AMEDICA Corp Form 10-Q

November 14, 2017
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 September 30, 2017
OR
TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
Commission File Number 001-33624

Amedica	Cor	poration

(Exact name of registrant as specified in its charter)

DELAWARE 84-1375299 (State or other jurisdiction of (IRS Employer

incorporation or organization) Identification No.)

1885 West 2100 South, Salt Lake City, UT 84119 (Address of principal executive offices) (Zip Code)

(801) 839-3500

(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 [X] 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 [X] No [ ]

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

Large accelerated filer [ ]	Accelerated filer	[]
Non-accelerated filer [ ] (Do not check if a smaller reporting co	mpany) Smaller reporting company	y [X]
Indicate by check mark whether the registrant is a shell company (Yes [X] No	as defined in Rule 12b-2 of the Excha	ange Act): [
Indicate the number of shares outstanding of each of the issuer's c date:	lasses of common stock, as of the late	est practicable
3,022,073 shares of common stock, \$0.01 par value, were outstand	ling at November 14, 2017	

# **Amedica Corporation**

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## Part I. Financial Information

# Item 1. Financial Statements

# **Amedica Corporation**

# **Condensed Consolidated Balance Sheets**

# (in thousands, except share and per share data)

	September 30, 2017 (Unaudited)	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	\$ 2,816	\$6,915
Trade accounts receivable, net of allowance of \$22 and \$22, respectively	1,587	1,620
Prepaid expenses and other current assets	176	239
Inventories, net	1,733	7,213
Total current assets	6,312	15,987
Inventories, net	3,933	-
Property and equipment, net	1,372	889
Intangible assets, net	2,785	3,187
Goodwill	6,163	6,163
Other long-term assets	35	35
Total assets	\$ 20,600	\$26,261
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,159	\$658
Accrued liabilities	2,356	3,183
Debt	4,614	7,012
Total current liabilities	8,129	10,853
Deferred rent	215	319
Other long-term liabilities	278	188
Derivative liabilities	506	528
Total liabilities	9,128	11,888
Commitments and contingencies		
Stockholders' equity:		
Convertible preferred stock, \$0.01 par value, 130,000,000 shares authorized; no shares issued and outstanding at September 30, 2016.	-	-

Common stock, \$0.01 par value, 250,000,000 shares authorized, 3,022,073 and 2,280,407 shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively.	363	274
		227 224
Additional paid-in capital	231,314	227,234
Accumulated deficit	(220,206)	(213,135)
Total stockholders' equity	11,471	14,373
Total liabilities and stockholders' equity	\$ 20,600	\$26,261

The condensed consolidated balance sheet as of December 31, 2016, has been prepared using information from the audited consolidated balance sheet as of that date.

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

# **Amedica Corporation**

# **Condensed Consolidated Statements of Operations - Unaudited**

# (in thousands, except share and per share data)

	Three Months Ended		Nine Mor	nths Ended
	September 30,		Septembe	er 30,
	2017	2016	2017	2016
Product revenue	\$2,956	\$3,378	\$8,793	\$11,574
Costs of revenue	1,408	765	2,791	2,675
Gross profit	1,548	2,613	6,002	8,899
Operating expenses:				
Research and development	1,433	1,582	3,790	4,743
General and administrative	1,092	1,912	3,288	4,834
Sales and marketing	1,579	2,326	5,005	7,514
Total operating expenses	4,104	5,820	12,083	17,091
Loss from operations	(2,556	) (3,207	) (6,081	) (8,192 )
Other income (expenses):				
Interest expense	(270	) (745	) (1,008	) (3,998 )
Loss on extinguishment of debt	-	(417	) -	(661)
Change in fair value of derivative liabilities	11	26	21	50
Other income	-	5	-2	11
Total other expense, net	(259	) (1,131	) (989	) (4,598 )
Net loss before income taxes	(2,815	) (4,338	) (7,070	) (12,790 )
Provision for income taxes	-	-	-	-
Net loss	\$(2,815	) \$(4,338	) \$(7,070	) \$(12,790 )
Deemed dividend related to beneficial conversion feature and accretion of a discount on Series A Preferred Stock	-	(6,278	) -	(6,278 )
Net loss attributable to common stockholders	\$(2,815	) \$(10,616	) \$(7,070	) \$(19,068 )
Net loss per share	Ψ(2,013	) ψ(10,010	) ψ(1,070	) ψ(15,000 )
Basic and diluted	\$(0.93	) \$(5.53	) \$(2.42	) \$(14.56)
Weighted average common shares outstanding:	Ψ(0.75	, ψ(3.33	, ψ(2.π2	, ψ(14.50 )
Basic and diluted	3,022,07	73 1,920,74	5 2,918,24	1,309,286

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

# **Amedica Corporation**

# **Condensed Consolidated Statements of Cash Flows - Unaudited**

(in thousands)

	Nine Months Ended September 30,	
	2017 2016	
Cash flow from operating activities		
Net loss	\$(7,070) \$(12,790)	
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	432 1,123	
Amortization of intangible assets	402 375	
Amortization of lease incentive for tenant improvements	15 15	
Non-cash interest expense	675 1,778	
Loss on extinguishment of debt	- 661	
Stock based compensation	173 197	
Change in fair value of derivative liabilities	(21 ) (50 )	
Loss (gain) on disposal of equipment	2 (13)	
Provision for inventory reserve	1,300 861	
Changes in operating assets and liabilities:		
Trade accounts receivable	33 1,390	
Prepaid expenses and other current assets	63 (138 )	
Inventories	246 428	
Accounts payable and accrued liabilities	(646 ) 906	
Net cash used in operating activities	(4,396) (5,257)	
Cash flows from investing activities		
Purchase of property and equipment	(917 ) (427 )	
Proceeds from sale of property and equipment	- 30	
Net cash used in investing activities	(917 ) (397 )	
Cash flows from financing activities		
Proceeds from issuance of common stock, net of issuance costs	3,807 11,480	
Proceeds from issuance of stock in connection with exercise of warrants	- 448	
Proceeds from issuance of debt	2,500 -	
Payments on debt	(5,043) (5,071)	
Issuance costs paid for debt	(50 ) (267 )	
Debt extinguishment payments	- (1,728 )	
Payments for capital lease	- (8 )	
Net cash provided by financing activities	1,214 4,782	
Net decrease in cash and cash equivalents	(4,099) (872)	
Cash and cash equivalents at beginning of period	6,915 11,485	
Cash and cash equivalents at end of period	\$2,816 \$10,613	

Non-cash investing and financing activities

Deemed dividend related to beneficial conversion feature of preferred convertible stock and	\$-	\$6,278
accretion of a discount	φ-	\$0,276
Debt converted to common stock	-	2,480
Capital lease for property and equipment	-	60
Debt discount from warrants issued with debt	189	-
Supplemental cash-flow information		
Cash paid for interest	\$333	\$1,330

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

#### AMEDICA CORPORATION

#### NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

#### 1. Organization and Summary of Significant Accounting Policies

Organization

Amedica Corporation was incorporated in the state of Delaware on December 10, 1996. Amedica Corporation is a materials company focused on developing, manufacturing and selling silicon nitride ceramics that are used in medical implants and in a variety of industrial devices. At present, Amedica Corporation commercializes silicon nitride in the spine implant market and believes that its silicon nitride manufacturing expertise positions it favorably to introduce new and innovative devices in the medical and non- medical fields. Amedica Corporation also believes that it is the first and only company to commercialize silicon nitride medical implants. Amedica Corporation acquired US Spine, Inc. ("US Spine"), a Delaware spinal products corporation with operations in Florida, on September 20, 2010. Amedica Corporation and US Spine are collectively referred to as "Amedica" or "the Company in these condensed consolidated financial statements. The Company's products are sold primarily in the United States.

Basis of Presentation

These unaudited condensed consolidated financial statements have been prepared in accordance with the rules and regulations of the United States Securities and Exchange Commission ("SEC"), and include all assets and liabilities of the Company and its wholly-owned subsidiary, US Spine. All material intercompany transactions and balances have been eliminated in consolidation. SEC rules and regulations allow the omission of certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States, so long as the statements are not misleading. In the opinion of management, these financial statements and accompanying notes contain all adjustments (consisting of normal recurring adjustments) necessary to present fairly the financial position and results of operations for the periods presented herein. These condensed consolidated financial statements should be read in conjunction with the consolidated audited financial statements and notes thereto contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2016, filed with the SEC on September 20, 2017. The results of operations for the nine months ended September 30, 2017 are not necessarily indicative of the results to be expected for the year ending December 31, 2017. The Company's significant accounting policies are set forth in Note 1 to the consolidated financial statements in its Annual Report on Form 10-K for the year ended December 31, 2016.

#### Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States ("U.S. GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of revenue and expenses during the periods then ended. Actual results could differ from those estimates. The most significant estimates relate to inventory, stock-based compensation, long-lived and intangible assets and the liability for preferred stock and common stock warrants.

## Liquidity and Capital Resources

The condensed consolidated financial statements have been prepared assuming the Company will continue to operate as a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business, and does not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from uncertainty related to its ability to continue as a going concern within one year from the date of issuance of these condensed consolidated financial statements.

For the nine months ended September 30, 2017 and 2016, the Company incurred net losses of \$7.1 million and \$12.8 million, respectively, and used cash in operations of \$4.4 million and \$5.3 million, respectively. The Company had an accumulated deficit of \$220 million and \$213 million as of September 30, 2017 and December 31, 2016, respectively. To date, the Company's operations have been principally financed by proceeds received from the issuance of preferred and common stock, convertible debt and bank debt and, to a lesser extent, cash generated from product sales. It is anticipated that the Company will continue to generate operating losses and use cash in operating activities. The Company's continuation as a going concern is dependent upon its ability to increase sales, implement cost saving measures, maintain compliance with debt covenants and/or raise additional funds through the capital markets. Whether and when the Company can attain profitability and positive cash flows from operating activities or obtain additional financing is uncertain.

In 2016, the Company implemented certain cost saving measures, including workforce and office space reductions, and will continue to evaluate additional cost savings alternatives during 2017. These additional cost savings measures may include additional workforce and research and development reductions, as well as cuts to certain other operating expenses. In addition to these costs saving measures, an experienced and highly successful leader for the Sales and Marketing team was recruited and hired. This individual has subsequently hired additional experienced personnel in Sales and Marketing. The Company is actively generating additional scientific and clinical data to have it published in leading industry publications. The unique features of the Company's silicon nitride material are not well known, and publication of such data would help sales efforts as the Company approaches new prospects. The Company is also making additional changes to the sales strategy, including a focus on revenue growth of silicon nitride lateral lumbar implants and the newly developed pedicle screw system (known as Taurus).

As discussed further in Note 7, in June 2014 the Company entered into a term loan with Hercules Technology Growth Capital, Inc. ("Hercules Technology"), as administrative and collateral agent for the lenders thereunder and as lender, and Hercules Technology III, LP, ("HT III" and, together with Hercules Technology, "Hercules") as lender (the "Hercules Term Loan"). The Hercules Term Loan has a liquidity covenant that requires the Company to maintain a cash balance of the lesser of \$2.5 million or the outstanding balance of the Hercules Term Loan. As of September 30, 2017, the outstanding balance on the Hercules Term Loan was \$2.3 million and the Company's cash balance was \$2.8 million. The Company believes it will be in position to maintain compliance with the liquidity covenant related to the Hercules Term Loan at least through November 2017. On July 28, 2017, the Company entered into a \$2.5 million term loan with a related party that will assist the Company in its cash needs through November 2017. The Company has common stock that is publicly traded and has been able to successfully raise capital when needed since the date of the Company's initial public offering. The Company is engaged in discussions with investment and banking firms to examine financing alternatives, including options to encourage the exercise of outstanding warrants and other lending alternatives.

If the Company is unable to access additional funds prior to becoming non-compliant with the financial and liquidity covenants related to its debt, the outstanding balances of its debt would become immediately due and payable at the option of the lender. Although the Company is seeking to obtain additional equity and/or debt financing, such funding is not assured and may not be available to the Company on favorable or acceptable terms, and may involve significant restrictive covenants. Any additional equity financing is also not assured and, if available to the Company, will most likely be dilutive to its current stockholders. If the Company is not able to obtain additional debt or equity financing on a timely basis, the impact on the Company will be material and adverse.

Reverse Stock Split

On November 10, 2017, the Company effected a 1 for 12 reverse stock split of the Company's common stock. The par value and the authorized shares of the common and convertible preferred stock were not adjusted as a result of the reverse stock split. All common stock share and per-share amounts for all periods presented in these condensed consolidated financial statements prior to November 10, 2017 have been adjusted retroactively to reflect the reverse stock split.

Significant Accounting Policies

There have been no significant changes to the Company's significant accounting policies as described in the Company's Annual Report on Form 10-K for the year ended December 31, 2016.

In January 2017, the FASB issued ASU 2017-04 *Intangibles—Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment.* The amendments in this guidance eliminate the requirement to calculate the implied fair value of goodwill used to measure goodwill impairment charge (Step 2). As a result, an impairment charge will equal the amount by which a reporting unit's carrying amount exceeds its fair value, not to exceed the amount of goodwill allocated to the reporting unit. An entity still has the option to perform the qualitative assessment for a reporting unit to determine if the quantitative impairment test is necessary. The amendment should be applied on a prospective basis. The guidance is effective for goodwill impairment tests in fiscal years beginning after December 15, 2021. Early adoption is permitted for goodwill impairment tests performed after January 1, 2017. The impact of this guidance for the Company will depend on the outcomes of future goodwill impairment tests.

In August 2016, the Financial Accounting Standards Board ("FASB") updated accounting guidance on the following eight specific cash flow classification issues: (1) debt prepayment or debt extinguishment costs; (2) settlement of zero-coupon debt instruments or other debt instruments with coupon interest rates that are insignificant in relation to the effective interest rate of the borrowing; (3) contingent consideration payments made after a business combination; (4) proceeds from the settlement of insurance claims; (5) proceeds from the settlement of corporate-owned life insurance policies, including bank-owned life insurance policies; (6) distributions received from equity method investees; (7) beneficial interests in securitization transactions; and (8) separately identifiable cash flows and application of the predominance principle. Under existing U.S. GAAP, there is no specific guidance on the eight cash flow classification issues aforementioned. These updates are effective for the Company for its annual period beginning January 1, 2019, and interim periods therein, with early adoption permitted. The guidance in this standard is not expected to have a material impact on the financial statements of the Company.

In March 2016 the FASB updated the accounting guidance related to stock compensation. This update simplifies the accounting for employee share-based payment transactions, including the accounting for income taxes, forfeitures, and statutory tax withholding requirements, as the well as classification in the statement of cash flows. The standard is effective for the Company for its annual period beginning January 1, 2018. The guidance in this standard is not expected to have a material impact on the financial statements of the Company.

In February 2016, the FASB updated the accounting guidance related to leases as part of a joint project with the International Accounting Standards Board ("IASB") to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. Under the new guidance, a lessee will be required to recognize assets and liabilities for capital and operating leases with lease terms of more than 12 months. Additionally, this update will require disclosures to help investors and other financial statement users better understand the amount, timing, and uncertainty of cash flows arising from leases, including qualitative and quantitative requirements. The standard is effective for the Company for its annual period beginning January 1, 2020, and interim periods therein, with early adoption permitted. The Company is currently evaluating the potential impact this new standard may have on its financial statements, but believes the most significant change will relate to building leases.

In May 2014, in addition to several amendments issued during 2016, the FASB updated the accounting guidance related to revenue from contracts with customers, which supersedes nearly all existing revenue recognition guidance

under U.S. GAAP. The core principle is that a company should recognize revenue when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services. The standard defines a five-step process to achieve this core principle and, in doing so, more judgment and estimates may be required within the revenue recognition process than are required under existing U.S. GAAP. The standard is effective for the Company for its annual period beginning January 1, 2019, and interim periods therein, and shall be applied either retrospectively to each period presented or as a cumulative-effect adjustment as of the date of adoption. The Company is in the preliminary stages of evaluating the impact that the new standard will have on its financial statements.

The Company has reviewed all other recently issued, but not yet adopted, accounting standards, in order to determine their effects, if any, on its results of operations, financial position or cash flows. Based on that review, the Company believes that no other pronouncements will have a significant effect on its financial statements.

#### 2. Basic and Diluted Net Loss per Common Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by dividing the net loss by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method. Dilutive common stock equivalents are primarily comprised of warrants for the purchase of common stock and stock options. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding because their effect would have been anti-dilutive due to the Company reporting a net loss. The Company had potentially dilutive securities, shares of common stock, totaling approximately 1.5 million and 1.1 million as of September 30, 2017 and 2016, respectively.

