016

Revenue and Cost of Goods Sold

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
	(in thousands)			
Revenue	$ 701	$ 122	$ 957	$ 217
Cost of goods sold	2,696	878	4,725	1,909
Gross loss	$ (1,995)	$ (756)	$ (3,768)	$ (1,692)

The Company commenced commercial operations in the United States in the first quarter of 2017.

Revenue. The increase in revenue of $0.6 million in the second quarter of 2017 relative to the comparable period in 2016 was a result of the commencement of commercial operations in the United States in the first quarter of 2017, resulting in revenue of $0.5 million, as well as an increase in Australia revenue due to continued growth in unit sales. The increase in revenue of $0.8 million in the six months ended June 30, 2017 relative to the comparable period in 2016 was a result of the commencement of commercial operations in the United States in the first quarter of 2017, resulting in revenue of $0.6 million, as well as an increase in Australia revenue due to continued growth in unit sales.

Cost of Goods Sold. The increase in cost of goods sold of $1.8 million in the second quarter of 2017 relative to the comparable period of 2016 was primarily related to an increase in revenue. In addition, we recorded an inventory write-down and other inventory reserves of $1.6 million in the second quarter of 2017 relative to approximately $0.4 million in the comparable period in 2016, primarily related to lower of cost or market, or LCM, adjustments. The increase in cost of goods sold of $2.8 million in the six months ended June 30, 2017 relative to the comparable period of 2016 was primarily related to an increase in revenue. In addition, we recorded an inventory write-down and other inventory reserves of $2.4 million in the six months ended June 30, 2017 relative to approximately $0.4 million in the comparable period in 2016, primarily related to lower of cost or market, or LCM, adjustments.

We expect to continue to experience gross losses in 2017 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 June 30,		Six Months Ended June 30,		QTD Change	YTD Change
	2017	2016	2017	2016	%	%
	(in thousands)					
Research and development	$ 2,319	$ 2,015	$ 4,377	$ 3,318	15%	32%
Selling, general and administrative	3,724	2,005	7,215	3,750	86%	92%
Total operating expenses	$ 6,043	$ 4,020	$ 11,592	$ 7,068	50%	64%

Research and Development Expense. Research and development expenses increased by $0.3 million in the second quarter of 2017 relative to the comparable period of 2016, primarily due to an increase in expenses, including related travel expenses, associated with the expansion of manufacturing capability at our third-party contract manufacturer. Research and development expenses increased by $1.1 million in the six months ended June 30, 2017 relative to the comparable period of 2016, primarily due to an increase in expenses, including related travel expenses, associated with the expansion of manufacturing capability at our third-party contract manufacturer of $0.6 million, and an increase in personnel expenses of $0.4 million due to an increase in the number of employees.

Selling, General and Administrative Expense. Selling, general and administrative expense increased by $1.7 million in the second quarter of 2017 relative to the comparable period of 2016, principally due an increase in personnel expenses of $0.9 million as we hired our initial sales force in the United States and other key personnel to develop infrastructure to support commercialization efforts in the U.S. Marketing expenses, primarily public relations, advertising and product evaluations and demonstration units, increased by $0.5 million to support the commercial launch in the United States. Professional service and consulting fees increased by $0.2 million primarily due to director search fees and increased legal and other consulting expenses.

Selling, general and administrative expense increased by $3.5 million in the six months ended June 30, 2017 relative to the comparable period of 2016, principally due an increase in personnel expenses of $2.0 million as we hired our initial sales force in the United States and other key personnel to develop infrastructure to support commercialization efforts in the U.S. Marketing expenses, primarily public relations, advertising and product evaluations and demonstration units, increased by $0.9 million to support the commercial launch in the United States. Professional service and consulting fees increased by $0.5 million primarily due to director search fees and increased legal and other consulting expenses.

Total Other Expense (Income), Net

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
	(in thousands)			
Interest expense	$ 39	$ 65	$ 86	$ 119
Other expense (income), net	(57)	75	(128)	(39)
Total other expense (income), net	$ (18)	$ 140	$ (42)	$ 80

Interest Expense. The decrease in interest expense in the second quarter of 2017 and the six months ended June 30, 2017, and relative to the comparable period in 2016 was due to lower outstanding debt balances.