#### 3. Inventories, net

Inventories consisted of the following (in thousands):

	September	December
	30, 2017	31, 2016
Raw materials	\$ 676	\$ 761
WIP	101	75
Finished goods	4,889	6,377
	\$ 5,666	\$ 7,213

Finished goods included consigned inventory totaling approximately \$2.8 million and \$5.6 million as of September 30, 2017 and December 31, 2016, respectively. As of September 30, 2017, inventories totaling \$1.7 million and \$3.9 million were classified as current and long-term, respectively. Inventories classified as current represent the carrying value of inventories at September 30, 2017 that management estimates will be sold by September 30, 2018. As of December 31, 2016, all inventories were classified as current.

#### 4. Intangible Assets

Intangible assets consisted of the following (in thousands):

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	September	December
	30, 2017	31, 2016
Developed technology	\$ 4,685	\$ 4,685
Customer relationships	3,990	3,990
Other patents and patent applications	562	562
Trademarks	350	350
	9,587	9,587
Less: accumulated amortization	(6,802)	(6,400 )
	\$ 2,785	\$ 3,187

Amortization expense is expected to approximate \$134,000 for the remainder of 2017, \$536,000 per year through 2021, \$369,000 in 2022 and a total of \$140,000 thereafter, until fully amortized.

#### 5. Fair Value Measurements

Financial Instruments Measured and Recorded at Fair Value on a Recurring Basis

The Company has issued certain warrants to purchase shares of common stock, which are considered mark-to-market liabilities and are re-measured to fair value at each reporting period in accordance with accounting guidance. Fair value is based on the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date, under a three-tier fair value hierarchy which prioritizes the inputs used in measuring fair value as follows:

Level -quoted market prices for identical assets or liabilities in active markets.

Level 2 - observable prices that are based on inputs not quoted on active markets, but corroborated by market data.

Level unobservable inputs reflecting management's assumptions, consistent with reasonably available assumptions made by other market participants. These valuations require significant judgment.

The Company classifies assets and liabilities measured at fair value in their entirety based on the lowest level of input that is significant to their fair value measurement. No financial assets were measured on a recurring basis as of September 30, 2017 and December 31, 2016. The following tables set forth the financial liabilities measured at fair value on a recurring basis by level within the fair value hierarchy as of September 30, 2017 and December 31, 2016:

Fair Value
Measurements as of
September 30, 2017
Levellevel Level
1 2 3 Total

Derivative liability

Description

Common stock warrants \$- \$ - \$506 \$506

Fair Value

Measurements as of December 31, 2016

Description

Levellevel Level Total
1 2 3

Derivative liability

Common stock warrants \$- \$ - \$528 \$528

The Company did not have any transfers of assets and liabilities between Level 1 and Level 2 of the fair value measurement hierarchy during the nine months ended September 30, 2017 and 2016.

The assumptions used in estimating the common stock warrant liability as of September 30, 2017 and December 31, 2016 were as follows:

	September		Decembe	er
	30, 2017		31, 2016	
Weighted-average risk free interest rate	1.6	%	0.9	%
Weighted-average expected life (in years)	2.7		2.5	
Expected dividend yield	-	%	-	%
Weighted-average expected volatility	120.0	%	136.0	%

Other Financial Instruments

The Company's recorded values of cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities approximate their fair values based on their short-term nature. The recorded value of debt approximates the fair value as the interest rates are reflective of market interest rates.

#### 6. Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	September	December
	30, 2017	31, 2016
Commissions	\$ 16	\$ 466
Payroll and related expenses	357	461
Royalties	182	416
Interest payable	24	76
Final loan payment fees	1,624	1,333
Other	153	431
	\$ 2,356	\$ 3,183

#### 7. Debt

North Stadium Term Loan

On July 28, 2017, the Company entered into a \$2.5 million term loan (the "North Stadium Loan") with North Stadium Investments, LLC ("North Stadium"), a company owned and controlled by the Company's Chief Executive Officer and Chairman of the Board. The North Stadium Loan bears interest at 10% per annum and requires the Company to make monthly interest only payments from September 5, 2017 through July 5, 2018. All principal and unpaid interest (if any) under the North Stadium Loan is due and payable on July 28, 2018. The North Stadium Loan is secured by substantially all of the assets of the Company but is junior to security interest in assets encumbered by the Hercules Term Loan (see below). In connection with the North Stadium Loan the Company also issued North Stadium a warrant to purchase up to 55,000 shares of the Company's common stock at a purchase price of \$5.04 per share, subject to a 5-year term. The relative estimated value of the warrants on the date of grant approximated \$0.2 million, which is being amortized as interest expense over the life of the term loan. The assumptions used in the calculation of the fair value of the warrants issued on July 28, 2017, were as follows:

Weighted-average risk-free interest rate	1.8	%
Weighted-average expected life (in years)	4.8	
Expected dividend yield	-	%
Weighted-average expected volatility	122.	0%

On June 30, 2014, the Company entered into a Loan and Security Agreement with Hercules which provided the Company with a \$20 million term loan. The Hercules Term Loan matures on January 1, 2018. The Hercules Term Loan included a \$0.2 million closing fee, which was paid to Hercules on the closing date of the loan. The closing fee was recorded as a debt discount and is being amortized to interest expense over the life of the loan. The Hercules Term Loan also includes a non-refundable final payment fee of \$1.7 million. The final payment fee is being accrued and recorded to interest expense over the life of the loan. The Hercules Term Loan bears interest at the rate of the greater of either (i) the prime rate plus 7.7%, and (ii) 10.95%, provided however, that during an adjustment period, the term loan interest rate shall mean for any day a per annum rate of interest equal to the grater of either (i) the prime rate plus 9.2%, and (ii) 12.45%. The applicable rate was 11.95% as of September 30, 2017. Interest accrues from the closing date of the loan and interest payments are due monthly. Principal payments commenced August 1, 2015 and are currently being made in equal monthly installments totaling approximately \$500,000, with the remainder due at maturity. The Hercules Term Loan is secured by a first priority security interest in substantially all of its assets, including intellectual property, of the Company and contains covenants restricting payments to certain Company affiliates and certain financial reporting requirements.

On September 8, 2015, the Company entered into a Consent and First Amendment to Loan and Security Agreement (the "Amendment") with Hercules. The Amendment modified the liquidity covenant to reduce the required minimum cash and cash equivalents balance by \$500,000 for every \$1.0 million in principal paid, up to a minimum of \$2.5 million. Once the Hercules Term Loan principal balance is below \$2.5 million the Company is only required to maintain a cash and cash equivalents balance equal to the outstanding principal balance on the Hercules Term loan. The minimum cash and cash equivalents balance required to maintain compliance with the minimum liquidity covenant as of September 30, 2017, was \$2.5 million. The Company believes it will maintain compliance with the liquidity covenant related to the Hercules Term Loan at least through November 2017. To maintain compliance beyond that date, the Company will likely require additional cash.

See discussion below with respect to the assignment of \$3.0 million of the principal balance of the Hercules Term Loan to Riverside Merchant Partners, LLC ("Riverside") and the subsequent agreement between the Company and Riverside to exchange the \$3.0 million of the Hercules Term Loan held by Riverside for subordinated convertible promissory notes in the aggregate principal amount of \$3.0 million.

#### Hercules and Riverside Debt Exchange

On April 4, 2016, the Company entered into an Assignment and Second Amendment to Loan and Security Agreement (the "Assignment Agreement") with Riverside and Hercules, pursuant to which Hercules sold \$1.0 million of the principal amount outstanding under the Hercules Term Loan to Riverside. In addition, pursuant to the terms of the Assignment Agreement, Riverside acquired an option to purchase an additional \$2.0 million of the principal amount outstanding under the Hercules Term Loan from Hercules. On April 18, 2016, Riverside exercised and purchased an additional \$1.0 million of the principal amount of the Hercules Term Loan and on April 27, 2016, Riverside exercised the remainder of its option and purchased an additional \$1.0 million of the principal amount of the Hercules Term Loan from Hercules.

#### Riverside Debt

On April 4, 2016, the Company entered into an exchange agreement (the "Exchange Agreement") with Riverside, pursuant to which the Company agreed to exchange \$1.0 million of the principal amount outstanding under the Hercules Term Loan held by Riverside for a subordinated convertible promissory note in the principal amount of \$1.0 million (the "First Exchange Note") and a warrant to purchase 8,333 shares of common stock of the Company at a fixed exercise price of \$0.14 per share (the "First Exchange Warrant") (the "Exchange"). All principal accrued under the Exchange Notes was convertible into shares of common stock at the election of the Holder at any time at a fixed conversion price of \$0.12 per share (the "Conversion Price"). The closing stock price on April 4, 2016, was \$0.14 and a beneficial conversion feature of \$245,000 was recorded to equity and as a debt discount. The warrant value of \$106,000 was recorded to equity and as a debt discount.