Other expense (income), net. Net other income increased by $0.1 million in the second quarter of 2017 relative to the comparable period in 2016 due to a decrease in foreign currency translation and remeasurement losses, and an increase in interest income due to an increase in cash balances invested in interest bearing investments. Net other income increased by $89,000 in the six months ended June 30, 2017 relative to the comparable period in 2016 due to an increase in foreign currency translation and remeasurement gains, and an increase in interest income due to an increase in cash balances invested in interest bearing investments.

Liquidity and Capital Resources

We have incurred losses since our inception in 2005 including net losses after taxes of $19.4 million, $11.2 million and $7.0 million in 2016, 2015 and 2014, respectively, and as of June 30, 2017, we had an accumulated deficit of approximately $81.6 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 through the issuance of 29,629,654 shares of Common Stock in connection with an IPO on the ASX, a Concurrent Placement and the issuance of convertible bridge notes, which were converted to common shares 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, net of issuance costs, in an equity offering.

In January 2014, the Company borrowed $3,500,000 under a loan and security agreement with a financial institution which matures in July 2017. The loan was paid in full at maturity in July 2017. No amounts are available to borrow under the agreement.

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 is secured by substantially all of our assets, excluding intellectual property, which intellectual property is subject to a negative pledge in favor of Oxford. Under the terms of the agreement, interest-only payments are due monthly through September 2019, with principal payments commencing in October 2019, due in 35 equal monthly installments. If we are in compliance with certain financial milestones, the interest-only payments can be extended by twelve months through September 2020, in which case the principal payments would commence in October 2020, due in 23 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.

We believe that the cash from the February 2017 offering and August 2017 borrowings, along with our cash and cash equivalents balance of $11.5 million as of December 31, 2016, are sufficient to remain in operations for at least the next twelve months..

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

	Six Months Ended June 30,	
	2017	2016
	(in thousands)	
Net cash used in operating activities	$ (14,316)	$ (8,735)
Net cash used in investing activities	(26,887)	(486)
Net cash provided by financing activities	31,941	13,447
Net (decrease) increase in cash and cash equivalents	$ (9,262)	$ 4,226

Cash Flows from Operating Activities

For the six months ended June 30, 2017, cash used in operating activities of $14.3 million resulted primarily from a net loss of $15.3 million, reduced by noncash adjustments, primarily inventory reserve adjustments of $2.4 million and stock based compensation of $0.4 million. Additional operating cash requirements consisted of $3.8 million for inventory purchases to support a ramp up in commercial activity in advance of a U.S. launch, offset by $2.1 million due to timing of payments of expenditures.

For the six months ended June 30, 2016, cash used in operating activities of $8.7 million resulted primarily from a net loss of $8.8 million, reduced by noncash adjustments, primarily inventory reserve adjustments of $0.4 million and stock based compensation of $0.2 million. Additional operating cash requirements consisted of $0.6 million for inventory purchases to support commercial activity in Australia.

Cash Flows from Investing Activities

For the six months ended June 30, 2017, cash used in investing activities consisted of $25.0 million for the purchase of short-term investments and $1.9 million for capital expenditures to support scaling up of manufacturing capacity.

For the six months ended June 30, 2016, cash used in investing activities consisted of $0.5 million for capital expenditures to support scaling up of manufacturing capacity.

Cash Flows from Financing Activities

For the six months ended June 30, 2017, cash provided by financing activities of $31.9 million resulted primarily from approximately $32.6 million in net proceeds from our February 2017 equity offering in which we issued approximately 16.3 million shares of Common Stock. This was slightly offset by $0.8 million in principal payments we made on our outstanding note due July 2017.

For the six months ended June 30, 2016, cash provided by financing activities of $13.4 million resulted primarily from approximately $14.2 million in net proceeds from our June 2016 equity offering in which we issued approximately 8.8 million shares of Common Stock. This was slightly offset by $0.7 million in principal payments we made on our outstanding note due July 2017.

Our outstanding note due July 2017 was paid in full on its due date. No amounts are available to borrow under the loan agreement.