In addition, pursuant to the terms and conditions of the Exchange Agreement, the Company and Riverside had the option to exchange an additional \$2.0 million of the principal amount of the Hercules Term Loan for an additional subordinated convertible promissory note in the principal amount of up to \$2.0 million and an additional warrant to purchase 8,333 shares of common stock (the "Second Exchange Warrant"). The Exchange Agreement also provided that if the volume-weighted average price of the Company's common stock was less than the Conversion Price, the Company would issue up to an additional 12,500 shares of common stock (the "True-Up Shares") to Riverside, which was subsequently reduced to 11,667 shares of common stock.

On April 18, 2016, the Company and Riverside exercised their option to exchange an additional \$1.0 million of the principal amount of the Hercules Term Loan for an additional subordinated convertible promissory note in the principal amount of \$1.0 million (the "Second Exchange Note"). The closing stock price on April 18, 2016, was \$0.17 and a beneficial conversion feature of \$412,000 was recorded to equity and as a debt discount. Additionally, on April 27, 2016, the Company and Riverside exercised their option to exchange an additional \$1.0 million of the principal amount of the Term Loan for an additional subordinated convertible promissory note in the principal amount of \$1.0 million (the "Third Exchange Note") and an additional warrant to purchase 8,333 shares of the Company's common

stock at a fixed exercise price of \$0.14 per share. The warrant value of \$107,000 was recorded to equity and as a debt discount. The closing stock price on April 27, 2016, was \$0.14 and a beneficial conversion feature of \$268,000 was recorded to equity and as a debt discount. Financing costs were \$267,000 and were recorded to interest expense. The unamortized deferred financing costs and debt discount of the Hercules Term Loan exchanged were \$244,000 at the time of the exchange and were recorded as a loss on extinguishment of debt related to the debt exchange. The First Exchange Note, the Second Exchange Note and the Third Exchange Note are collectively referred to herein as the "Exchange Notes."

Pursuant to the terms of the Exchange Notes, since the volume-weighted average price of the Company's common stock was less than the Conversion Price on May 6, 2016, the Company issued an additional 11,667 shares of common stock to Riverside and recorded the value of the True-Up Shares of \$199,000 to interest expense and equity.

All principal outstanding under each of the Exchange Notes was to be due on April 3, 2018 (the "Maturity Date"). Each of the Exchange Notes bore interest at a rate of 6% per annum, with the interest that would accrue on the initial principal amount of the Exchange Notes during the first 12 months being guaranteed and deemed earned as of the date of issuance. Prior to the Maturity Date, all interest accrued under the Exchange Notes was payable in cash or, if certain conditions were met, payable in shares of common stock at the Company's option, at a conversion price of \$0.11 per share. During 2016, the entire principal amount of the First and Second Exchange Notes, \$300,000 of the Third Exchange Note, and the interest related to the First, Second, and Third Exchange Notes was converted into 145,227 shares of common stock. In July 2016, the Company paid Riverside \$840,000 to redeem in full the remaining principal balance of the Third Exchange Note. The debt discounts associated with the converted debt was recorded to interest expense.

Long-term debt consisted of the following (in thousands):

	September 30, 2017									
		Uı	namortized	1						
		Di	scount		Net		D	iscount	Net	
	Outstandi	Outstanding Principal Debt Issuance			INCL	Outstand	net			
	Principal				Carrying Amount	Principal	l Debt		Carrying	
				ssuance			Issuance		Amount	
		$\mathbf{C}\mathbf{c}$	osts				C	osts		
Hercules Term Loan	\$2,377	\$	(58	)	\$ 2,319	\$7,421	\$	(409	\$ 7,0	12
North Stadium Term Loan	2,500		(205	)	2,295	-		-	-	
Less: Current portion	(4,877)		263		(4,614)	(7,421)		409	(7,	012 )
Long-term debt	\$-	\$	-		\$ -	\$-	\$	-	\$ -	

Based on contractual principal payment obligations on the Hercules term loan as of September 30, 2017, before considering acceleration of maturity payments due to potential non-compliance with loan covenants, the entire principal balance is due January 1, 2018, and therefore current.

#### 8. Equity

During the nine months ended September 30, 2017, the Company completed a secondary offering in which the Company sold 741,667 shares of common stock and warrants to purchase 333,750 shares of common stock for \$0.04 per unit (each unit consisting of one share of common stock and 0.45 warrants). The Company received approximately \$3.8 million in proceeds from the offering, which was net of approximately \$732,000 in total underwriting expenses, commission and other offering expenses. The warrants became exercisable on the closing date, expire on the five-year anniversary of the closing date, and have an initial exercise price per share equal to \$0.05 per share, subject to adjustments for events of recapitalization, stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events affecting the Company's common stock.

On February 24, 2017, the underwriter in the 2017 secondary offering exercised its option to purchase additional warrants for 30,000 shares of the Company's common stock.

#### 9. Stock-Based Compensation

A summary of the Company's outstanding stock option activity for the nine months ended September 30, 2017, is as follows:

		September 30, 2017					
			Weighted-				
	Options	Weighted-A Exercise Price	Average verage. Remaining Contractual Life (Years)	Intrinsic Value			
As of December 31, 2016	11,446	\$ 2.55	8.2	\$ -			
Granted	-	-	-	-			
Exercised	-	-	-	-			
Forfeited	-	-	-	-			
Expired	(47)	63.78	-	-			
As of September 30, 2017	11,399	\$ 2.30	7.3	-			
Exercisable as of September 30, 2017	11,025	\$ 2.82	7.3	-			
Expected to vest as of September 30, 2017	11,399	\$ 2.30	7.3	-			

The Company estimates the fair value of each stock option on the grant date using the Black-Scholes-Merton valuation model, which requires several estimates including an estimate of the fair value of the underlying common stock on grant date. The expected volatility was based on an average of the historical volatility of a peer group of similar companies. The expected term was calculated utilizing the simplified method. The risk-free interest rate was based on the U.S. Treasury yield curve in effect at the time of grant for the expected term of the option. The following weighted average assumptions were used in the calculation to estimate the fair value of options granted to employees during the nine months ended September 30, 2016 (no options were granted for the nine months ended September 30, 2017):

	Nine	
	Months	
	Ended	
	Septembe	er
	30, 2016	
Weighted-average risk-free interest rate	1.6	%
Weighted-average expected life (in years)	6.3	
Expected dividend yield	-	%
Weighted-average expected volatility	65.0	%

Summary of Stock-Based Compensation Expense

Total stock-based compensation expense included in the condensed consolidated statements of operations is allocated as follows (in thousands):

	Three Monti Ended	hs	Nine Months Ended September 30,			
	Septe 30,	mber				
	2017	2016	2017	2016		
Cost of revenue	\$ -	\$6	\$10	\$13		
Research and development	11	18	61	71		
General and administrative	23	20	69	95		
Selling and marketing	20	1	33	18		
Capitalized into inventory	-	11	-	14		
-	\$ 54	\$ 56	\$173	\$211		

Unrecognized stock-based compensation as of September 30, 2017 is as follows (in thousands):

		Weighted
		Average
	Unracagnized	Remaining
	Unrecognized Stock-Based	of
	Stock-based	Recognition
	Compensation	(in years)
Stock options	\$ 88	0.65

## 10. Commitments and Contingencies

From time to time, the Company is subject to various claims and legal proceedings covering matters that arise in the ordinary course of its business activities. Management believes any liability that may ultimately result from the resolution of these matters will not have a material adverse effect on the Company's consolidated financial position, operating results or cash flows.

# ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our consolidated financial statements for the year ended December 31, 2016 and the notes thereto, along with Management's Discussion and Analysis of Financial Condition and Results of Operations, included in our Annual Report on Form 10-K for the year ended December 31, 2016, filed separately with the U.S. Securities and Exchange Commission. This discussion and analysis contains forward-looking statements based upon current beliefs, plans, expectations, intentions and projections that involve risks, uncertainties and assumptions, such as statements regarding our plans, objectives, expectations, intentions and projections. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2016, and any updates to those risk factors filed from time to time in our Quarterly Reports on Form 10-Q.

#### Overview

We are a materials company focused on developing, manufacturing and selling silicon nitride ceramics that are used in medical implants and in a variety of industrial devices. At present, we commercialize silicon nitride in the spine implant market. We believe that our silicon nitride manufacturing expertise positions us favorably to introduce new and innovative devices in the medical and non-medical fields. We also believe that we are the first and only company to commercialize silicon nitride medical implants.

We have received 510(k) regulatory clearance in the United States, a CE mark in Europe, and ANVISA approval in Brazil for a number of our devices that are designed for spinal fusion surgery. To date, more than 28,000 of our silicon nitride devices have been implanted into patients, with an 8-year successful track record. We intend to file an FDA 510(k) submission for clearance in the United States of a novel composite spinal fusion device that combines porous and solid silicon nitride. The FDA sent us questions about our upcoming submission and we are currently in the process of submitting a response.

We believe that silicon nitride has a superb combination of properties that make it ideally suited for human implantation. Other biomaterials are based on bone grafts, metal alloys, and polymers; all of which have practical limitations. In contrast, silicon nitride has a legacy of success in the most demanding and extreme industrial environments. As a human implant material, silicon nitride offers bone ingrowth, resistance to bacterial infection, resistance to corrosion, superior strength and fracture resistance, and ease of diagnostic imaging, among other advantages.

We market and sell our Valeo brand of silicon nitride implants to surgeons and hospitals in the United States and to selected markets in Europe and South America through more than 50 independent sales distributors who are supported by an in-house sales and marketing management team. These implants are designed for use in cervical (neck) and thoracolumbar (lower back) spine surgery. We are also working with other partners in Japan to obtain regulatory approval for silicon nitride in that country.

In addition to our silicon nitride-based spinal fusion products, we market a line of non-silicon nitride spinal fixation products which allows us to provide surgeons and hospitals with a broader range of products. These additional products are complementary to our fusion products and are designed for the treatment of deformity and degenerative spinal procedures. Although our non-silicon nitride products have accounted for approximately 54% and 49% of our product revenues for the nine months ended September 30, 2017 and 2016, respectively, we believe the continued promotion and potential for adoption of our silicon nitride products and product candidates, if approved, provides us the greatest opportunity to grow our business in new and existing markets and achieve our goal to become a leading biomaterial company.

In addition to direct sales, we have targeted original equipment manufacturers ("OEM") and private label partnerships which offer additional avenues for the adoption of silicon nitride but they are not an area of focus at the moment. Existing biomaterials, based on plastics, metals, and bone grafts have well-recognized limitations that we believe are addressed by silicon nitride, and we are uniquely positioned to convert existing, successful implant designs made by other companies into silicon nitride. We believe OEM and private label partnerships will allow us to work with a variety of partners, accelerate the adoption of silicon nitride, and realize incremental revenue at improved operating margins, when compared to the cost-intensive direct sales model.

We believe that silicon nitride addresses many of the biomaterial-related limitations in fields such as hip and knee replacements, dental implants, sports medicine, extremities, and trauma surgery. We further believe that the inherent material properties of silicon nitride, and the ability to formulate the material in a variety of compositions, combined with precise control of the surface properties of the material, opens up a number of commercial opportunities across orthopedic surgery, neurological surgery, maxillofacial surgery, and other medical disciplines.

We operate a 30,000 square foot manufacturing facility at our corporate headquarters in Salt Lake City, Utah, and we believe we are the only vertically integrated silicon nitride medical device manufacturer in the world.

## **Components of our Results of Operations**

We manage our business within one reportable segment, which is consistent with how our management reviews our business, makes investment and resource allocation decisions and assesses operating performance.

#### **Product Revenue**

We derive our product revenue primarily from the sale of spinal fusion and fixation devices and related products used in the treatment of spine disorders. Our product revenue is generated from sales to three types of customers: (1) surgeons and hospitals; (2) stocking distributors; and (3) private label customers. Most of our products are sold on a consignment basis through a network of independent sales distributors; however, we also sell our products to independent stocking distributors and private label customers. Product revenue is recognized when all four of the following criteria are met: (1) persuasive evidence that an arrangement exists; (2) delivery of the products has occurred; (3) the selling price of the product is fixed or determinable; and (4) collectability is reasonably assured. We generate the majority of our revenue from the sale of inventory that is consigned to independent sales distributors that sell our products to surgeons and hospitals. For these products, we recognize revenue at the time we are notified the product has been used or implanted and all other revenue recognition criteria have been met. For all other transactions, we recognize revenue when title and risk of loss transfer to the stocking distributor or private label customers, and all other revenue recognition criteria have been met. We generally recognize revenue from sales to stocking distributors

and private label customers at the time the product is shipped to the distributor. Stocking distributors and private label customers, who sell the products to their customers, take title to the products and assume all risks of ownership at time of shipment. Our stocking distributors and private label customers are obligated to pay within specified terms regardless of when, if ever, they sell the products. Our policy is to classify shipping and handling costs billed to customers as an offset to total shipping expense in the statement of operations, primarily within sales and marketing. In general, our customers do not have any rights of return or exchange.

We believe our product revenue will increase due to our sales and marketing efforts and as we continue to introduce new products into the market. We expect that our product revenue will continue to be primarily attributable to sales of our products in the United States.

#### **Cost of Revenue**

The expenses that are included in cost of revenue include all direct product costs if we obtained the product from third-party manufacturers and our in-house manufacturing costs for the products we manufacture. We obtain our non-silicon nitride products, including our metal products, from third-party manufacturers, while we currently manufacture our silicon-nitride products in-house.

Specific provisions for excess or obsolete inventory are also included in cost of revenue. In addition, we pay royalties attributable to the sale of specific products to some of our surgeon advisors that assisted us in the design, regulatory clearance or commercialization of a particular product. These payments are recorded as cost of revenue.

#### **Gross Profit**

Our gross profit measures our product revenue relative to our cost of revenue. We expect our gross profit to decrease as we expand the penetration of our silicon nitride technology platform through OEM and private label partnerships, which offer additional avenues for the adoption of silicon nitride, but they are not an area of focus at the moment.

## **Research and Development Expenses**

Our research and development costs are expensed as incurred. Research and development costs consist of engineering, product development, clinical trials, test-part manufacturing, testing, developing and validating the manufacturing process, manufacturing, facility and regulatory-related costs. Research and development expenses also include employee compensation, employee and non-employee stock-based compensation, supplies and materials, consultant services, and travel and facilities expenses related to research activities. To the extent that certain research and development expenses are directly related to our manufactured products, such expenses and related overhead costs are allocated to inventory.

We expect to incur additional research and development costs as we continue to develop new spinal fusion products, our product candidates for total joint replacements, such as our total hip replacement product candidate, and dental applications which, may increase our total research and development expenses.

#### **Sales and Marketing Expenses**

Sales and marketing expenses consist of salaries, benefits and other related costs, including stock-based compensation, for personnel employed in sales, marketing, medical education and training. In addition, our sales and marketing expenses include commissions and bonuses, generally based on a percentage of sales, to our sales managers and independent sales distributors. We provide our products in kits or banks that consist of a range of device sizes and separate instruments sets necessary to perform the surgical procedure. We generally consign our instruments to our distributors or our hospital customers that purchase the device used in spinal fusion surgery. Our sales and marketing expenses include depreciation of the surgical instruments.

We expect our commissions to increase in absolute terms over time but remain approximately the same or decrease as a percentage of product revenue.

#### **General and Administrative Expenses**

General and administrative expenses consist primarily of salaries, benefits and other related costs, including stock-based compensation for certain members of our executive team and other personnel employed in finance, legal, compliance, administrative, information technology, customer service, executive and human resource departments. General and administrative expenses also include other expenses not part of the other cost categories mentioned above, including facility expenses and professional fees for accounting and legal services.

We expect our general and administrative expenses to remain stable or slightly decline as we continue to manage costs closely and look for opportunities to make improvements.

#### **Reverse Stock Split**

On November 10, 2017, we effected a 1 for 12 reverse stock split of our common stock. The par value and the authorized shares of the common and convertible preferred stock were not adjusted as a result of the reverse stock split. All common stock share and per-share amounts for all periods presented in the accompanying condensed consolidated financial statements prior to November 10, 2017 have been adjusted retroactively to reflect the reverse stock split.