Funding Considerations

As of June 30, 2017, our primary source of liquidity was our cash, cash equivalents and short-term investments on hand of approximately $27.2 million. In August 2017, we received $15.0 million, net of issuance cost, from borrowings under a loan and security agreement. We believe our current cash balances will be sufficient to meet our anticipated cash requirements to fund our initial and full commercial launch of AeroForm in the U.S. in 2017, and build our supporting manufacturing infrastructure and salesforce to support our commercialization efforts for at least the next twelve months.

Our forecast of the adequacy of our financial resources to support our operations and further expand the commercialization of our product, 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 registration statement. 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 may, from time to time, consider additional funding through additional equity and debt financings or from other sources. 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

As of June 30, 2017, 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 subsidiaries.

Contractual Obligations and Commitments

Our most significant clinical trial expenditures are to our clinical research organizations. The contracts with clinical research organizations are cancellable, with notice, at our option and do not have any cancellation penalties. These items are not included in the table below.

Our commitments for operating leases below relate to our lease of office, laboratory and manufacturing space in Palo Alto, California, San Jose, California and Sydney, Australia.

The following table summarizes our outstanding contractual obligations as of June 30, 2017:

	Total	Remaining Six Months 2017	2018-2019	2020-2021	2022 and beyond
			(in thousands)		
Operating lease obligations	$ 1,828	$ 294	$ 1,516	$ 18	$ —
Current portion of long-term debt, net of discount	510	510	—	—	—
	$ 2,338	$ 804	$ 1,516	$ 18	$ —

The above table excludes contractual obligations under the loan and security agreement signed on August 4, 2017.

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 Form 10.

ITEM 3. Quantitative and Qualitative Disclosures About Market Risk

We design, manufacture, sell and distribute the AeroForm Tissue Expander System in the U.S. and Australia. We commenced initial marketing launch in the U.S. in January 2017. Our earnings and cash flows are exposed to market risk from changes in currency exchange rates and interest rates in Australia.

Interest Rate Sensitivity

Our cash balances of $27.2 million at June 30, 2017 consisted of cash, money market funds and investments in U.S. Treasury Securities, all of which will be used or be available for working capital purposes. We do not enter into investments for trading or speculative purposes. When excess cash is available for investment, the goals of our investment policy are preservation of capital, fulfillment of liquidity needs and fiduciary control of cash and investments. We also seek to maximize income from our investments without assuming significant risk. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of interest rates in the United States and Australia. Because of the short-term nature of our cash, cash equivalents and short-term investments, we do not believe that we have any material exposure to changes in their fair values as a result of changes in interest rates. The continuation of historically low interest rates in the United States will limit our earnings on investments held in U.S. dollars.

Our debt bears interest at a fixed rate and therefore has minimal exposure to changes in interest rates. As of June 30, 2017, the outstanding principal balance of long-term debt was $0.5 million due in July 2017.

Foreign Currency Risk

We conduct business in foreign currencies in Australia. Our reporting currency is the U.S. dollar. For U.S. reporting purposes, we translate all monetary assets and liabilities of our non-U.S. operations at the period-end exchange rate, all non-monetary assets and liabilities of our non-U.S. operations at historical rates and items in the statement of operations at the average exchange rates in effect during the periods. The net effect of these translation adjustments is shown in the accompanying consolidated financial statements within other expense (income) as a component of net loss.

Through 2016, we generated all of our revenue and receivables in the Australian dollar (A$). Fluctuations in the exchange rate of the U.S. dollar against the Australian dollar, may result in foreign currency exchange gains and losses that may significantly impact our financial results. The first six months of 2017, foreign currency translation and remeasurement losses included in other expense (income), net in the consolidated statements of operations and comprehensive loss was approximately $6,000. In 2016 and 2015, foreign currency translation and remeasurement gains or losses included in other expense (income), net in the consolidated statements of operations and comprehensive loss was a loss of under $0.1 million and a gain of $0.3 million, respectively. There were no foreign currency gains or losses in 2014.

All of the proceeds from our 2016 and 2015 offerings were denominated in Australian dollars and as of June 30, 2017 we held approximately U.S.$0.4 million denominated as Australian dollars. Accordingly, we have had and will continue to have exposure to foreign currency exchange rate fluctuations. A change of 10% or more in foreign currency exchange rates of the Australian dollar could have a material impact on our financial position and results of operations if our revenue continues to be denominated in or if we retain a substantial portion of our cash and cash equivalents in Australian dollars.

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 at the reasonable assurance level.

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 Registration Statement on Form 10. 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.

Risks Related to Our Business

We may 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 $1.0 million for the six months ended June 30, 2017, and $0.6 million for the year ended December 31, 2016 and, as of June 30, 2017, we had cash, cash equivalents and short-term investments of approximately $27.2 million. Our existing capital, which since February 2017 includes $32.6 million in net cash proceeds raised from an equity offering on the ASX, and borrowings of $15.0 million, less issuance costs, may be insufficient to meet our requirements. These requirements include, but not limited to, funding our initial and full commercial launch of AeroForm in the U.S., building our supporting manufacturing infrastructure, building a dependable partnership with our contract manufacturer, building our salesforce to support our commercialization efforts, conducting clinical trials, obtaining regulatory approvals, and covering any losses.

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.

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 $15.3 million in the six months ended June 30, 2017, $19.4 million in 2016, $11.2 million in 2015 and $7.0 million in 2014. As of June 30, 2017, our accumulated deficit was approximately $81.6 million. Although we have started to generate revenues from sales in Australia and are beginning commercialization activities in the U.S., 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 contract manufacturer, conducting ongoing clinical trials that the FDA may require to ensure that our product is maintaining compliance, attempting to secure regulatory approvals for our products in Europe and Asia 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, we granted Oxford a security interest in all of our assets, with a negative pledge on 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. 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 significantly harm our business and would likely cause the price of our common stock to decline.

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.

Our business is dependent on future clinical trials that may be required for commercialization of Aeroform in other markets.

To date, we have conducted clinical trials in Australia and the U.S. demonstrating the safety, efficacy and convenience of AeroForm for sales in the Australian and U.S. markets. However, the success of these earlier clinical trials may not necessarily be predictive of the results of future clinical trials, which may be required for commercialization in other markets, like Europe and Asia, or for future products which may require additional clinical trials prior to approval.

Trial results can also be susceptible to varying interpretations and analyses. Although we consider that the data on AeroForm to date (including the preliminary data from the XPAND trial) demonstrates AeroForm's safety and effectiveness, there is no assurance that the device will meet its endpoints in future clinical trials. This would limit the size of the market opportunity for AeroForm in other markets.

If we undertake additional clinical trials for AeroForm in the future, those trials may be impacted by a number of factors including failure to recruit a sufficient number of patients, failure to meet trial endpoints, lack of product effectiveness during the trial, safety issues and modifications to trial protocols or changes to regulatory requirements for trials. Clinical trials may also be delayed, suspended or terminated due to decisions by the institutional review board (IRB) responsible for overseeing the study at a particular site.

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;
- 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.

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 intend to utilize a hybrid sale distribution model 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 intend to rely on a third party in Costa Rica to manufacture AeroForm.

We intend to have the main manufacturing of AeroForm 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.

We intend to rely on an automated manufacturing process to increase production volumes of AeroForm.

AeroForm has not yet been produced on a large scale. We have developed an automation process for the production of AeroForm which should significantly reduce the time required to produce each unit and allow for AeroForm to be produced in much greater volumes at a lower cost. This process has not been validated yet. It is intended that the automation process will be validated in the California location and then implemented by our contract manufacturer in Costa Rica, meaning that we will only have limited control over the process. The implementation of the automation process by the manufacturer may encounter some unforeseen problems or production delays beyond our control. If we are unable to keep up with demand for AeroForm, our revenues could be impaired and market acceptance of AeroForm may be adversely affected. In particular, 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.

Furthermore, if the automated manufacturing process is unsuccessful, this may adversely impact the gross margins that we believe we can achieve for AeroForm, which in turn will negatively affect our financial results.

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 expect that AeroForm will benefit 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, 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.