## **RESULTS OF OPERATIONS - UNAUDITED**

The following is a tabular presentation of our condensed consolidated operating results for the three and nine months ended September 30, 2017 and 2016 (*in thousands*):

	Three Mo Ended Septembe				ths Ended r 30,	d				
	2017	2016	\$ Change	% Change		2017	2016	\$ Change	% Change	<b>;</b>
Product revenue	\$2,956	\$3,378	\$(422)	-12	%	\$8,793	\$11,574	\$(2,781)	-24	%
Cost of revenue	1,408	765	643	84	%	2,791	2,675	116	4	%
Gross profit	1,548	2,613	(1,065)	-41	%	6,002	8,899	(2,897)	-33	%
Gross profit %	52 %	77 %		10	%	68 %	77 %	1	-9	%
Operating expenses:										
Research and development	1,433	1,582	(149)	-9	%	3,790	4,743	(953)	-20	%
General and administrative	1,092	1,912	(820)	-43	%	3,288	4,834	(1,546)	-32	%
Sales and marketing	1,579	2,326	(747)	-32	%	5,005	7,514	(2,509)	-33	%
Total operating expenses	4,104	5,820	(1,716)	-29	%	12,083	17,091	(5,008)	-29	%
Loss from operations	(2,556)	(3,207)	651	20	%	(6,081)	(8,192)	2,111	26	%
Other expense, net	(259)	(1,131)	872	77	%	(989)	(4,598)	3,609	78	%
Net loss before taxes	(2,815)	(4,338)	1,523	35	%	(7,070)	(12,790)	5,720	45	%
Provision for income taxes	-	-	-	-	%	-	-	-	-	%
Net loss	\$(2,815)	\$(4,338)	\$1,523	35	%	\$(7,070)	\$(12,790)	\$5,720	45	%

Product Revenue - Unaudited

The following table sets forth our product revenue from sales of the indicated product category for the three and nine months ended September 30, 2017 and 2016 (in thousands):

	Three M Ended Septem			Nine M Ended Septem						
	2017	2016	\$ Change	% Change		2017	2016	\$ Change	% Change	;
Silicon Nitride	\$1,204	\$1,849	\$ (645	-35	%	\$4,080	\$5,932	\$(1,852)	-31	%
Non-Silicon Nitride	1,752	1,529	223	15	%	4,713	5,642	(929)	-16	%
Total product revenue	\$2,956	\$3,378	\$ (422	) -12	%	\$8,793	\$11,574	\$(2,781)	-24	%

For the three months ended September 30, 2017, total product revenue was \$3.0 million as compared to \$3.4 million in the same period in 2016, a decrease of \$0.4 million, or 12%. This decrease was primarily due to the loss of surgeons and the consequences from our restructuring, both of which occurred the latter part of 2016.

For the nine months ended September 30, 2017, total product revenue was \$8.8 million as compared to \$11.6 million in the same period 2016, a decrease of \$2.8 million, or 24%. This decrease was primarily due to the loss of surgeons and the consequences from our restructuring, both of which occurred the latter part of 2016.

The following table sets forth, for the periods indicated, our product revenue by geographic area (in thousands):

	Three M Ended Septem			Nine M Ended Septem						
	2017	2016	\$ Change	% Change		2017	2016	\$ Change	% Change	
Domestic	\$2,903	\$3,352	\$ (449	) -13	%	\$8,673	\$11,312	\$(2,639)	-23	%
International	\$53	\$26	\$ 27	104	%	\$120	\$262	\$(142)	-54	%
Total product revenue	\$2,956	\$3,378	\$ (422	) -12	%	\$8,793	\$11,574	\$(2,781)	-24	%

For the three months ended September 30, 2017, domestic revenue decreased by \$0.4 million, or 12%. This is attributable to the loss of surgeons and the consequences from our restructuring, both of which occurred the latter part of 2016. International revenue increased \$0.03 million, or 104% as compared to the same period in 2016.

For the nine months ended September 30, 2017, domestic revenue decreased \$2.6 million, or 23%. This is attributable to the loss of surgeons and the consequences from our restructuring, both of which occurred the latter part of 2016. International revenue decreased \$0.1 million, or 54% as compared to the same period in 2016. This is due to our Brazilian distributor moving from building inventory during the nine months ended September 30, 2016 to maintaining inventory levels during the same period in 2017.

#### Cost of Revenue and Gross Profit

For the three months ended September 30, 2017, our cost of revenue increased \$0.6 million, or 84%, as compared to the same period in 2016 even though our sales decreased. The increase was primarily due to an increase in the provision for inventory reserve of \$0.9 million. Gross profit decreased \$1.1 million, or 41%, primarily due to an increase in the provision for inventory reserve.

For the nine months ended September 30, 2017, our cost of revenue increased \$0.1 million, or 4%, as compared to the same period in 2016. The increase was primarily due to an increase in the provision for inventory reserve of \$0.4 million. Gross profit decreased \$2.9 million, or 33%, primarily due to the increase in the provision for inventory reserve.

#### Research and Development Expenses

For the three months ended September 30, 2017, research and development expenses decreased \$0.15 million, or 9%, as compared to the same period in 2016. This decrease was primarily due to a \$0.14 million decrease in personnel related expenses due to a reduction in force in October 2016.

For the nine months ended September 30, 2017, research and development expenses decreased \$1.0 million, or 20%, as compared to the same period in 2016. This decrease was primarily due to a \$0.5 million decrease in personnel related expenses related to the October 2016 reduction in force and a \$0.5 million decrease in product testing and validation related expenses.

#### General and Administrative Expenses

For the three months ended September 30, 2017, general and administrative expenses decreased \$0.8 million, or 43%, as compared to the same period in 2016. This decrease was primarily due to a \$0.01 million decrease in personnel related expenses related to the October 2016 reduction in force, a \$0.9 million decrease in legal and patent expenses and the Company's efforts to reduce costs, offset by a \$0.2 million increase in administrative expenses.

For the nine months ended September 30, 2017, general and administrative expenses decreased \$1.5 million, or 32%, as compared to the same period in 2016. This decrease was primarily due to a \$0.4 million decrease in personnel

related expenses related to the October 2016 reduction in force, a \$0.8 million decrease in legal and patent expenses, a \$0.3 million decrease in investor relations expenses and the Company's efforts to reduce costs.

Sales and Marketing Expenses

For the three months ended September 30, 2017, sales and marketing expenses decreased \$0.7 million, or 32%, as compared to the same period in 2016. This decrease was primarily due to a \$0.2 reduction in commissions, a \$0.12 million decrease in personnel related expenses related to the October 2016 reduction in force and a \$0.17 million decrease in depreciation expenses.

For the nine months ended September 30, 2017, sales and marketing expenses decreased \$2.5 million, or 33%, as compared to the same period in 2016. This decrease was primarily due to a \$1.0 million decrease in commissions, a \$0.5 million in personnel related expenses related to the October 2016 reduction in force and a \$0.6 million decrease in depreciation expense.

Other (Expense), Net

For the three months ended September 30, 2017, other expense decreased \$0.9 million, or 79%, as compared to the same period in 2016. This decrease was due to a \$0.5 million decrease in interest expense and a \$0.4 decrease in expense due to the extinguishment of debt.

For the nine months ended September 30, 2017, other expense decreased \$3.6 million, or 79%, as compared to the same period in 2016. This decrease was primarily due to a \$3.0 million decrease in interest expense and a \$0.6 million decrease in expense due to the extinguishment of debt.

## **Liquidity and Capital Resources**

The condensed consolidated financial statements have been prepared assuming the Company will continue to operate as a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business, and does not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from uncertainty related to its ability to continue as a going concern within one year from the date of issuance of these condensed consolidated financial statements.

For the nine months ended September 30, 2017 and 2016, the Company incurred net losses of \$7.1 million and \$12.8 million, respectively, and used cash in operations of \$4.4 million and \$5.3 million, respectively. The Company had an accumulated deficit of \$220 million and \$213 million as of September 30, 2017 and December 31, 2016, respectively. To date, the Company's operations have been principally financed by proceeds received from the issuance of preferred and common stock, convertible debt and bank debt and, to a lesser extent, cash generated from product sales. It is anticipated that the Company will continue to generate operating losses and use cash in operating activities. The Company's continuation as a going concern is dependent upon its ability to increase sales, implement cost saving measures, maintain compliance with debt covenants and/or raise additional funds through the capital markets. Whether and when the Company can attain profitability and positive cash flows from operating activities or obtain additional financing is uncertain.

In 2016, the Company implemented certain cost saving measures, including workforce and office space reductions, and will continue to evaluate additional cost savings alternatives during 2017. These additional cost savings measures may include additional workforce and research and development reductions, as well as cuts to certain other operating expenses. In addition to these costs saving measures, an experienced and highly successful leader for the Sales and Marketing team was recruited and hired. This individual has subsequently hired additional experienced personnel in Sales and Marketing. The Company is actively generating additional scientific and clinical data to have it published in leading industry publications. The unique features of the Company's silicon nitride material are not well known and publication of such data would help sales efforts as the Company approaches new prospects. The Company is also making additional changes to the sales strategy, including a focus on revenue growth of silicon nitride lateral lumbar implants and the newly developed pedicle screw system (known as Taurus).