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, 2016, 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.

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 particular, if Mr. Scott Dodson, our President and CEO, were to leave us, we would lose significant technical and business expertise, and we might not be able to find a suitable replacement in a timely manner. This would 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.

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. In addition, the current Trump administration and Congress may continue to seek legislative and regulatory changes, including repeal and replacement of certain provisions of the ACA. President Trump also signed an Executive Order in January 2017 directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, health care providers, health insurers, or manufacturers of pharmaceuticals or medical devices. 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.

The manufacturing facilities for AeroForm must meet stringent standards. As we intend to outsource our main manufacturing to a contract manufacturer located in Costa Rica, we will have limited direct control over the compliance of the facility which manufactures AeroForm. If the manufacturer does not comply with any relevant requirements, this may adversely affect our ability to sell AeroForm. The FDA routinely inspects all medical device companies, including contract manufacturers, for compliance with the Quality Systems Regulation, or QSR. Furthermore, to maintain the CE Mark, National Standards Authority of Ireland, 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 presence in the international marketplace exposes us to foreign operational risks.

We will seek to sell AeroForm in markets across Australia, the U.S., Europe, Canada, Latin America and Asia. As it is intended that the main manufacturing of AeroForm will be performed in Costa Rica, we will be 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 June 30, 2017, 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.

Upon the effectiveness of this registration statement, we will become subject to the periodic reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Although we have been listed on the ASX for about 2 years 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 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 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

In the second quarter of 2017, we sold unregistered securities as described below.

We granted stock options under our 2015 Equity Incentive Plan and Australian Sub Plan to purchase an aggregate of 754,750 shares of our common stock at exercise price equal to $1.86 per share 24 employees, directors and consultants. 714,750 of these options remain outstanding as of June 30, 2017.

The issuances of securities described above were exempt from registration under the Securities Act of 1933, as amended, or the Securities Act, in reliance on Section 4(2) of the Securities Act, and Regulation D promulgated thereunder, or Rule 701 promulgated under Section 3(b) of the Securities Act as transactions by an issuer not involving any public offering or pursuant to benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of the securities in each of these transactions represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were placed upon the stock certificates issued in these transactions.

Item 6. Exhibits

See the Exhibit Index following the signature page to this Quarterly Report on Form 10-Q which is incorporated herein by reference.

SIGNATURE

Pursuant to the requirements of Section 12 of the Securities Exchange Act of 1934, the registrant has duly caused this registration statement 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: August 9, 2017

INDEX TO EXHIBITS

Exhibit No.	Description of Document
3.1*	Amended and Restated Certificate of Incorporation
3.2*	Amended and Restated By-Laws
10.1**	Loan and Security Agreement between Registrant and Oxford Finance LLC dates August 4, 2017
10.2**	Warrants to Purchase Common Stock issued to Oxford Finance LLC on August 4, 2017
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
32.2***	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.

SingerLewak
Accountants & Consultants

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders
AirXpanders, Inc.

We have reviewed the accompanying condensed consolidated balance sheet of AirXpanders, Inc. as of June 30, 2017, and the related condensed consolidated statements of operations and comprehensive loss for the three- and six-month periods ended June 30, 2017 and 2016, the related condensed consolidated statements of cash flows for the six-month periods ended June 30, 2017 and 2016, and the statement of stockholders' equity for the six-month period ended June 30, 2017. These condensed consolidated financial statements are the responsibility of the Company's management.

We conducted our reviews in accordance with the standards of the Public Company Accounting Oversight Board (United States). A review of interim financial information consists principally of applying analytical procedures to financial data and making inquiries of persons responsible for financial and accounting matters. It is substantially less in scope than an audit conducted in accordance with the standards of the Public Company Accounting Oversight Board, the objective of which is the expression of an opinion regarding the financial statements taken as a whole. Accordingly, we do not express such an opinion.

Based on our reviews, we are not aware of any material modifications that should be made to the accompanying condensed consolidated financial statements referred to above for them to be in conformity with U.S. generally accepted accounting principles.

SingerLewak LLP

SingerLewak LLP

San Jose, California
August 9, 2017