As discussed further in Note 7, in June 2014 the Company entered into a term loan with Hercules Technology Growth Capital, Inc. ("Hercules Technology"), as administrative and collateral agent for the lenders thereunder and as lender, and Hercules Technology III, LP, ("HT III" and, together with Hercules Technology, "Hercules") as lender (the "Hercules Term Loan"). The Hercules Term Loan has a liquidity covenant that requires the Company to maintain a cash balance of the lesser of \$2.5 million or the outstanding balance of the Hercules Term Loan. As of September 30, 2017, the outstanding balance on the Hercules Term Loan was \$2.3 million and the Company's cash balance was \$2.8 million. The Company believes it will be in position to maintain compliance with the liquidity covenant related to the Hercules Term Loan at least through November 2017. On July 28, 2017, the Company entered into a \$2.5 million term loan with a related party that will assist the Company in its cash needs through November 2017. The Company has

common stock that is publicly traded and has been able to successfully raise capital when needed since the date of the Company's initial public offering. The Company is engaged in discussions with investment and banking firms to examine financing alternatives, including options to encourage the exercise of outstanding warrants and other lending alternatives.

If the Company is unable to access additional funds prior to becoming non-compliant with the financial and liquidity covenants related to its debt, the outstanding balances of its debt would become immediately due and payable at the option of the lender. Although the Company is seeking to obtain additional equity and/or debt financing, such funding is not assured and may not be available to the Company on favorable or acceptable terms, and may involve significant restrictive covenants. Any additional equity financing is also not assured and, if available to the Company, will most likely be dilutive to its current stockholders. If the Company is not able to obtain additional debt or equity financing on a timely basis, the impact on the Company will be material and adverse.

#### **Cash Flows**

Net cash used in operating activities

Net cash used in investing activities

The following table summarizes, for the periods indicated, cash flows from operating, investing and financing activities (in thousands) - unaudited:

**Nine Months Ended September** 2017 2016 \$(4,396) \$(5,257) (917) (397) Net cash provided by financing activities 1,214 4,782 \$(4,099) \$(872)

19

Net cash used

Net Cash Used in Operating Activities

Net cash used in operating activities decreased \$0.9 million to \$4.4 million during the nine months ended September 30, 2017, as compared to \$5.3 million for the same period in 2016. Offset by the decrease in the net loss, and related non-cash add backs to the net loss, the increase in cash used in operating activities during 2017 was primarily due to changes in the movement of working capital items during the nine months ended September 30, 2017 as compared to the same period in 2016 as follows: a \$1.4 million decrease in trade accounts receivable, a \$0.2 increase in prepaid expenses and other current assets, a \$0.18 decrease in inventories and a \$1.6 million increase in accounts payable and accrued liabilities.

Net Cash Used in Investing Activities

Net cash used in investing activities increased \$0.5 million to \$0.9 million during the nine months ended September 30, 2017, compared to \$0.4 million for the same period in 2016. The increase in cash used in investing activities during 2017 was due to increased purchases of property and equipment.

Net Cash Used in Financing Activities

Net cash from financing activities was \$1.2 million during the nine months ended September 30, 2017, compared to \$4.8 million for the same period in 2016. The \$3.6 million decrease in 2017 was primarily due to the \$3.8 million in net proceeds received from a common stock offering.

#### **Indebtedness**

North Stadium Term Loan

On July 28, 2017, the Company entered into a \$2.5 million term loan (the "North Stadium Loan") with North Stadium Investments, LLC ("North Stadium"), a company owned and controlled by the Company's Chief Executive Officer and Chairman of the Board. The North Stadium Loan bears interest at 10% per annum and requires the Company to make monthly interest only payments from September 5, 2017 through July 5, 2018. All principal and unpaid interest (if any) under the North Stadium Loan is due and payable on July 28, 2018. The North Stadium Loan is secured by substantially all of the assets of the Company but is junior to security interest in assets encumbered by the Hercules

Term Loan (see below). In connection with the North Stadium Loan the Company also issued North Stadium a warrant to purchase up to 55,000 shares of the Company's common stock at a purchase price of \$5.04 per share, subject to a 5-year term. The relative estimated value of the warrants on the date of grant approximated \$0.2 million, which is being amortized as interest expense over the life of the term loan. The assumptions used in the calculation of the fair value of the warrants issued on July 28, 2017, were as follows:

Weighted-average risk-free interest rate
Weighted-average expected life (in years)

Expected dividend yield
Weighted-average expected volatility

1.8 %
4.8

Expected dividend yield
- %
1.22.0%

Hercules Term Loan

On June 30, 2014, the Company entered into a Loan and Security Agreement with Hercules which provided the Company with a \$20 million term loan. The Hercules Term Loan matures on January 1, 2018. The Hercules Term Loan included a \$200,000 closing fee, which was paid to Hercules on the closing date of the loan. The closing fee was recorded as a debt discount and is being amortized to interest expense over the life of the loan. The Hercules Term Loan also includes a non-refundable final payment fee of \$1.7 million. The final payment fee is being accrued and recorded to interest expense over the life of the loan. The Hercules Term Loan bears interest at the rate of the greater of either (i) the prime rate plus 7.7%, and (ii) 10.95%, provided however, that during an adjustment period, the term loan interest rate shall mean for any day a per annum rate of interest equal to the greater of either (i) the prime rate plus 9.2%, and (ii) 12.45%. The applicable rate was 11.95% as of September 30, 2017. Interest accrues from the closing date of the loan and interest payments are due monthly. Principal payments commenced August 1, 2015 and are currently being made in equal monthly installments totaling approximately \$500,000, with the remainder due at maturity. The Hercules Term Loan is secured by a first priority security interest in substantially all of its assets, including intellectual property, of the Company and contains covenants restricting payments to certain Company affiliates and certain financial reporting requirements.

On September 8, 2015, the Company entered into a Consent and First Amendment to Loan and Security Agreement (the "Amendment") with Hercules. The Amendment modified the liquidity covenant to reduce the required minimum cash and cash equivalents balance by \$500,000 for every \$1.0 million in principal paid, up to a minimum of \$2.5 million. Once the Hercules Term Loan principal balance is below \$2.5 million the Company is only required to maintain a cash and cash equivalents balance equal to the outstanding principal balance on the Hercules Term loan. The minimum cash and cash equivalents balance required to maintain compliance with the minimum liquidity covenant as of September 30, 2017, was \$2.5 million. The Company believes it will maintain compliance with the liquidity covenant related to the Hercules Term Loan at least through November 2017. To maintain compliance beyond that date, the Company will likely require additional cash.

See discussion below with respect to the assignment of \$3.0 million of the principal balance of the Hercules Term Loan to Riverside and the subsequent agreement between the Company and Riverside to exchange the \$3.0 million of the Hercules Term Loan held by Riverside for subordinated convertible promissory notes in the aggregate principal amount of \$3.0 million.

Hercules and Riverside Debt Assignment

In April 2016, we entered into an Assignment Agreement with Riverside, and Hercules, pursuant to which Hercules sold \$3.0 million of the principal amount outstanding under the Hercules Term Loan to Riverside. For a more detailed description of the Assignment Agreement refer to Note 7 in the condensed consolidated financial statements of this Report.

Riverside Debt

On April 4, 2016, the Company entered into an exchange agreement (the "Exchange Agreement") with Riverside, pursuant to which the Company agreed to exchange \$1.0 million of the principal amount outstanding under the Hercules Term Loan held by Riverside for a subordinated convertible promissory note in the principal amount of \$1.0 million (the "First Exchange Note") and a warrant to purchase 8,333 shares of our common stock at a fixed exercise price of \$0.14 per share (the "First Exchange Warrant") (the "Exchange"). All principal under the Exchange Notes is convertible into shares of common stock at the election of the Holder at any time at a fixed conversion price of \$0.12 per share (the "Conversion Price").

In addition, pursuant to the terms and conditions of the Exchange Agreement, the Company and Riverside had the option to exchange an additional \$2.0 million of the principal amount of the Hercules Term Loan for an additional subordinated convertible promissory note in the principal amount of up to \$2.0 million and an additional warrant to purchase 8,333 shares of common stock (the "Second Exchange Warrant"). The Exchange Agreement also provided that if the volume-weighted average price of our common stock was less than the Conversion Price, the Company would issue up to an additional 12,500 shares of common stock (the "True-Up Shares") to Riverside, which was subsequently reduced to 11,667 shares of common stock.

On April 18, 2016, the Company and Riverside exercised their option to exchange an additional \$1.0 million of the principal amount of the Hercules Term Loan for an additional subordinated convertible promissory note in the principal amount of \$1.0 million (the "Second Exchange Note"). Additionally, on April 28, 2016, the Company and Riverside exercised their option to exchange an additional \$1.0 million of the principal amount of the Term Loan for an additional subordinated convertible promissory note in the principal amount of \$1.0 million (the "Third Exchange Note") and an additional warrant to purchase 8,333 shares of the Company's common stock at a fixed exercise price of \$0.14 per share. The First Exchange Note, the Second Exchange Note and the Third Exchange Note are collectively referred to herein as the "Exchange Notes."

Pursuant to the terms of the Exchange Notes, since the volume-weighted average price of our common stock was less than the Conversion Price on May 6, 2016, the Company issued an additional 11,667 shares of common stock to Riverside.

All principal outstanding under each of the Exchange Notes was to be due on April 3, 2018 (the "Maturity Date"). Each of the Exchange Notes bears interest at a rate of 6% per annum, with the interest that would accrue on the initial principal amount of the Exchange Notes during the first 12 months being guaranteed and deemed earned as of the date of issuance. Prior to the Maturity Date, all interest accrued under the Exchange Notes is payable in cash or, if certain conditions are met, payable in shares of common stock at the Company's option, at a conversion price of \$0.11 per share. As of June 30, 2016, the entire principal amount of the First and Second Exchange Notes, \$300,000 of the Third Exchange Note, and the interest related to the First, Second, and Third Exchange Notes has been converted into 145,227 shares of common stock. In July 2016, the Company paid Riverside \$840,000 to redeem in full the remaining principal balance of the Third Exchange Note.

The Company classifies all future debt obligations as current due to uncertainties in their ability to comply with debt covenant requirements.

### **Off-Balance Sheet Arrangements**

The Company does not have any off-balance sheet arrangements, as defined in Item 303(a)(4) of Regulation S-K.

## **Critical Accounting Policies and Estimates**

A summary of our significant accounting policies and estimates is discussed in Management's Discussion and Analysis of Financial Condition and Results of Operations and in Note 1 to our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2016. There have been no material changes to those policies during the nine months ended September 30, 2017. The preparation of the financial statements in accordance with U.S. generally accepted accounting principles requires us to make judgments, estimates and assumptions regarding uncertainties that affect the reported amounts of assets and liabilities. Significant areas of uncertainty that require judgments, estimates and assumptions include the accounting for income taxes and other contingencies as well as valuation of derivative liabilities, asset impairment and collectability of accounts receivable. We use historical and other information that we consider to be relevant to make these judgments and estimates. However, actual results may differ from those estimates and assumptions that are used to prepare our financial statements.

### **New Accounting Pronouncements**

See discussion under Note 1, *Organization and Summary of Significant Accounting Policies*, to the Condensed Consolidated Financial Statements included in Item 1 of Part I of this Quarterly Report on Form 10-Q, for information on new accounting pronouncements.

## ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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## ITEM 4. CONTROLS AND PROCEDURES

This Report includes the certifications of our Chief Executive Officer and Principal Financial Officer required by Rule 13a-14 of the Securities Exchange Act of 1934 (the "Exchange Act"). See Exhibits 31.1 and 31.2. This Item 4 includes information concerning the controls and control evaluations referred to in those certifications.

#### **Evaluation of Disclosure Controls and Procedures**

We maintain disclosure controls and procedures, as such term is defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934 (the "Exchange Act"), that are designed to ensure that information required to be disclosed in the reports filed or submitted under the Exchange Act, is recorded, processed, summarized, and reported within the time periods specified by the Commission's rules and forms. Disclosure controls and procedures include controls and procedures designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act are properly recorded, processed, summarized and reported within the time periods required by the Commission's rules and forms.

We carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer (principal executive officer and principal financial officer), of the effectiveness of the design and operation of these disclosure controls and procedures, as such term is defined in Exchange Act Rule 13a-15(e), as of September 30, 2017. Based on this evaluation, the Chief Executive Officer concluded that our disclosure controls and procedures were not effective as of September 30, 2017, the end of the period covered by this Quarterly Report on Form 10-Q due to the material weaknesses described below.

As defined in SEC Regulation S-X, a material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. Based on this assessment, management determined that, as of December 31, 2016, the Company's internal control over financial reporting was not effective because of the material weaknesses described below.

The design and operating effectiveness of our controls were inadequate to ensure that complex accounting matters are properly accounted for and reviewed in a timely manner. As a result, we failed to accurately record a complex equity transaction which caused the restatement of our third quarter 2016 financial results as set forth in our Quarterly Report on Form 10-Q for the third quarter filing 2016. In addition, we failed to properly evaluate and test certain long-lived assets for impairment, which ultimately resulted in recognition of an impairment charge. These errors are a result of the following control deficiencies:

Control Environment and Risk Assessment – The Company did not have an effective control environment with the structure necessary for effective internal controls over financial reporting. Furthermore, the Company did not have an effective risk assessment to identify and assess risks associated with changes to the Company's structure and the resultant impact on internal controls. With the dismissal of the Company's CFO, the Company did not have qualified personnel necessary to meet the Company's control objectives. The Company does not have personnel with an appropriate level of knowledge and experience with U.S. GAAP to properly review and evaluate the work performed by other Company personnel and experts related to complex accounting matters.

Control Activities – The Company did not have control activities that were designed and operating effectively including management review controls, controls related to monitoring and assessing the work of technical experts and consultants, and controls to verify the completeness and adequacy of information. Specifically, the Company did not have procedures for competent personnel to review work performed by technical experts and consultants in relation to complex debt and equity transactions and impairment evaluations.

Monitoring Activities – The Company did not maintain effective monitoring controls related to the financial reporting process. The Company did not effectively monitor the changes in internal control related to changes in the roles and responsibilities associated with the changes in personnel and organizational structure. The failure to properly monitor impacted the timing, accuracy, and completion of the work related to significant accounting matters.

Our Chief Executive Officer is in the preliminary stage of a review of our controls relating to complex accounting matters. Although our analysis is not complete, we will be adding additional resources with expertise in accounting for complex accounting matters including timely review and evaluation of assets for potential impairment. We are also considering redesigning controls to add additional layers of review and approval whenever entering into or subsequently converting, exercising, amending, repricing, exiting or otherwise experiencing changes in or to complex financial instruments.

Notwithstanding the identified material weaknesses, the Company believes the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q fairly represent in all material respects our financial condition, results of operations and cash flows at and for the periods presented in accordance with accounting principles generally accepted in the United States of America.

Other than as described above, there were no changes in our internal control over financial reporting that occurred during the second quarter of 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**PART II** 

#### ITEM 1. LEGAL PROCEEDINGS

We are not aware of any pending or threatened legal proceeding against us that could have a material adverse effect on our business, operating results or financial condition. The medical device industry is characterized by frequent claims and litigation, including claims regarding patent and other intellectual property rights as well as improper hiring practices. As a result, we may be involved in various additional legal proceedings from time to time.

## ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Previously furnished in the Company's Current Report on Form 8-K filed on August 3, 2017, with the US Securities and Exchange Commission.

## ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

### ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

# **ITEM 5. OTHER INFORMATION**

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# **ITEM 6. EXHIBITS**

			Incorporated		
Exhi		Filed Herewith	by Reference	Filing Date	SEC File/
Num	Exhibit Description ber				Reg. Number
			Schedule		
4.1	Secured Promissory Note with North Stadium Investments, LLC		8-K	08/03/17	001-33624
4.2	North Stadium Investments, LLC Warrant to Purchase Common Stock		8-K	08/03/17	001-33624
10.01	Security Agreement, dated July 28, 2017, by and between the Company and North Stadium Investments, LLC.		8-K	08/03/17	001-33624
31.1	Certificate of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X			
31.2	Certificate of the Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X			
32	Certifications of the Chief Executive Officer and Principal Accounting Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X			
101	IN ACCORDANCE WITH THE TEMPORARY HARDSHIP EXEMPTION PROVIDED BY RULE 201 OF REGULATION S-T, THE DATE BY WHICH THE INTERACTIVE DATA FILE IS REQUIRED TO BE SUBMITTED HAS BEEN EXTENDED BY SIX BUSINESS DAYS				

## **SIGNATURES**

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

## AMEDICA CORPORATION

Date: November 14, 2017 /s/B. Sonny Bal
B. Sonny Bal
Chief Executive Officer

(Principal Executive Officer)